

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 II

### **FOOD BUSINESS OPERATORS' OBLIGATIONS**

#### *Article 3*

#### **General obligations**

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

[<sup>F12</sup> Food business operators must 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 prescribed by the appropriate authority. Food business operators must comply with any conditions of use that may be prescribed by the appropriate authority. The use of a prescribed substance does not affect the food business operator's duty to comply with the requirements of this Regulation.]

#### **Textual Amendments**

- F1** Art. 3(2) substituted (31.12.2020) by [The Specific Food Hygiene \(Regulation \(EC\) No. 853/2004\) \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/1247\)](#), regs. 1(3), 4; 2020 c. 1, Sch. 5 para. 1(1)

#### *Article 4*

#### **Registration and approval of establishments**

1 Food business operators shall place products of animal origin <sup>F2</sup>... 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

---

**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 II. (See end of Document for details)

---

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<sup>(1)</sup>:

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 <sup>F3</sup>... 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.

#### Textual Amendments

**F2** Words in [Art. 4\(1\)](#) omitted (31.12.2020) by virtue of [The Specific Food Hygiene \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/640\)](#), regs. 1, [7\(a\)](#); 2020 c. 1, Sch. 5 para. 1(1)

**F3** Word in [Art. 4\(5\)\(a\)](#) omitted (31.12.2020) by virtue of [The Specific Food Hygiene \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/640\)](#), regs. 1, [7\(b\)](#); 2020 c. 1, Sch. 5 para. 1(1)

### 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 [<sup>F4</sup>Great Britain]

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

- a the <sup>F5</sup>... country of dispatch appears on a list, drawn up in accordance with Article 11 of Regulation (EC) No 854/2004, of <sup>F5</sup>... 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 <sup>F6</sup>...,  
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 <sup>F7</sup>... 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<sup>(2)</sup>;
  - b importation complies with the requirements of Directive 2002/99/EC<sup>(3)</sup>;
- and

---

**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 II. (See end of Document for details)

---

- 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)).]

#### Textual Amendments

- F4** Words in Art. 6 heading substituted (31.12.2020) by [The Specific Food Hygiene \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/640\)](#), **reg. 8(a)** (as substituted by S.I. 2020/1504, regs. 1(2), **9(4)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F5** Word in Art. 6(1)(a) omitted (31.12.2020) by virtue of [The Specific Food Hygiene \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/640\)](#), regs. 1, **8(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F6** Words in Art. 6(1)(b)(ii) omitted (31.12.2020) by virtue of [The Specific Food Hygiene \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/640\)](#), regs. 1, **8(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F7** Word in Art. 6(1)(c)(iii) omitted (31.12.2020) by virtue of [The Specific Food Hygiene \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/640\)](#), regs. 1, **8(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(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 II. (See end of Document for details)

---

- (1) [<sup>X1</sup>See page 83 of this Official Journal.]
- (2) [<sup>X1</sup>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) [<sup>X1</sup>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).]

---

**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 II.