

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

[<sup>X1</sup>CHAPTER IV

**FINAL PROVISIONS**

*<sup>F1</sup>Article 9*

**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**

[<sup>F21</sup> The appropriate authority may prescribe amendments to Annexes 2 and 3 to take account of—

- a the development of guides to good practice;
- b the experience gained from the implementation of HACCP-based systems pursuant to Article 5 of Regulation (EC) No 852/2004;
- c the 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; and
- f changes in patterns of consumption.]

[<sup>F31A</sup> Amendments under paragraph 1 may, in particular, prescribe—

- 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 (specific requirements for pectinidae, marine gastropods and echinoderms which are not filter feeders harvested outside classified production areas), to live bivalve molluscs other than pectinidae;

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. (See end of Document for details)

- 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 (requirements concerning parasites);
- j the additional health standards for live bivalve molluscs in cooperation with the relevant 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.]

[<sup>F42</sup> Without prejudice to the general application of Article 10(1), the appropriate authority may, provided that they do not affect the achievement of the objectives of this Regulation, prescribe [<sup>F5</sup>derogations] from Annexes 2 and 3 [<sup>F6</sup>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].]

[<sup>F73</sup> Nothing in this Regulation prevents the appropriate authority from using any power which the appropriate authority has to make subordinate legislation adapting the requirements set down in Annex 3 where that legislation does not compromise the achievement of the objectives of this Regulation and—

- a the adaptations 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 geographical constraints;
- b in cases not involving the matters at (a), the adaptations apply only to the construction, layout and equipment of establishments.]

<sup>F84</sup> .....

<sup>F85</sup> .....

<sup>F86</sup> .....

<sup>F87</sup> .....

[<sup>F98</sup> Nothing in this Regulation prevents the appropriate authority from using any power which the appropriate authority has to make subordinate legislation—

- a prohibiting or restricting the placing on the market raw milk or raw cream intended for direct human consumption;

**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. (See end of Document for details)

- b permitting the use, with the authorisation of the competent authority, of raw milk not meeting the criteria laid down in Annex 3, Section 9 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** Art. 10(1) substituted (31.12.2020) by The Specific Food Hygiene (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/640), regs. 1, **11(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F3** Art. 10(1A) inserted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), **9(3)(a)**
- F4** Art. 10(2) substituted (31.12.2020) by The Specific Food Hygiene (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/640), regs. 1, **11(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F5** Word in Art. 10(2) substituted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), **9(3)(b)(i)**
- F6** Words in Art. 10(2) inserted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), **9(3)(b)(ii)**
- F7** Art. 10(3) substituted (31.12.2020) by The Specific Food Hygiene (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/640), regs. 1, **11(e)**; 2020 c. 1, Sch. 5 para. 1(1)
- F8** Art. 10(4)-(7) omitted (31.12.2020) by virtue of The Specific Food Hygiene (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/640), regs. 1, **11(d)**; 2020 c. 1, Sch. 5 para. 1(1)
- F9** Art. 10(8) substituted (31.12.2020) by The Specific Food Hygiene (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/640), regs. 1, **11(e)**; 2020 c. 1, Sch. 5 para. 1(1)

#### Article 11

#### Specific decisions

[<sup>F10</sup>Without prejudice to the general application of Article 10(1), the appropriate authority may prescribe implementing measures or amendments <sup>F11</sup>...—]

1. <sup>F1</sup>...
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. <sup>F1</sup>...
6. <sup>F1</sup>...
7. <sup>F1</sup>...
8. <sup>F1</sup>...
9. to lay down freshness criteria and limits with regard to histamine and total volatile nitrogen for fisheries products;

---

**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. (See end of Document for details)

---

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<sup>(1)</sup>, 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).
- F10** Words in Art. 11 substituted (31.12.2020) by virtue of The Specific Food Hygiene (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/640), regs. 1, **12(a)**; 2020 c. 1, **Sch. 5 para. 1(1)**
- F11** Words in Art. 11 omitted (31.12.2022) by virtue of The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), **9(4)**

#### <sup>F12</sup>Article 11a

#### Exercise of the delegation

#### Textual Amendments

- F12** Art. 11a omitted (31.12.2020) by virtue of S.I. 2019/640, **reg. 12A** (as substituted by The Food and Feed Hygiene and Safety (Miscellaneous Amendments etc.) (EU Exit) Regulations 2020 (S.I. 2020/1504), regs. 1(2), **9(7)**)

#### <sup>F14</sup>Article 12

#### <sup>F13</sup>Regulations and devolved powers]

- 1 Any power to make regulations under this Regulation—
  - a) so far as exercisable by a Minister of the Crown, is exercisable by statutory instrument;
  - b) so far as exercisable by the Welsh Ministers, is exercisable by statutory instrument.
- 2 For regulations made under this Regulation by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010 (Scottish statutory instruments).
- 3 Any power to make regulations under this Regulation includes power—
  - a) to make different provision in relation to different cases or classes of case (including different provision for different areas or different classes of business);

---

**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. (See end of Document for details)

---

- b) to provide for such exceptions, limitations and conditions, and to make such supplementary, incidental, consequential or transitional provisions, as the appropriate authority considers necessary or expedient.
4. Any statutory instrument or Scottish statutory instrument containing regulations under this Regulation is subject to annulment in pursuance of a resolution—
- a) in the case of England, of either House of Parliament;
  - b) in the case of Wales, of Senedd Cymru;
  - c) in the case of Scotland, of the Scottish Parliament.
5. In this Regulation, any power—
- a) of the Secretary of State to make regulations is limited to regulations which apply in relation to England only;
  - b) of the Welsh Ministers to make regulations is limited to regulations which apply in relation to Wales only;
  - c) of the Scottish Ministers to make regulations is limited to regulations which apply in relation to Scotland only.]

---

#### Textual Amendments

**F13** Art. 12 heading substituted (31.12.2020) by The Specific Food Hygiene (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/640), regs. 1, **13(a)**; 2020 c. 1, Sch. 5 para. 1(1)

**F14** Art. 12 substituted (31.12.2020) by The Specific Food Hygiene (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/640), regs. 1, **13(b)** (as amended by S.I. 2020/1504, regs. 1(2), **9(8)**); 2020 c. 1, **Sch. 5 para. 1(1)**

#### <sup>F16</sup> Article 13

#### Consultation of the <sup>F15</sup> ... Food Safety Authority

The appropriate authority must consult the Food Safety Authority on matters falling within the scope of this Regulation that could have a significant impact on public health and, in particular, before proposing to extend Annex 3, Section 3, to other animal species.]

---

#### Textual Amendments

**F15** Word in Art. 13 heading omitted (31.12.2020) by virtue of The Specific Food Hygiene (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/640), regs. 1, **14(a)**; 2020 c. 1, Sch. 5 para. 1(1)

**F16** Art. 13 substituted (31.12.2020) by The Specific Food Hygiene (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/640), regs. 1, **14(b)**; 2020 c. 1, Sch. 5 para. 1(1)

#### <sup>F17</sup> Article 14

#### Report to the European Parliament and to the Council

---

---

**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. (See end of Document for details)

---

#### Textual Amendments

- F17** Art. 14 omitted (31.12.2020) by virtue of [The Specific Food Hygiene \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/640\)](#), regs. 1, **15**; 2020 c. 1, Sch. 5 para. 1(1)

#### 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 \(Official Journal of the European Union L 139 of 30 April 2004\)](#).

---

**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. (See end of Document for details)

---

- (1) [<sup>XI</sup>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).]

---

**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 \(Official Journal of the European Union L 139 of 30 April 2004\)](#).

**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 .