



STATUTORY INSTRUMENTS.

**S.I. No. 111 of 2022**



EUROPEAN UNION (FOOD INTENDED FOR INFANTS AND YOUNG  
CHILDREN, FOOD FOR SPECIAL MEDICAL PURPOSES, AND TOTAL  
DIET REPLACEMENT FOR WEIGHT CONTROL) (AMENDMENT)  
REGULATIONS 2022

S.I. No. 111 of 2022

EUROPEAN UNION (FOOD INTENDED FOR INFANTS AND YOUNG CHILDREN, FOOD FOR SPECIAL MEDICAL PURPOSES, AND TOTAL DIET REPLACEMENT FOR WEIGHT CONTROL) (AMENDMENT) REGULATIONS 2022

I, STEPHEN DONNELLY, Minister for Health, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving effect to Commission Delegated Regulation (EU) 2021/571 of 20 January 2021<sup>1</sup> and Commission Delegated Regulation (EU) 2021/1040 of 16 April 2021<sup>2</sup>, hereby make the following regulations:

1. (1) These Regulations may be cited as the European Union (Food Intended for Infants and Young Children, Food for Special Medical Purposes, and Total Diet Replacement for Weight Control) (Amendment) Regulations 2022.

(2) The Principal Regulations and these Regulations may be cited together as the European Union (Food Intended for Infants and Young Children, Food for Special Medical Purposes, and Total Diet Replacement for Weight Control) Regulations 2019 and 2022.

2. In these Regulations –

“Principal Regulations” means the European Union (Food Intended for Infants and Young Children, Food for Special Medical Purposes, and Total Diet Replacement for Weight Control) Regulations 2019 (S.I. No. 425 of 2019).

3. Regulation 2 of the Principal Regulations is hereby amended –

(a) by substituting for the definition of “Annex II to EU Regulation 2016/128” the following:

“‘Annex II to EU Regulation 2016/128’ means Annex II to Commission Delegated Regulation (EU) 2016/128 of 25 September 2015<sup>3</sup> as amended by Commission Delegated Regulation (EU) 2021/1040 of 16 April 2021<sup>2</sup>;”,

(b) by substituting for the definition of “Annex III to EU Regulation 2016/128” the following:

“‘Annex III to EU Regulation 2016/128’ means Annex III to Commission Delegated Regulation (EU) 2016/128 of 25 September 2015<sup>3</sup> as amended by Commission Delegated Regulation (EU) 2021/1040 of 16 April 2021<sup>2</sup>;”,

---

<sup>1</sup> OJ No. L 120, 8.4.2021, p. 1.

<sup>2</sup> OJ No. L 225, 25.6.2021, p. 1.

<sup>3</sup> OJ No. L 25, 2.2.2016, p. 30.

- (c) by substituting for the definition of “EU Regulation 609/2013” the following:

“EU Regulation 609/2013’ means Regulation (EU) No. 609/2013 of the European Parliament and of the Council of 12 June 2013<sup>4</sup> as amended by Commission Delegated Regulation (EU) 2017/1091 of 10 April 2017<sup>5</sup> and Commission Delegated Regulation (EU) 2021/571 of 20 January 2021<sup>1</sup>;”,

- (d) by substituting for the definition of “EU Regulation 2016/128” the following:

“EU Regulation 2016/128’ means Commission Delegated Regulation (EU) 2016/128 of 25 September 2015<sup>3</sup> as amended by Commission Delegated Regulation (EU) 2021/1040 of 16 April 2021<sup>2</sup>;”,

- (e) by substituting for the definition of “residue” the following:

“‘residue’ means pesticide residue as referred to in point (c) of Article 3(2) of Regulation (EC) No. 396/2005 of the European Parliament and of the Council of 23 February 2005<sup>6</sup>;”, and

- (f) by substituting for the definition of “Union list” the following:

“‘Union list’ means the Union list annexed to Regulation (EU) No. 609/2013 of the European Parliament and of the Council of 12 June 2013<sup>4</sup> as amended by Commission Delegated Regulation (EU) 2017/1091 of 10 April 2017<sup>5</sup> and Commission Delegated Regulation (EU) 2021/571 of 20 January 2021<sup>1</sup> and which lists the various substances that may be added to one or more of the categories of food referred to in Regulation 3.”.



GIVEN under my Official Seal,  
8 March, 2022.

STEPHEN DONNELLY,  
Minister for Health.

---

<sup>4</sup> OJ No. L 181, 29.6.2013, p. 35.

<sup>5</sup> OJ No. L 158, 21.6.2017, p. 5.

<sup>6</sup> OJ No. L 70 16.3.2005, p. 1.

## EXPLANATORY NOTE

*(This note is not part of the Instrument and does not purport to be a legal interpretation).*

These Regulations give effect to Commission Delegated Regulation (EU) 2021/571 of 20 January 2021 and Commission Delegated Regulation (EU) 2021/1040 of 16 April 2021.

Commission Delegated Regulation (EU) 2021/571 amends the Annex to Regulation (EU) No. 609/2013 by authorising the use of calcium-L-methylfolate as a source of folate in infant formula, follow-on formula, processed cereal-based food and baby food.

Commission Delegated Regulation (EU) 2021/1040 amends the definition of residue in Commission Delegated Regulation (EU) 2016/128 to align it to the definition in Regulation (EC) No. 396/2005. It also replaces the Annex II and III to Commission Delegated Regulation (EU) 2016/128.

These Regulations amend the European Union (Food Intended for Infants and Young Children, Food for Special Medical Purposes, and Total Diet Replacement for Weight Control) Regulations 2019 (S.I. No. 425 of 2019) in the manner specified in these Regulations.

These Regulations may be cited as the European Union (Food Intended for Infants and Young Children, Food for Special Medical Purposes, and Total Diet Replacement for Weight Control) (Amendment) Regulations 2022.

BAILE ÁTHA CLIATH  
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR  
Le ceannach díreach ó  
FOILSEACHÁIN RIALTAIS,  
BÓTHAR BHAILE UÍ BHEOLÁIN,  
CILL MHAIGHNEANN,  
BAILE ÁTHA CLIATH 8,  
D08 XAO6

Tel: 046 942 3100  
r-phost: [publications@opw.ie](mailto:publications@opw.ie)

DUBLIN  
PUBLISHED BY THE STATIONERY OFFICE  
To be purchased from  
GOVERNMENT PUBLICATIONS,  
MOUNTSHANNON ROAD,  
KILMAINHAM, DUBLIN 8,  
D08 XAO6

Tel: 046 942 3100  
E-mail: [publications@opw.ie](mailto:publications@opw.ie)

€3.00

