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

[X1CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1 This Regulation lays down specific rules on the hygiene of food of animal origin for food business operators. These rules supplement those laid down by Regulation (EC) No 852/2004. They shall apply to unprocessed and processed products of animal origin.

2 Unless expressly indicated to the contrary, this Regulation shall not apply to food containing both products of plant origin and processed products of animal origin. However, processed products of animal origin used to prepare such food shall be obtained and handled in accordance with the requirements of this Regulation.

3 This Regulation shall not apply in relation to:

a primary production for private domestic use;

b the domestic preparation, handling or storage of food for private domestic consumption;

c the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer;

d the direct supply, by the producer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer as fresh meat;

e hunters who supply small quantities of wild game or wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer.

4 Member States shall establish, according to national law, rules governing the activities and persons referred to in paragraph 3(c), (d) and (e). Such national rules shall ensure the achievement of the objectives of this Regulation.

5

a Unless expressly indicated to the contrary, this Regulation shall not apply to retail.

b However, this Regulation shall apply to retail when operations are carried out with a view to the supply of food of animal origin to another establishment, unless:

(i) the operations consist only of storage or transport, in which case the specific temperature requirements laid down in Annex III shall nevertheless apply;

or

(ii) the supply of food of animal origin from the retail establishment is to other retail establishments only and, in accordance with national law, is a marginal, localised and restricted activity.

c Member States may adopt national measures to apply the requirements of this Regulation to retail establishments situated on their territory to which it would not apply pursuant to subparagraphs (a) or (b).

6 This Regulation shall apply without prejudice to:

a relevant animal and public health rules, including more stringent rules laid down for the prevention, control and eradication of certain transmissible spongiform encephalopathies;

b animal welfare requirements;

and

c requirements concerning the identification of animals and the traceability of products of animal origin.

Article 2

Definitions

The following definitions shall apply for the purposes of this Regulation:

1. the definitions laid down in Regulation (EC) No 178/2002;

2. the definitions laid down in Regulation (EC) No 852/2004;

3. the definitions laid down in Annex I;

and

4. any technical definitions contained in Annexes II and III.

Editorial Information

X1 Substituted by Corrigendum 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 (Official Journal of the European Union L 139 of 30 April 2004).

CHAPTER II

FOOD BUSINESS OPERATORS' OBLIGATIONS

Article 3

General obligations

1 Food business operators shall comply with the relevant provisions of Annexes II and III.

[[F1]2 Food business operators shall not use any substance other than potable water or, when Regulation (EC) No 852/2004 or this Regulation permits its use, clean water, to remove surface contamination from products of animal origin, unless use of the substance has been approved by the Commission. For that purpose the Commission is empowered to adopt delegated acts in accordance with Article 11a supplementing this Regulation. Food business operators shall also comply with any conditions for use that may be adopted under the same procedure. The use of an approved substance shall not affect the food business operator's duty to comply with the requirements of this Regulation.**]**

Textual Amendments

F1 Substituted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).

Article 4

Registration and approval of establishments

1 Food business operators shall place products of animal origin manufactured in the Community on the market only if they have been prepared and handled exclusively in establishments:

a that meet the relevant requirements of Regulation (EC) No 852/2004, those of Annexes II and III of this Regulation and other relevant requirements of food law;

and

b that the competent authority has registered or, where required in accordance with paragraph 2, approved.

2 Without prejudice to Article 6(3) of Regulation (EC) No 852/2004, establishments handling those products of animal origin for which Annex III to this Regulation lays down requirements shall not operate unless the competent authority has approved them in accordance with paragraph 3 of this Article, with the exception of establishments carrying out only:

a primary production;

b transport operations;

c the storage of products not requiring temperature-controlled storage conditions;

or

d retail operations other than those to which this Regulation applies pursuant to Article 1(5)(b).

3 An establishment subject to approval in accordance with paragraph 2 shall not operate unless the competent authority has, in accordance with 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[(1)]:

a granted the establishment approval to operate following an on-site visit;

or

b provided the establishment with conditional approval.

4 Food business operators shall cooperate with the competent authorities in accordance with Regulation (EC) No 854/2004. In particular, food business operators shall ensure that an establishment ceases to operate if the competent authority withdraws its approval or, in the case of conditional approval, fails to prolong it or to grant full approval.

5 This Article shall not prevent an establishment from placing food on the market between the date of application of this Regulation and the first subsequent inspection by the competent authority, if the establishment:

a is subject to approval in accordance with paragraph 2 and placed products of animal origin on the market in accordance with Community legislation immediately prior to the application of this Regulation;

or

b is of a type in respect of which there was no requirement for approval before the application of this Regulation.

Article 5

Health and identification marking

1 Food business operators shall not place on the market a product of animal origin handled in an establishment subject to approval in accordance with Article 4(2) unless it has either:

a a health mark applied in accordance with Regulation (EC) No 854/2004;

or

b when that Regulation does not provide for the application of a health mark, an identification mark applied in accordance with Annex II, Section I, of this Regulation.

2 Food business operators may apply an identification mark to a product of animal origin only if the product has been manufactured in accordance with this Regulation in establishments meeting the requirements of Article 4.

3 Food business operators may not remove a health mark applied in accordance with Regulation (EC) No 854/2004 from meat unless they cut or process it or work upon it in another manner.

Article 6

Products of animal origin from outside the Community

1 Food business operators importing products of animal origin from third countries shall ensure that importation takes place only if:

a the third country of dispatch appears on a list, drawn up in accordance with Article 11 of Regulation (EC) No 854/2004, of third countries from which imports of that product are permitted;

b

(i) the establishment from which that product was dispatched, and in which it was obtained or prepared, appears on a list, drawn up in accordance with Article 12 of Regulation (EC) No 854/2004, of establishments from which imports of that product are permitted, when applicable,

(ii) in the case of fresh meat, minced meat, meat preparations, meat products and MSM, the product was manufactured from meat obtained in slaughterhouses and cutting plants appearing on lists drawn up and updated in accordance with Article 12 of Regulation (EC) No 854/2004 or in approved Community establishments,

and

(iii) in the case of live bivalve molluscs, echinoderms, tunicates and marine gastropods, the production area appears on a list drawn up in accordance with Article 13 of that Regulation, when applicable;

c the product satisfies:

(i) the requirements of this Regulation, including the requirements of Article 5 on health and identification marking;

(ii) the requirements of Regulation (EC) No 852/2004;

and

(iii) any import conditions laid down in accordance with Community legislation governing import controls for products of animal origin,

and

d the requirements of Article 14 of Regulation (EC) No 854/2004 concerning certificates and documents are satisfied, when applicable.

2 By way of derogation from paragraph 1, the importation of fishery products may also take place in accordance with the special provisions laid down in Article 15 of Regulation (EC) No 854/2004.

3 Food business operators importing products of animal origin shall ensure that:

a products are made available for control upon importation in accordance with Directive 97/78/EC[(2)];

b importation complies with the requirements of Directive 2002/99/EC[(3)];

and

c operations under their control that take place after importation are carried out in accordance with the requirements of Annex III.

4 Food business operators importing food containing both products of plant origin and processed products of animal origin shall ensure that the processed products of animal origin contained in such food satisfy the requirements of paragraphs 1 to 3. They must be able to demonstrate that they have done so (for example, through appropriate documentation or certification, which need not be in the format specified in paragraph 1(d)).

CHAPTER III

TRADE

Article 7

Documents

1 When required in accordance with Annex II or III, food business operators shall ensure that certificates or other documents accompany consignments of products of animal origin.

2 In accordance with the procedure referred to in Article 12(2):

a model documents may be established;

and

b provision may be made for the use of electronic documents.

Article 8

Special guarantees

1 Food business operators intending to place the following food of animal origin on the market in Sweden or Finland shall comply with the rules set out in paragraph 2 in respect of salmonella:

a meat from bovine and porcine animals, including minced meat but excluding meat preparations and MSM;

b meat from poultry of the following species: domestic fowl, turkeys, guinea-fowl, ducks and geese, including minced meat but excluding meat preparations and MSM;

and

c eggs.

2

a In the case of meat from bovine and porcine animals and meat from poultry, samples of consignments shall have been taken in the dispatching establishment and been subjected to a microbiological test with negative results in accordance with Community legislation.

b In the case of eggs, packing centres shall provide a guarantee that consignments originate from flocks that have been subjected to a microbiological test with negative results in accordance with Community legislation.

c In the case of meat from bovine and porcine animals, the test provided for in subparagraph (a) need not be carried out for consignments intended for an establishment for the purposes of pasteurisation, sterilisation or treatment having a similar effect. In the case of eggs, the test provided for in subparagraph (b) need not be carried out for consignments intended for the manufacture of processed products by a process that guarantees the elimination of salmonella.

d The tests provided for in subparagraphs (a) and (b) need not be carried out for foodstuffs originating in an establishment that is subject to a control programme recognised, in respect of the food of animal origin concerned and in accordance with the procedure referred to in Article 12(2), as equivalent to that approved for Sweden and Finland.

e In the case of meat from bovine and porcine animals and meat from poultry, a trade document or certificate conforming to a model laid down by Community legislation shall accompany the food and state that:

(i) the checks referred to in subparagraph (a) have been carried out with negative results;

or

(ii) the meat is intended for one of the purposes referred to in subparagraph (c);

or

(iii) the meat comes from an establishment covered by subparagraph (d).

f In the case of eggs, a certificate stating that the tests referred to in subparagraph (b) have been carried out with negative results, or that the eggs are destined to be used in the manner referred to in subparagraph (c), must accompany consignments.

[[F2]3

[[F1](a) The Commission is empowered to adopt delegated acts in accordance with Article 11a amending paragraphs 1 and 2 of this Article in order to update the requirements set out in those paragraphs, taking into account changes in Member States' control programmes or the adoption of microbiological criteria in accordance with Regulation (EC) No 852/2004.**]**

b In accordance with the regulatory procedure referred to in Article 12(2), the rules laid down in paragraph 2 of this Article in respect of any of the foodstuffs referred to in paragraph 1 of this Article may be extended, in whole or in part, to any Member State, or any region of a Member State, that has a control programme recognised as equivalent to that approved for Sweden and Finland in respect of the food of animal origin concerned.**]**

4 For the purposes of this Article, 'control programme' means a control programme approved in accordance with Regulation (EC) No 2160/2003.

Textual Amendments

F1 Substituted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).

F2 Substituted by Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Two.

CHAPTER IV

FINAL PROVISIONS

[F3]*Article 9*

. . . . . .

Textual Amendments

F3 Deleted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).

Article 10

Amendment and adaptation of Annexes II and III

[[F1]1 The Commission is empowered to adopt delegated acts in accordance with Article 11a amending Annexes II and III. The amendments shall have the aim of ensuring and facilitating the achievement of the objectives of this Regulation, taking into account the relevant risk factors, and shall be justified on the basis of:

a the experience gained by food business operators and/or competent authorities, in particular on the implementation of HACCP-based systems pursuant to Article 5;
b the experience gained by the Commission, in particular on the outcome of its audits;
c technological developments and their practical consequences, and consumer expectations with regard to food composition;
d scientific advice, particularly new risk assessments;
e microbiological and temperature criteria for foodstuffs;
f changes in patterns of consumption.

The amendments referred to in the first subparagraph shall concern:
a the requirements on the identification marking of products of animal origin;
b the objectives of HACCP-based procedures;
c the requirements on the food chain information;
d the specific hygiene requirements for the premises, including means of transport, where products of animal origin are produced, handled, processed, stored or distributed;
e the specific hygiene requirements for the operations involving the production, handling, processing, storage, transport or distribution of products of animal origin;
f the rules for the transport of meat while it is warm;
g the health standards or checks, where there is scientific evidence indicating that they are necessary to protect public health;
h the extension of Annex III, Section VII, Chapter IX, to live bivalve molluscs other than pectinidae;
i the criteria for determining when epidemiological data indicate that a fishing ground does not present a health hazard with regard to the presence of parasites and, consequently, for determining when the competent authority may authorise food business operators not to freeze fishery products in accordance with Annex III, Section VIII, Chapter III, Part D;
j the additional health standards for live bivalve molluscs in cooperation with the relevant Union Reference Laboratory, including:

(i) limit values and analysis methods for other marine biotoxins;

(ii) virus testing procedures and virological standards; and

(iii) sampling plans and the methods and analytical tolerances to be applied to check compliance with the health standards.

2 The Commission is empowered to adopt delegated acts in accordance with Article 11a in order to supplement this Regulation by granting derogations from Annex II and III, taking into account the relevant risk factors and provided that such derogations do not affect the achievement of the following objectives of this Regulation:
a to facilitate the fulfilment, by small businesses, of the requirements laid down in the Annexes;
b to enable the continued use of traditional methods at any of the stages of production, processing or distribution of food;
c to accommodate the needs of food businesses situated in regions that are subject to special geographic constraints;
d to facilitate the work of establishments producing raw material which is intended for the production of highly refined food products and which has undergone a treatment ensuring its safety.**]**

3 Member States may, without compromising achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4 to 8, national measures adapting the requirements laid down in Annex III.

4

a The national measures referred to in paragraph 3 shall have the aim of:

(i) enabling the continued use of traditional methods at any of the stages of production, processing or distribution of food;

or

(ii) accommodating the needs of food businesses situated in regions that are subject to special geographic constraints.

b In other cases, they shall apply only to the construction, layout and equipment of establishments.

5 Any Member State wishing to adopt national measures as referred to in paragraph 3 shall notify the Commission and other Member States. Each notification shall:

a provide a detailed description of the requirements that that Member State considers need to be adapted and the nature of the adaptation sought;

b describe the foodstuffs and establishments concerned;

c explain the reasons for the adaptation, including, where relevant, by providing a summary of the hazard analysis carried out and any measures to be taken to ensure that the adaptation will not compromise the objectives of this Regulation;

and

d give any other relevant information.

6 The other Member States shall have three months from the receipt of a notification referred to in paragraph 5 to send written comments to the Commission. In the case of adaptations arising from paragraph 4(b), this period shall, at the request of any Member State, be extended to four months. The Commission may, and when it receives written comments from one or more Member States shall, consult Member States within the committee referred to in Article 12(1). The Commission may decide, in accordance with the procedure referred to in Article 12(2), whether the envisaged measures may be implemented, subject, if necessary, to appropriate amendments. Where appropriate, the Commission may propose general measures in accordance with paragraph 1 or 2 of this Article.

7 A Member State may adopt national measures adapting the requirements of Annex III only:

a in compliance with a decision adopted in accordance with paragraph 6;

b if, one month after the expiry of the period referred to in paragraph 6, the Commission has not informed Member States that it has received written comments or that it intends to propose the adoption of a decision in accordance with paragraph 6;

or

c in accordance with paragraph 8.

8 A Member State may, of its own initiative and subject to the general provisions of the Treaty, maintain or establish national rules:

a prohibiting or restricting the placing on the market within its territory of raw milk or raw cream intended for direct human consumption;

or

b permitting the use, with the authorisation of the competent authority, of raw milk not meeting the criteria laid down in Annex III, Section IX, as regards plate count and somatic cell count of the manufacture of cheeses with an ageing or ripening period of at least 60 days, and dairy products obtained in connection with the manufacture of such cheeses, provided that this does not prejudice the achievement of the objectives of this Regulation.

Textual Amendments

F1 Substituted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).

Article 11

Specific decisions

[[F1]Without prejudice to the general application of Article 9 and Article 10(1), the Commission may lay down the following measures by means of implementing act. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 12(2):**]**

1. **[**[F3]. . . . .**]**
2. to specify, in respect of MSM, which calcium content is not significantly higher than that of minced meat;
3. to lay down other treatments that may be applied in a processing establishment to live bivalve molluscs from class B or C production areas that have not been submitted to purification or relaying;
4. to specify recognised testing methods for marine biotoxins;
5. **[**[F3]. . . . .
6. . . . .
7. . . . .
8. . . . .**]**
9. to lay down freshness criteria and limits with regard to histamine and total volatile nitrogen for fisheries products;
10. to permit the use for the manufacture of certain dairy products of raw milk not meeting the criteria laid down in Annex III, Section IX, as regards its plate count and somatic cell count;
11. without prejudice to Directive 96/23/EC[(4)], to fix a maximum permitted value for the combined total of residues of antibiotic substances in raw milk;

    and

12. to approve equivalent processes for the production of gelatine or collagen.

Textual Amendments

F1 Substituted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).

F3 Deleted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).

[F4 Article 11a

Exercise of the delegation

1 The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2 The power to adopt delegated acts referred to in Article 3(2), Article 8(3)(a) and Article 10(1) and (2) shall be conferred on the Commission for a period of five years from 26 July 2019. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3 The delegation of powers referred to in Article 3(2), Article 8(3)(a) and Article 10(1) and (2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4 Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[(5)].

5 As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6 A delegated act adopted pursuant to Article 3(2), Article 8(3)(a) and Article 10(1) and (2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.**]**

Textual Amendments

F4 Inserted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny

to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).

Article 12

Committee procedure

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period provided for in Article 5(6) of Decision 1999/468/EC shall be set at three months.

[F3]3 . . . . . .

Textual Amendments

F3 Deleted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).

Article 13

Consultation of the European Food Safety Authority

The Commission shall consult the European Food Safety Authority on any matter falling within the scope of this Regulation that could have a significant impact on public health and, in particular, before proposing to extend Annex III, Section III, to other animal species.

Article 14

Report to the European Parliament and to the Council

1 The Commission shall, not later than 20 May 2009, submit a report to the European Parliament and the Council reviewing the experience gained from the implementation of this Regulation.

2 The Commission shall, if appropriate, accompany the report with relevant proposals.

Article 15

This Regulation shall enter into force on the 20th day after that of its publication in the *Official Journal of the European Union*.

It shall apply 18 months after the date on which all of the following acts have entered into force:

(a) Regulation (EC) No 852/2004;

(b) Regulation (EC) No 854/2004;

and

(c) Directive 2004/41/EC.

However, it shall apply no earlier than 1 January 2006.

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

(1) **[**[X1]See page 83 of this Official Journal.**]**

(2) **[**[X1]Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9). Directive amended by the 2003 Act of Accession.**]**

(3) **[**[X1]Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption (OJ L 18, 23.1.2003, p. 11).**]**

(4) **[**[X1]Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products (OJ L 125, 23.5.1996, p. 10). Directive as amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).**]**

(5) **[**[X1]**[**[F4]OJ L 123, 12.5.2016, p. 1.**]]**

Editorial Information

X1 Substituted by Corrigendum 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 (Official Journal of the European Union L 139 of 30 April 2004).

Textual Amendments

F4 Inserted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).

Status:
Point in time view as at 31/01/2020.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 853/2004 of the European Parliament and of the Council.