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 IV

FINAL PROVISIONS

F1*Article 9*

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Textual Amendments

F1 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

[F21 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.

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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

F2 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

[[F2]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. **[**F1. . . . .**]**

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. **[**F1. . . . .

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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[(1)], 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 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).

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I[F3] *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[(2)].

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

F3 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.

[F1]3 . . . . . .

Textual Amendments

F1 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.**]**

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).

(1) **[**[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).**]**

(2) **[**[X1]**[**[F3]OJ L 123, 12.5.2016, p. 1.**]]**

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Status:
Point in time view as at 26/07/2019.

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, CHAPTER IV.