

---

DRAFT STATUTORY INSTRUMENTS

---

**2019 No.**

**The Nutrition (Amendment etc.) (EU Exit) Regulations 2019**

**PART 3**

**AMENDMENT OF SUBORDINATE LEGISLATION**

**Amendment of the Medical Food (England) Regulations 2000**

- 10.**—(1) The Medical Food (England) Regulations 2000(1) are amended as follows.
- (2) Regulation 2 (interpretation)(2) is renumbered as paragraph (1) of that regulation.
- (3) After paragraph (1) as so renumbered, insert—
- “(2) In these Regulations, any reference to compliance with a provision of the Directive is to be read as a reference to complying with that provision as would be required if the provision formed part of domestic law.
- (3) For the purposes of these Regulations, Articles 4 to 5 of, and the Annex to, the Directive are to be read subject to the modifications set out in Schedule 1.”
- (4) In regulation 5A(3) (application of the improvement notice provisions of the Act), for “Schedule”, in each place where it appears, substitute “Schedule 2”.
- (5) The Schedule is renumbered as Schedule 2.
- (6) Before Schedule 2 as so renumbered, insert—

“SCHEDULE 1

Regulation 2(3)

Modifications to the Directive

1. The Directive is modified as follows.
2. Article 4(2) is to be read as if for “Article 3 of [Directive 79/112/EEC](#),” there were substituted “Article 9 of Regulation (EU) No 1169/2011”.
3. Article 5 is to be read as if—
  - (a) in paragraph 1—
    - (i) for “where a product is manufactured in a third country” there were substituted “where a product is manufactured outside of the United Kingdom”;
    - (ii) for the first reference to “Member States” there were substituted “territories within the United Kingdom”;
    - (iii) the words “Member States may, if they can demonstrate that notification is not necessary in order to monitor those products efficiently in their territory, not impose that obligation” were omitted.

---

(1) [S.I. 2000/845](#), amended by [S.I. 2005/2626](#), [2007/3521](#), [2008/2445](#), [2011/3012](#), [2016/688](#), 2019/.

(2) A relevant amendment to regulation 2 was made by [S.I. 2007/3251](#).

(3) Regulation 5A was inserted by [S.I. 2016/688](#).

(b) in paragraph 2, for “are those referred to in Article 9(4) of [Directive 89/398/EEC](#)” there were substituted—

“are—

- (a) in respect of England, the Secretary of State,
- (b) in respect of Scotland, Food Standards Scotland<sup>(4)</sup>,
- (c) in respect of Wales, the Welsh Ministers,
- (d) in respect of Northern Ireland, the Food Standards Agency<sup>(5)</sup>.”

4. In the Annex, paragraph 4 is to be read as if for “[Directive 91/321/EEC](#) and its subsequent modifications” there were substituted “[Directive 2006/141/EC](#)”<sup>(6)</sup>.”.

### **Amendment of the Kava-kava in Food (England) Regulations 2002**

11.—(1) The Kava-kava in Food (England) Regulations 2002<sup>(7)</sup> are amended as follows.

(2) In regulation 2 (interpretation)<sup>(8)</sup>—

- (a) omit the definitions of “EEA Agreement”, “EEA State” and “free circulation in member States”;
- (b) after the definition of port health authority, insert—

““third country” means a country other than the United Kingdom.”.

(3) In regulation 3 (prohibition on sale etc of food consisting of or containing Kava-kava)<sup>(9)</sup> for paragraph (2), substitute—

“(2) The prohibition imposed by paragraph (1) shall not apply where the food consisting of or containing Kava-kava is imported from a third country if the food is being, or is to be, exported to a third country.”.

### **Amendment of the Food Supplements (England) Regulations 2003**

12.—(1) The Food Supplements (England) Regulations 2003<sup>(10)</sup> are amended as follows.

(2) In regulation 2<sup>(11)</sup> (interpretation) omit—

- (a) the definitions of “Directive 2001/83” and “Directive 2002/46”;
- (b) paragraphs (3) and (4).

(3) In regulation 3 (scope of regulations) in paragraph (2), for “as defined by Directive 2001/83” substitute “as defined by regulation 2(1) of the Human Medicines Regulations 2012<sup>(12)</sup>”.

(4) In regulation 5<sup>(13)</sup> (prohibitions on sale relating to composition of food supplements)—

(a) in paragraph (1)—

- (i) in sub-paragraph (a) for “Annex I to Directive 2002/46” substitute “Schedule 1 to the Nutrition (Amendment) (EU Exit) Regulations 2019”;

---

(4) Food Standards Scotland was established by section 1 of the Food (Scotland) Act 2015 (asp 1).

(5) The Food Standards Agency was established by section 1 of the Food Standards Act 1999 (c. 28).

(6) OJNo. L 401, 30.12.2006, p. 1, last amended by Commission Delegated Regulation (EU) 2016/127 (OJ No. L 25, 2.2.2016, p. 1).

(7) S.I. 2002/3169, amended by S.I. 2004/455, 2012/1809.

(8) Regulation 2 was amended by S.I. 2004/455, 2012/1809.

(9) Paragraph 2 of regulation 3 was inserted by S.I. 2004/455.

(10) S.I. 2003/1387 relevant amending instruments are S.I. 2005/2626, 2009/3251 and 2014/1855.

(11) Relevant amendments to regulation 2 were made by S.I. 2009/3251.

(12) S.I. 2012/1916.

(13) Relevant amendments to regulation 5 were made by S.I. 2009/3251.

- (ii) in sub-paragraph (b)(i) for “Annex II to Directive 2002/46” substitute “Schedule 2 to the Nutrition (Amendment) (EU Exit) Regulations 2019”;
- (b) in paragraph (2) for sub-paragraph (a) substitute—
  - “(a) the purity criteria, if any, specified in EU-derived domestic legislation, retained direct EU legislation or in regulations made by the Secretary of State under regulation 3 of the Nutrition (Amendment) (EU Exit) Regulations 2019; or”.
- (5) In regulation 6(14) (restrictions on sale relating to labelling etc of food supplements) in paragraph (3)(b) for “Annex I to Directive 2002/46” substitute “Schedule 1 to the Nutrition (Amendment) (EU Exit) Regulations 2019”.

### **Amendment of the Addition of Vitamins, Minerals and Other Substances (England) Regulations 2007**

**13.**—(1) The Addition of Vitamins, Minerals and Other Substances (England) Regulations 2007(15) are amended as follows.

- (2) In regulation 4 (offences and penalties)—
  - (a) in paragraph (1), omit “Subject to the transitional measures contained in Article 18 (relating to foods placed on the market before 1 July 2007),”;
  - (b) in paragraph (2)(a), omit “as read with Article 17(1) (transitional application of national rules)”.

### **Amendment of the Infant Formula and Follow-on Formula (England) Regulations 2007**

**14.**—(1) The Infant Formula and Follow-on Formula (England) Regulations 2007(16) are amended as follows.

- (2) In regulation 2 (interpretation)(17), after paragraph (6) insert—
  - “(7) In these Regulations, any reference to compliance with a provision of the Directive is to be read as a reference to complying with that provision as would be required if the provision formed part of domestic law.”.
- (3) In regulation 12 (listed substances and their purity criteria (infant formula and follow-on formula))(18), in paragraph (3)(a) for “EU legislation” substitute “retained EU law”.

### **Amendment of the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2009**

**15.**—(1) The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2009(19) are amended as follows.

- (2) In Schedule 1 (specified provisions)(20), in the “subject matter” column of the table—
  - (a) in the entry relating to Article 2(1), for “covered by Directive 2009/39 of the European Parliament and the Council on foodstuffs intended for particular nutritional uses” substitute “(foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are

---

(14) Regulation 6 was amended by [S.I. 2009/3251](#) and [2014/1855](#).

(15) [S.I. 2007/1631](#), to which there are amendments not relevant to these regulations.

(16) [S.I. 2007/3521](#).

(17) Regulation 2 was amended by [S.I. 2011/3012](#), [2013/3243](#).

(18) Regulation 12 was amended by [S.I. 2011/1043](#).

(19) [S.I. 2009/3051](#).

(20) Schedule 1 was amended by [S.I. 2011/1043](#) and [2016/688](#).

suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability);

- (b) in the entry relating to Article 3(2), for “competent authority referred to in Article 11 of Directive 2009/39” substitute “Secretary of State, Welsh Ministers, Food Standards Scotland or the Food Standards Agency in Northern Ireland”;
- (c) in the entries relating to Article 4(2) and (3), for “EU legislation” substitute “retained EU law”.

### **Amendment of the Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016**

**16.**—(1) The Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016<sup>(21)</sup> are amended as follows.

(2) In regulation 2 (interpretation), omit paragraph (5).

(3) In regulation 7 (review), omit paragraph (2).

(4) In Schedule 1 (Specified EU requirements)<sup>(22)</sup> in the entry in column 1, for “Article 15(1) (Union list)” substitute “Article 15(1) (UK list)”.

---

<sup>(21)</sup> S.I. 2016/688 as amended by S.I. 2019/.

<sup>(22)</sup> Schedule 1 was amended by S.I. 2019/.