

*This Statutory Instrument has been printed partially to correct errors in [S.I. 2019/651](#) and is being issued free of charge to all known recipients of that Statutory Instrument.*

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## STATUTORY INSTRUMENTS

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# 2023 No. 28

## FOOD

### The Food Supplements and Food for Specific Groups (Miscellaneous Amendments) Regulations 2023

*Made - - - - 11th January 2023*

*Laid before Parliament 13th January 2023*

*Coming into force in accordance with regulation 1(2)*

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 16(1)(a) and 48(1) of the Food Safety Act 1990<sup>(1)</sup>, Articles 11(1)(b) and (g), 16(1)(a) and 16A(2) of Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control<sup>(2)</sup> and regulation 2(2) of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019<sup>(3)</sup>.

The Secretary of State has consulted in accordance with Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 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<sup>(4)</sup>.

In accordance with Article 16A of Regulation (EU) No 609/2013 and regulation 5(2) of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019, these Regulations are made with the consent of the Scottish and Welsh Ministers.

The Secretary of State has had regard to relevant advice given by the Food Standards Agency in accordance with section 48(4A) of the Food Safety Act 1990.

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(1) 1990 c.16. Section 16(1) was amended by section 40(1), of, and paragraphs 7 and 8 of Schedule 5 to, the Food Standards Act 1999 (c. 28) (“the 1999 Act. Section 48 was amended by section 40(1) of, and paragraphs 7 and 8 of Schedule 5 to, the 1999 Act. There are other amendments which are not relevant to these Regulations.

(2) EUR 2013/609, amended by EUR 2017/1091, [S.I. 2019/651](#) and [S.I. 2020/1476](#).

(3) [S.I. 2019/651](#), amended by [S.I. 2020/1476](#).

(4) EUR 2002/178. Article 9 requires open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it. There are other amendments to this Regulation which are not relevant to these Regulations.

**Changes to legislation:** *The Food Supplements and Food for Specific Groups (Miscellaneous Amendments) Regulations 2023 is up to date with all changes known to be in force on or before 09 June 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

### Citation, commencement and extent

1.—(1) These Regulations may be cited as the Food Supplements and Food for Specific Groups (Miscellaneous Amendments) Regulations 2023.

[<sup>F1</sup>(2) Subject to paragraph (2A), these Regulations come into force on 10th February 2023.]

[<sup>F2</sup>(2A) Regulation 6(2)(a) comes into force on 10th August 2024.]

(3) Any amendment made by these Regulations has the same extent as the provision amended.

- F1** Reg. 1(2) substituted (9.2.2023 at 11.59 p.m.) by [The Food Supplements and Food for Specific Groups \(Miscellaneous Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/131\)](#), regs. 1(3), **2(2)**
- F2** Reg. 1(2A) inserted (9.2.2023 at 11.59 p.m.) by [The Food Supplements and Food for Specific Groups \(Miscellaneous Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/131\)](#), regs. 1(3), **2(3)**

#### Commencement Information

- I1** [Reg. 1](#) in force at 10.2.2023 , see [reg. 1\(2\)](#) (as amended by [S.I. 2023/131](#), **reg. 2(2)**)

### Amendment to the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003

2.—(1) The Processed Cereal-based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003(**5**) are amended as follows.

(2) In Schedule 4 (Nutritional Substances)—

- (a) in paragraph 1 (Vitamins) after “Folic acid” insert “Calcium-L-methylfolate”; and
- (b) in paragraph 4 (Salts of minerals and trace elements) after—
- (i) “Ferrous carbonate” insert “Ferrous bisglycinate”; and
- (ii) “Zinc acetate” insert “Zinc chloride”.

#### Commencement Information

- I2** [Reg. 2](#) in force at 10.2.2023 , see [reg. 1\(2\)](#) (as amended by [S.I. 2023/131](#), **reg. 2(2)**)

### Amendment to Regulation (EU) No 609/2013

3.—(1) Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control is amended as follows.

(2) In the Annex, in the section of the table entitled “Vitamins”, under the substance “Folate”, for the entry in respect of “calcium-L-methylfolate”, substitute—

“calcium-L-methylfolate	X	X	X”
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#### Commencement Information

- I3** [Reg. 3](#) in force at 10.2.2023 , see [reg. 1\(2\)](#) (as amended by [S.I. 2023/131](#), **reg. 2(2)**)

#### **Amendment to Commission Delegated Regulation (EU) 2016/127**

4.—(1) Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding<sup>(6)</sup> is amended as follows.

(2) In Article 4 (requirements on pesticides), for paragraph 1, substitute—

“(1) For the purposes of this Article, ‘residue’ means pesticide residue as referred to in sub-paragraph (c) of Article 3(2) of Regulation (EC) No 396/2005.”.

#### **Commencement Information**

**I4** Reg. 4 in force at 10.2.2023 , see reg. 1(2) (as amended by S.I. 2023/131, reg. 2(2))

#### **Amendment to Commission Delegated Regulation (EU) 2016/128**

5.—(1) Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes<sup>(7)</sup> is amended as follows.

(2) In Article 3 (requirements on pesticides in food for special medical purposes developed to satisfy the nutritional requirements of infants and young children), for paragraph 1, substitute—

“(1) For the purposes of this Article, ‘residue’ means pesticide residue as referred to in sub-paragraph (c) of Article 3(2) of Regulation (EC) No 396/2005.”.

#### **Commencement Information**

**I5** Reg. 5 in force at 10.2.2023 , see reg. 1(2) (as amended by S.I. 2023/131, reg. 2(2))

#### **Amendment to the Nutrition (Amendment etc.) (EU Exit) Regulations 2019**

6.—(1) The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 are amended as follows.

(2) In Schedule 1 (Vitamins and minerals which may be used in the manufacture of food supplements), in the second column of the table (Minerals)—

(a) in the entry for Copper, for “(µg)” substitute “(mg)”; and

(b) in the entry for Zinc, for “(µg)” substitute “(mg)”.

(3) In Schedule 2 (Vitamin and mineral substances which may be used in the manufacture of food supplements)—

(a) in Part A of the table (Vitamins), in entry 7 after “(c) inositol hexanicotinate (inositol hexaniacinate)” insert “(d) nicotinamide riboside chloride”; and

(b) in Part B of the table (Minerals), after the entry “magnesium acetyl taurate” insert “magnesium citrate malate”.

#### **Commencement Information**

**I6** Reg. 6(1)(2)(b)(3) in force at 10.2.2023 , see reg. 1(2) (as amended by S.I. 2023/131, reg. 2(2))

<sup>(6)</sup> EUR 2016/127, amended by S.I. 2020/1476.

<sup>(7)</sup> EUR 2016/128, amended by S.I. 2019/651.

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**Changes to legislation:** *The Food Supplements and Food for Specific Groups (Miscellaneous Amendments) Regulations 2023* is up to date with all changes known to be in force on or before 09 June 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

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**I7** [Reg. 6\(2\)\(a\)](#) in force at 10.8.2024 , see [reg. 1\(2A\)](#) (as amended by [S.I. 2023/131](#), [reg. 2\(3\)](#))

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

11th January 2023

*Neil O'Brien*  
Parliamentary Under-Secretary of State,  
Department of Health and Social Care

## EXPLANATORY NOTE

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

These Regulations make provision in relation to vitamins and minerals permitted in the manufacture of food supplements and certain categories of food. Regulation 6(2)(b) corrects a copying error made in [SI 2019/651](#). Following consultation with the SI Registrar, this instrument has been issued under the free issue procedure.

Regulation 2 amends Schedule 4 to the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003 to permit the addition of calcium-L-methylfolate, ferrous bisglycinate and zinc chloride as permitted forms of substances which can be added to processed cereal-based foods and baby foods.

Regulation 3 amends the Annex ('Great Britain List') to the retained EU Regulation No 609/2013 to permit the addition of calcium-L-methylfolate as a permitted form of substances which can be added to infant formula and follow-on formula.

Regulation 4 amends the definition of pesticide residue in the retained Article 4 of the EU Commission Delegated Regulation 2016/127 which pertains to infant formula and follow-on formula.

Regulation 5 amends the definition of pesticide residue in the retained Article 3 of the EU Commission Delegated Regulation 2016/128 which pertains to food for special medical purposes developed to satisfy the nutritional requirements of infants and young children.

Regulation 6 amends the units of measurement for copper and zinc from micrograms ( $\mu\text{g}$ ) to milligrams (mg) in Schedule 1 (Vitamins and Minerals which may be used in the manufacture of food supplements) to the Nutrition (Amendment etc.) (EU Exit) Regulations 2019. It also amends Schedule 2 to the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 to permit the addition of nicotinamide riboside chloride and magnesium citrate malate as permitted forms of vitamins and mineral substances which may be used in the manufacture of food supplements.

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

**Changes to legislation:**

The Food Supplements and Food for Specific Groups (Miscellaneous Amendments) Regulations 2023 is up to date with all changes known to be in force on or before 09 June 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.

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**Changes and effects yet to be applied to :**

- reg. 6(2)(a) coming into force by