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STATUTORY INSTRUMENTS

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**2019 No. 641**

**EXITING THE EUROPEAN UNION  
AGRICULTURE  
FOOD**

**The General Food Law (Amendment  
etc.) (EU Exit) Regulations 2019**

*Made - - - - 18th March 2019*

*Coming into force in accordance with regulation 1*

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 8(1) of the European Union (Withdrawal) Act 2018 <sup>M1</sup>.

In accordance with paragraph 1(1) of Schedule 7 to that Act, a draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament.

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety there has been open and transparent public consultation during the preparation of these Regulations.

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**Marginal Citations**

**M1** 2018 c. 16.

**PART 1 U.K.**

Introduction

**Citation and commencement U.K.**

1. These Regulations may be cited as the General Food Law (Amendment etc.) (EU Exit) Regulations 2019 and come into force on exit day.

#### Commencement Information

- I1** Reg. 1 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

#### Interpretation **U.K.**

##### 2. In these Regulations—

“Regulation 178/2002” means Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;

“Regulation 16/2011” means Commission Regulation (EU) No. 16/2011 laying down implementing measures for the Rapid alert system for food and feed;

“Regulation 931/2011” means Commission Implementing Regulation (EU) No. 931/2011 on the traceability requirements set by Regulation (EC) No. 178/2002 of the European Parliament and of the Council for food of animal origin.

#### Commencement Information

- I2** Reg. 2 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

## PART 2 **U.K.**

### Amendment of subordinate legislation

#### Amendment of the Food Safety and Hygiene (England) Regulations 2013 **U.K.**

##### 3. The Food Safety and Hygiene (England) Regulations 2013 <sup>M2</sup> are amended as follows.

#### Commencement Information

- I3** Reg. 3 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

#### Marginal Citations

- M2** [S.I. 2013/2996](#), amended by [S.I. 2014/1855](#), [S.I. 2014/2748](#), [S.I. 2014/2885](#) and [S.I. 2016/868](#).

#### **U.K.**

##### [<sup>F1</sup>3A. In regulation 19—

- (a) in paragraph (1), for “(8)” substitute “(9)”; and
- (b) after paragraph (8), substitute—

“(9) A person is to be considered not to have contravened or failed to comply with Article 5(1) of Regulation 853/2004 if—

- (a) in the case of a health mark—

- (i) the health mark was applied to a product of animal origin in accordance with Article 5(1) before IP completion day; and
  - (ii) the health mark complied with Article 5(1) as that Article applied immediately before IP completion day;
- (b) in the case of an identification mark—
- (i) the identification mark was applied to a product of animal origin subject to Article 5(1) before IP completion day; or
  - (ii) the identification mark is applied to a product of animal origin in accordance with Article 5(1) as that Article applied immediately before IP completion day, no later than 21 months after IP completion day ends, using a label, wrapping or packaging bearing that identification mark which is owned by the food business operator immediately before IP completion day.”.]

#### Textual Amendments

- F1** Reg. 3A inserted (31.12.2020 immediately before IP completion day) by [The Food and Feed Hygiene and Safety \(Miscellaneous Amendments etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1504\)](#), regs. 1(2), **10(2)**

#### Commencement Information

- I4** Reg. 3A in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

### U.K.

4. For Schedule 2, substitute the Schedule set out in the Schedule to these Regulations.

#### Commencement Information

- I5** Reg. 4 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

## PART 3 U.K.

### Amendment of retained direct EU legislation

#### Amendment of Regulation 178/2002 U.K.

5. Regulation 178/2002 is amended as follows.

#### Commencement Information

- I6** Reg. 5 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

**U.K.**

6. In Article 1—
- (a) in paragraph 1, omit “internal”;
  - (b) in paragraph 2, omit “at Community and national level. It establishes the European Food Safety Authority.”.

**Commencement Information**

- I7** Reg. 6 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

**U.K.**

7. In Article 3—
- (a) in paragraph 1, omit “whether at Community or national level”;
  - [<sup>F2</sup>(b) at the end insert—

“19. “appropriate authority” means—

- (a) in relation to England, the Secretary of State;
- (b) in relation to Wales, the Welsh Ministers;
- (c) in relation to Scotland, the Scottish Ministers;

20. “third country” means any country or territory other than the British Islands.”.]

**Textual Amendments**

- F2** Reg. 7(b) substituted (31.12.2020 immediately before IP completion day) by [The Food and Feed Hygiene and Safety \(Miscellaneous Amendments etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1504\)](#), regs. 1(2), **10(3)**

**Commencement Information**

- I8** Reg. 7 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

**U.K.**

8. In Article 4, omit paragraphs 3 and 4.

**Commencement Information**

- I9** Reg. 8 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

**U.K.**

9. In Article 5—

(a) omit paragraph 2;

[<sup>F3</sup>(b) in paragraph 3, for “the Community” substitute “ Great Britain ”.]

#### Textual Amendments

**F3** Reg. 9(b) substituted (31.12.2020 immediately before IP completion day) by [The Food and Feed Hygiene and Safety \(Miscellaneous Amendments etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1504\)](#), regs. 1(2), **10(4)**

#### Commencement Information

**I10** Reg. 9 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

#### U.K.

**10.** In Article 6(3), omit “in particular, the opinions of the Authority referred to in Article 22,”.

#### Commencement Information

**I11** Reg. 10 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

#### U.K.

[<sup>F4</sup>**11.** In Article 7, in both places it occurs, for “the Community” substitute “ Great Britain ”.]

#### Textual Amendments

**F4** Reg. 11 substituted (31.12.2020 immediately before IP completion day) by [The Food and Feed Hygiene and Safety \(Miscellaneous Amendments etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1504\)](#), regs. 1(2), **10(5)**

#### Commencement Information

**I12** Reg. 11 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

#### U.K.

**12.** In Article 10, at the beginning, omit “Without prejudice to the applicable provisions of Community and national law on access to documents,”.

#### Commencement Information

**I13** Reg. 12 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

#### U.K.

[<sup>F5</sup>**13.** For Article 11 substitute—

### “Food and feed imported into Great Britain

11. Food and feed imported into Great Britain for placing on the market within Great Britain must comply with the relevant requirements of food law or conditions recognised by Great Britain to be at least equivalent thereto or, where a specific agreement exists between the United Kingdom and an exporting country, with requirements contained therein.”.]

#### Textual Amendments

- F5** Reg. 13 substituted (31.12.2020 immediately before IP completion day) by [The Food and Feed Hygiene and Safety \(Miscellaneous Amendments etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1504\)](#), regs. 1(2), **10(6)**

#### Commencement Information

- I14** Reg. 13 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

### U.K.

14. In Article 12—

- [<sup>F6</sup>(a) in the heading, for “the Community” substitute “ Great Britain ”;  
(b) in paragraph 1, in both places it occurs, for “the Community” substitute “ Great Britain ”;]  
(c) for paragraph 2, substitute—

“2. Where the provisions of a bilateral agreement concluded between the United Kingdom and a third country are applicable, food and feed exported from the United Kingdom to that third country must comply with those provisions.”.

#### Textual Amendments

- F6** Reg. 14(a)(b) substituted (31.12.2020 immediately before IP completion day) by [The Food and Feed Hygiene and Safety \(Miscellaneous Amendments etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1504\)](#), regs. 1(2), **10(7)(a)**

#### Commencement Information

- I15** Reg. 14 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

### U.K.

15. In Article 13—

- (a) at the beginning, for “Without prejudice to their rights and obligations, the Community and the Member States shall.”, substitute “ The appropriate authorities must— ”;  
[<sup>F7</sup>(b) in paragraph (e), for “the Community” substitute “ Great Britain ”.]

#### Textual Amendments

- F7** Reg. 15(b) substituted (31.12.2020 immediately before IP completion day) by [The Food and Feed Hygiene and Safety \(Miscellaneous Amendments etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1504\)](#), regs. 1(2), **10(8)**

#### Commencement Information

- I16** Reg. 15 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

### U.K.

16. In Article 14—

[<sup>F8</sup>(a) in paragraph 7—

(i) in the first place it occurs, for “Community provisions” substitute “legislation in force in the relevant constituent territory of Great Britain”;

(ii) omit “Community” in the second place it occurs;]

(b) omit paragraph 9.

#### Textual Amendments

- F8** Reg. 16(a) substituted (31.12.2020 immediately before IP completion day) by [The Food and Feed Hygiene and Safety \(Miscellaneous Amendments etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1504\)](#), regs. 1(2), **10(9)**

#### Commencement Information

- I17** Reg. 16 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

### U.K.

17. In Article 15—

[<sup>F9</sup>(a) in paragraph 4—

(i) in the first place “Community provisions” occurs, substitute “legislation in force in the relevant constituent territory of Great Britain”;

(ii) in the second place “Community provisions” occurs, omit “Community”];

(b) omit paragraph 6.

#### Textual Amendments

- F9** Reg. 17(a) substituted (31.12.2020 immediately before IP completion day) by [The Food and Feed Hygiene and Safety \(Miscellaneous Amendments etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1504\)](#), regs. 1(2), **10(10)**

#### Commencement Information

- I18** Reg. 17 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

**U.K.**

18. In Article 17, omit—

- (a) paragraph 2;
- (b) the words from and including “For that purpose” to and including “dissuasive”.

**Commencement Information**

**I19** Reg. 18 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see [reg. 1](#)

**U.K.**

19. In Article 18—

[<sup>F10</sup>(a) in paragraph (4), for “the Community” substitute “ Great Britain ”;]

[<sup>F11</sup>(b) for paragraph (5) substitute—

“5. The appropriate authority may make regulations for the purpose of applying the requirements of this Article in respect of specific sectors.”]

[<sup>F12</sup>(c) . . . . .

**Textual Amendments**

**F10** Reg. 19(a) substituted (31.12.2020 immediately before IP completion day) by [The Food and Feed Hygiene and Safety \(Miscellaneous Amendments etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1504\)](#), [regs. 1\(2\)](#), **10(11)(a)**

**F11** Reg. 19(b) substituted (31.12.2020 immediately before IP completion day) by [The Food and Feed Hygiene and Safety \(Miscellaneous Amendments etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1504\)](#), [regs. 1\(2\)](#), **10(11)(b)**

**F12** Reg. 19(c) omitted (31.12.2020 immediately before IP completion day) by virtue of [The Food and Feed Hygiene and Safety \(Miscellaneous Amendments etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1504\)](#), [regs. 1\(2\)](#), **10(11)(c)**

**Commencement Information**

**I20** Reg. 19 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see [reg. 1](#)

**U.K.**

20. Omit—

- (a) Article 21;
- (b) Chapter 3;
- [<sup>F13</sup>(c) Chapter 4 except Article 53.]



### Textual Amendments

- F13** Reg. 20(c) substituted (31.12.2020 immediately before IP completion day) by [The Food and Feed Hygiene and Safety \(Miscellaneous Amendments etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1504\)](#), regs. 1(2), **10(12)**

### Commencement Information

- I21** Reg. 20 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

## U.K.

[<sup>F14</sup>**20A.** In Article 53—

- (a) in the heading, omit “of Community origin or imported from a third country”;
- (b) in paragraph 1—
  - (i) for the text before subparagraph (a), substitute—

“Where it is evident that food or feed originating in the United Kingdom, or imported into Great Britain from outside the United Kingdom, is likely to constitute a serious risk to human health, animal health or the environment, the appropriate authority may made regulations, containing one or more the following measures, depending on the gravity of the situation—”;
  - (ii) in subparagraph (a), for “of Community origin” substitute “originating in the United Kingdom”;
  - (iii) for the opening line of subparagraph (b), substitute—

“(b)in the case of food or feed imported from outside the United Kingdom—”;
  - (iv) in subparagraphs (b)(i) and (ii), omit “third”;
- (c) omit paragraph 2.]

### Textual Amendments

- F14** Reg. 20A inserted (31.12.2020 immediately before IP completion day) by [The Food and Feed Hygiene and Safety \(Miscellaneous Amendments etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1504\)](#), regs. 1(2), **10(13)**

### Commencement Information

- I22** Reg. 20A in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

## U.K.

**21.** In Chapter 5—

[<sup>F15</sup>(aa) for Article 57a substitute—

*“Article 57a  
Procedure*

1. Regulations made by the Secretary of State or the Welsh Ministers under this Regulation are to be made by statutory instrument.

2. For regulations made by the Scottish Ministers under this Regulation, see section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010.

3. A statutory instrument containing regulations made by the Secretary of State under this Regulation is subject to annulment in pursuance of a resolution of either House of Parliament.

4. A statutory instrument containing regulations made by the Welsh Ministers under this Regulation is subject to annulment in pursuance of a resolution of Senedd Cymru.

5. Regulations made by the Scottish Ministers under this Regulation are subject to the negative procedure (see section 28 of the Interpretation and Legislative Reform (Scotland) Act 2010).

6. Regulations made under this Regulation may—

(a) contain consequential, incidental, supplementary, transitional or saving provision;

(b) make different provision for different purposes.”.]

(a) omit Article 58, 59, 60, 61, 62, 63 and 64;

(b) in Article 65, omit—

“Articles 29, 56, 57 and 60 and Article 62(1) shall apply as from the date of appointment of the members of the Scientific Committee and of the Scientific Panels which shall be announced by means of a notice in the ‘C’ series of the Official Journal.”.

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**Textual Amendments**

**F15** Reg. 21(aa) inserted (31.12.2020 immediately before IP completion day) by [The Food and Feed Hygiene and Safety \(Miscellaneous Amendments etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1504\)](#), regs. 1(2), **10(14)**

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**Commencement Information**

**I23** Reg. 21 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

**U.K.**

22. After Article 65, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

**Commencement Information**

**I24** Reg. 22 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

**Amendment of Regulation 931/2011** **U.K.**

23. Regulation 931/2011 is amended as follows.

**Commencement Information**

**I25** Reg. 23 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

**U.K.**

24. In Article 3(2), omit “Union”.

**Commencement Information**

**I26** Reg. 24 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

**U.K.**

25. After Article 4, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

**Commencement Information**

**I27** Reg. 25 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

**PART 4** **U.K.**

Revocation of retained direct EU legislation

**Revocation of Regulation 16/2011** **U.K.**

26. Regulation 16/2011 is revoked.

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**Changes to legislation:** There are currently no known outstanding effects for the The General Food Law (Amendment etc.) (EU Exit) Regulations 2019. (See end of Document for details)

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**Commencement Information**

**I28** Reg. 26 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

Signed by the authority of the Secretary of State for Health and Social Care.

Department of Health and Social Care

*Steve Brine*  
Parliamentary Under-Secretary of State,

SCHEDULE **U.K.**

Regulation 4

**Commencement Information**

**I29** Sch. in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

“Schedule 2 **U.K.**

Specified EU provisions

| <i>1. Provision of retained EU law</i>   | <i>2. Subject matter</i>   |
|--|--|
| Article 12 of Regulation 178/2002, as it relates to food                               | Requirement that food exported or re-exported from [ <sup>F16</sup> Great Britain] to third countries must comply with the relevant requirements of food law, except in certain specified circumstances.   |
| Article 14(1) of Regulation 178/2002   | Requirement that unsafe food must not be placed on the market.   |
| Article 16 of Regulation 178/2002, as it relates to food                               | Requirement that the labelling, advertising and presentation of food must not mislead consumers.   |
| Article 18(2) and (3) of Regulation 178/2002, as it relates to food business operators | Requirement that food business operators must ensure traceability of food, including having systems in place to identify businesses from which they have been supplied and to which they have supplied food.   |
| Article 19 of Regulation 178/2002  | Requirement that where there has been a breach of food safety requirements food business operators must, in specified circumstances, recall and/or withdraw the affected food and inform consumers and the competent authorities.  |
| Article 3 of Regulation 852/2004   | Requirement that food business operators ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in Regulation 852/2004.   |
| Article 4(1) of Regulation 852/2004  | Requirement that food business operators carrying out primary production and specified associated operations comply with the general hygiene provisions laid down in Part A of Annex 1 to Regulation 852/2004 and any specific requirements provided for in Regulation 853/2004. |
| Article 4(2) of Regulation 852/2004  | Requirement that food business operators carrying out any stage of production, processing and distribution of food after those stages to which Article 4(1) applies comply with the general hygiene requirements laid down   |

**Changes to legislation:** There are currently no known outstanding effects for the The General Food Law (Amendment etc.) (EU Exit) Regulations 2019. (See end of Document for details)

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|  | in Annex 2 to Regulation 852/2004 and any specific requirements provided for in Regulation 853/2004 and Regulation 579/2014.   |
| Article 4(3) of Regulation 852/2004                    | Requirement that food business operators, as appropriate, adopt certain specific hygiene measures.   |
| Article 5(1) of Regulation 852/2004                    | Requirement that food business operators put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.   |
| Article 5(2) of Regulation 852/2004                    | Requirement that when any modification is made in the product, process, or any step, food business operators review the procedure referred to in Article 5(1) and make the necessary changes to it.                                  |
| Article 5(4)(a) of Regulation 852/2004                 | Requirement that food business operators provide the competent authority with evidence of their compliance with Article 5(1).  |
| Article 5(4)(b) of Regulation 852/2004                 | Requirement that food business operators ensure that any documents describing the procedures developed in accordance with Article 5 are up to date.  |
| Article 5(4)(c) of Regulation 852/2004                 | Requirement that food business operators retain documents and records for an appropriate period.   |
| Article 6(1) of Regulation 852/2004                    | Requirement that food business operators co-operate with the competent authorities in accordance with United Kingdom law.  |
| Article 6(2), first paragraph, of Regulation 852/2004  | Requirement that a food business operator notify the competent authority of each establishment under its control that carries out any of the stages of production, processing and distribution of food.                              |
| Article 6(2), second paragraph, of Regulation 852/2004 | Requirement that food business operators ensure that the competent authority has up to date information on establishments.   |
| Article 6(3) of Regulation 852/2004                    | Requirement that food business operators ensure that establishments are approved by the competent authority when approval is required.   |
| Article 3(1) of Regulation 853/2004                    | Requirement that food business operators comply with the relevant provisions of Annexes 2 and 3 to Regulation 853/2004.  |
| Article 3(2) of Regulation 853/2004                    | Requirement that food business operators do not use any substance other than potable water or, when Regulation 852/2004 or Regulation 853/2004 permits its use, clean water, to remove surface contamination from products of animal |

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|-------------------------------------|---|
|                                     | origin unless use of the substance has been approved.   |
| Article 4(1) of Regulation 853/2004 | Requirement that food business operators place products of animal origin on the market only if they have been prepared and handled exclusively in establishments—<br>(a) that meet the relevant requirements of Regulation 852/2004, those of Annexes 2 and 3 of Regulation 853/2004 and other relevant requirements of food law; and<br>(b) that the competent authority has registered or, where required in accordance with Article 4(2), approved.                |
| Article 4(2) of Regulation 853/2004 | Requirement that establishments handling those products of animal origin for which Annex 3 to Regulation 853/2004 lays down requirements do not operate unless the competent authority has approved them in accordance with Article 4(3).   |
| Article 4(3) of Regulation 853/2004 | Requirement that establishments subject to approval in accordance with Article 4(2) do not operate unless the competent authority has, in accordance with [F17Regulation 2017/625]—<br>(a) granted the establishment approval to operate following an on-site visit; or<br>(b) provided the establishment with conditional approval.  |
| Article 4(4) of Regulation 853/2004 | Requirement that food business operators co-operate with the competent authorities in accordance with [F17Regulation 2017/625] including ensuring that an establishment ceases to operate if it is no longer approved.  |
| Article 5(1) of Regulation 853/2004 | Requirement that food business operators do 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—<br>(a) a health mark applied in accordance with [F17Regulation 2017/625]; or<br>(b) when [F17Regulation 2017/625] does not provide for the application of a health mark, an identification mark applied in accordance with Section 1 of Annex 2 to Regulation 853/2004. |
| Article 5(2) of Regulation 853/2004 | Requirement that food business operators apply an identification mark to a product of animal origin only if the product has been manufactured in accordance with Regulation 853/2004 in establishments meeting the requirements of Article 4.   |
| Article 5(3) of Regulation 853/2004 | Requirement that food business operators do not remove a health mark applied in accordance with   |

**Changes to legislation:** There are currently no known outstanding effects for the The General Food Law (Amendment etc.) (EU Exit) Regulations 2019. (See end of Document for details)

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|---|--|
|   | [ <sup>F17</sup> Regulation 2017/625] from meat unless they cut or process it or work upon it in another manner.   |
| Article 6(1) and (2) of Regulation 853/2004 | Requirement that food business operators ensure that importation of products of animal origin only takes place where certain conditions are met.   |
| Article 6(3) of Regulation 853/2004         | Requirement that food business operators importing products of animal origin shall ensure that—<br>(a) products are made available for control upon importation in accordance with Council Directive <a href="#">97/78/EC</a> ;<br>(b) importation complies with the requirements of Council Directive <a href="#">2002/99/EC</a> ; and<br>(c) operations under their control that take place after importation are carried out in accordance with the requirements of Annex 3 to Regulation 853/2004. |
| Article 6(4) of Regulation 853/2004         | Requirement that food business operators importing food containing both products of plant origin and processed products of animal origin ensure that the processed products of animal origin satisfy the requirements of paragraphs (1) to (3) of Article 6.   |
| Article 7 of Regulation 853/2004            | Requirement that food business operators ensure that certificates or other documents accompany consignments of products of animal origin when required in accordance with Annex 2 or 3 to Regulation 853/2004.   |
| Article 7(1) of Regulation 2073/2005        | Requirement that food business operators take the measures laid down in paragraphs (2) to (4) of Article 7 when the results of testing against the criteria set out in Annex 1 to Regulation 2073/2005 (microbiological criteria for foodstuffs) are unsatisfactory.   |
| Article 9 of Regulation 2015/1375           | Requirement that food business operators of holdings officially recognised as applying controlled housing conditions must inform the competent authority of any requirement of Annex 4 to Regulation 2015/1375 that is no longer fulfilled or of any other change that might affect the holdings' Trichinella status.”   |

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#### Textual Amendments

**F16** Words in Sch. substituted (31.12.2020 immediately before IP completion day) by [The Food and Feed Hygiene and Safety \(Miscellaneous Amendments etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1504\)](#), regs. 1(2), **10(15)(a)**



**F17** Words in Sch. substituted (31.12.2020 immediately before IP completion day) by [The Food and Feed Hygiene and Safety \(Miscellaneous Amendments etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1504\)](#), regs. 1(2), **10(15)(b)**

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations are made in exercise of the powers conferred by section 8(1) of the European Union (Withdrawal) Act 2018 (c. 16) in order to address failures of retained EU law to operate effectively and other deficiencies arising from the withdrawal of the United Kingdom from the European Union. In particular, the Regulations address the deficiency specified in section 8(2)(b) of that Act, namely the conferral of functions by retained EU law on, or in relation to, EU entities which no longer have functions in that respect under EU law in relation to the United Kingdom. These Regulations make amendments to legislation relating to the safety of food and animal feed. Part 2 amends subordinate legislation in England. Part 3 amends retained direct EU legislation for the whole of the United Kingdom, and Part 4 revokes certain retained direct EU legislation for the whole of the United Kingdom.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the public, private or voluntary sector is foreseen.

**Changes to legislation:**

There are currently no known outstanding effects for the The General Food Law (Amendment etc.) (EU Exit) Regulations 2019.