

*Draft Regulations laid before Parliament under paragraph 1(1) of Schedule 7 to the European Union  
(Withdrawal) Act 2018, for approval by resolution of each House of Parliament.*

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DRAFT STATUTORY INSTRUMENTS

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**2019 No. 0000**

**EXITING THE EUROPEAN UNION  
AGRICULTURE  
FOOD**

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

*Made - - - -*

*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>(1)</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.

**PART 1**

**Introduction**

**Citation and commencement**

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

**Interpretation**

2. In these Regulations—

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(1) 2018 c. 16.

“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.

## PART 2

### Amendment of subordinate legislation

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

3. The Food Safety and Hygiene (England) Regulations 2013(2) are amended as follows.
4. For Schedule 2, substitute the Schedule set out in the Schedule to these Regulations.

## PART 3

### Amendment of retained direct EU legislation

#### **Amendment of Regulation 178/2002**

5. Regulation 178/2002 is amended as follows.
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.”.
7. In Article 3—
  - (a) in paragraph 1, omit “whether at Community or national level”;
  - (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;
      - (d) in relation to Northern Ireland, the Northern Ireland devolved authority;
    20. “third country” means a country or state other than the United Kingdom.”.
8. In Article 4, omit paragraphs 3 and 4.
9. In Article 5—
  - (a) omit paragraph 2;
  - (b) in paragraph 3, for “Community”, substitute “United Kingdom”.

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(2) S.I. 2013/2996, amended by S.I. 2014/1855, S.I. 2014/2748, S.I. 2014/2885 and S.I. 2016/868.

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

11. In Article 7, in both places in which it occurs, for “Community”, substitute “United Kingdom”.

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

13. In Article 11, for “Community”, in each place in which it occurs (including the heading), substitute “United Kingdom”.

14. In Article 12—

- (a) in the heading, for “Community”, substitute “United Kingdom”;
- (b) in paragraph 1, in both places in which it occurs, for “Community”, substitute “United Kingdom”;
- (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.”.

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—”;
- (b) in paragraph (e), for “Community”, substitute “United Kingdom”.

16. In Article 14—

- (a) in paragraph 7, in each place in which it occurs, for “Community”, substitute “United Kingdom”;
- (b) omit paragraph 9.

17. In Article 15—

- (a) in paragraph 4, in both places in which it occurs, for “Community”, substitute “United Kingdom”;
- (b) omit paragraph 6.

18. In Article 17, omit—

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

19. In Article 18—

- (a) in paragraph 4, for “Community”, substitute “United Kingdom”;
- (b) for paragraph 5, substitute—

“5. The Secretary of State may by regulations make provision for the purpose of applying the requirements of this Article in respect of specific sectors in England.”;

- (c) at the end, insert the following additional paragraphs—

“6. The power of the Secretary of State to make regulations under this Article—

- (a) is exercisable by statutory instrument;
- (b) includes power—

- (i) to make different provision in relation to different cases or classes of case (including different provision for different areas or different classes of business);
  - (ii) to provide for such exceptions, limitations and conditions, and to make such supplementary, incidental, consequential or transitional provisions, as the Secretary of State considers necessary or expedient.
- 7. Any statutory instrument containing regulations made the Secretary of State under this Article is subject to annulment in pursuance of a resolution of either House of Parliament.
- 8. The Welsh Ministers may by regulations make provision for the purpose of applying the requirements of this Article in respect of specific sectors in Wales.
- 9. The power of the Welsh Ministers to make regulations under this Article—
  - (a) is exercisable by statutory instrument;
  - (b) includes power—
    - (i) to make different provision in relation to different cases or classes of case (including different provision for different areas or different classes of business);
    - (ii) to provide for such exceptions, limitations and conditions, and to make such supplementary, incidental, consequential or transitional provisions, as the Welsh Ministers consider necessary or expedient.
- 10. Any statutory instrument containing regulations made the Welsh Ministers under this Article is subject to annulment in pursuance of a resolution of the National Assembly for Wales.
- 11. The Scottish Ministers may by regulations make provision for the purpose of applying the requirements of this Article in respect of specific sectors in Scotland.
- 12. The power of the Scottish Ministers to make regulations under this Article—
  - (a) is exercisable by Scottish statutory instrument within the meaning of section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010(3);
  - (b) includes power—
    - (i) to make different provision in relation to different cases or classes of case (including different provision for different areas or different classes of business);
    - (ii) to provide for such exceptions, limitations and conditions, and to make such supplementary, incidental, consequential or transitional provisions, as the Scottish Ministers consider necessary or expedient.
- 13. Any Scottish statutory instrument containing regulations made the Scottish Ministers under this Article is subject to annulment in pursuance of a resolution of the Scottish Parliament.
- 14. The Northern Ireland devolved authority may by regulations make provision for the purpose of applying the requirements of this Article in respect of specific sectors in Northern Ireland.
- 15. The power of the Northern Ireland devolved authority to make regulations under this Article—

- (a) is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979 (S.I. 1979/1573 (N.I. 12));
- (b) includes power—
  - (i) to make different provision in relation to different cases or classes of case (including different provision for different areas or different classes of business);
  - (ii) to provide for such exceptions, limitations and conditions, and to make such supplementary, incidental, consequential or transitional provisions, as the Northern Ireland devolved authority considers necessary or expedient.

16. Any statutory rule containing regulations made by the Northern Ireland devolved authority under this Article is subject to annulment in pursuance of a negative resolution within the meaning given by section 41(6) of the Interpretation Act (Northern Ireland) 1954(4).”.

**20. Omit—**

- (a) Article 21;
- (b) Chapter 3;
- (c) Chapter 4.

**21. In Chapter 5—**

- (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.”.

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

**Amendment of Regulation 931/2011**

23. Regulation 931/2011 is amended as follows.

24. In Article 3(2), omit “Union”.

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

## PART 4

### Revocation of retained direct EU legislation

**Revocation of Regulation 16/2011**

26. Regulation 16/2011 is revoked.

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

Address  
Date

*Name*  
Parliamentary Under-Secretary of State,  
Department of Health and Social Care

SCHEDULE

Regulation 4

“Schedule 2

Specified EU provisions

<b>1. Provision of retained EU law</b>	<b>2. Subject matter</b>
Article 12 of Regulation 178/2002, as it relates to food	Requirement that food exported or re-exported from the United Kingdom 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 in Annex 2 to Regulation 852/2004 and any specific requirements provided for in Regulation 853/2004 and Regulation 579/2014.

1. Provision of retained EU law	2. Subject matter
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 cooperate 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 origin unless use of the substance has been approved.

<b>1. Provision of retained EU law</b>	<b>2. Subject matter</b>
Article 4(1) of Regulation 853/2004	<p>Requirement that food business operators place products of animal origin on the market only if they have been prepared and handled exclusively in establishments—</p> <p>(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</p> <p>(b) that the competent authority has registered or, where required in accordance with Article 4(2), approved.</p>
Article 4(2) of Regulation 853/2004	<p>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).</p>
Article 4(3) of Regulation 853/2004	<p>Requirement that establishments subject to approval in accordance with Article 4(2) do not operate unless the competent authority has, in accordance with Regulation 854/2004—</p> <p>(a) granted the establishment approval to operate following an on-site visit; or</p> <p>(b) provided the establishment with conditional approval.</p>
Article 4(4) of Regulation 853/2004	<p>Requirement that food business operators cooperate with the competent authorities in accordance with Regulation 854/2004 including ensuring that an establishment ceases to operate if it is no longer approved.</p>
Article 5(1) of Regulation 853/2004	<p>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—</p> <p>(a) a health mark applied in accordance with Regulation 854/2004; or</p> <p>(b) when Regulation 854/2004 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.</p>
Article 5(2) of Regulation 853/2004	<p>Requirement that food business operators apply an identification mark to a product of animal origin only if the product has been manufactured</p>

1. Provision of retained EU law	2. Subject matter
Article 5(3) of Regulation 853/2004	<p>in accordance with Regulation 853/2004 in establishments meeting the requirements of Article 4.</p> <p>Requirement that food business operators do not remove a health mark applied in accordance with Regulation 854/2004 from meat unless they cut or process it or work upon it in another manner.</p>
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	<p>Requirement that food business operators importing products of animal origin shall ensure that—</p> <p>(a) products are made available for control upon importation in accordance with Council <a href="#">Directive 97/78/EC</a>;</p> <p>(b) importation complies with the requirements of Council <a href="#">Directive 2002/99/EC</a>; and</p> <p>(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.</p>
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

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<b>1. Provision of retained EU law</b>	<b>2. Subject matter</b>
	longer fulfilled or of any other change that might affect the holdings' Trichinella status.”

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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.