



STATUTORY INSTRUMENTS.

S.I. No. 128 of 2025

EUROPEAN UNION (FOOD INTENDED FOR INFANTS AND YOUNG
CHILDREN, FOOD FOR SPECIAL MEDICAL PURPOSES, AND TOTAL
DIET REPLACEMENT FOR WEIGHT CONTROL) (AMENDMENT)
REGULATIONS 2025

S.I. No. 128 of 2025

EUROPEAN UNION (FOOD INTENDED FOR INFANTS AND YOUNG CHILDREN, FOOD FOR SPECIAL MEDICAL PURPOSES, AND TOTAL DIET REPLACEMENT FOR WEIGHT CONTROL) (AMENDMENT) REGULATIONS 2025

I, JENNIFER CARROLL MACNEILL, 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 further effect to Regulation (EU) No. 609/2013 of the European Parliament and of the Council of 12 June 2013¹ and effect to Commission Delegated Regulation (EU) 2024/2684 of 2 February 2024², and Commission Delegated Regulation (EU) 2024/2791 of 29 January 2024³, 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 2025.

(2) The Principal Regulations, 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 (S.I. No. 111 of 2022), the European Union (Food Intended for Infants and Young Children, Food for Special Medical Purposes, and Total Diet Replacement for Weight Control) (Amendment) Regulations 2023 (S.I. No. 490 of 2023), the Regulations of 2024 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 to 2025.

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);

“Regulations of 2024” means the European Union (Food Intended for Infants and Young Children, Food for Special Medical Purposes, and Total Diet Replacement for Weight Control) (Amendment) Regulations 2024 (S.I. No. 411 of 2024).

3. Regulation 2(1) of the Principal Regulations (as last amended by Regulation 3 of the Regulations of 2024) is hereby amended –

¹ OJ No. L 181, 29.6.2013, p. 35.

² OJ L, 2024/2684, 11.10.2024.

³ OJ L, 2024/2791, 31.10.2024.

- (a) by substituting for the definition of “Annex I to EU Regulation 2016/127” the following:

“‘Annex I to EU Regulation 2016/127’ means Annex I to Commission Delegated Regulation (EU) 2016/127 of 25 September 2015⁴ as amended by Commission Delegated Regulation (EU) 2019/828 of 14 March 2019⁵, Commission Delegated Regulation (EU) 2022/519 of 14 January 2022⁶, Commission Delegated Regulation (EU) 2023/589 of 10 January 2023⁷ and Commission Delegated Regulation (EU) 2024/2684 of 2 February 2024²;”,

- (b) by substituting for the definition of “Annex II to EU Regulation 2016/127” the following:

“‘Annex II to EU Regulation 2016/127’ means Annex II to Commission Delegated Regulation (EU) 2016/127 of 25 September 2015⁴ as amended by Commission Delegated Regulation (EU) 2018/561 of 29 January 2018⁸, Commission Delegated Regulation 2019/828 of 14 March 2019⁵, Commission Delegated Regulation (EU) 2022/519 of 14 January 2022⁶, Commission Delegated Regulation (EU) 2023/589 of 10 January 2023⁷ and Commission Delegated Regulation (EU) 2024/2684 of 2 February 2024²;”,

- (c) by substituting for the definition of “Annex III to EU Regulation 2016/127” the following:

“‘Annex III to EU Regulation 2016/127’ means Annex III to Commission Delegated Regulation (EU) 2016/127 of 25 September 2015⁴ as amended by Commission Delegated Regulation (EU) 2022/519 of 14 January 2022⁶, Commission Delegated Regulation (EU) 2023/589 of 10 January 2023⁷ and Commission Delegated Regulation (EU) 2024/2684 of 2 February 2024²;”,

- (d) by substituting for the definition of “EU Regulation 2016/127” the following:

“‘EU Regulation 2016/127’ means Commission Delegated Regulation (EU) 2016/127 of 25 September 2015⁴ as amended by Commission Delegated Regulation (EU) 2018/561 of 29 January 2018⁸, Commission Delegated Regulation (EU) 2019/828 of 14 March 2019⁵, Commission Delegated Regulation (EU) 2021/572 of 20 January 2021⁹, Commission Delegated Regulation (EU) 2021/1041 of 16 April 2021¹⁰, Commission Delegated Regulation (EU) 2022/519 of 14 January 2022⁶, Commission Delegated

⁴ OJ No. L 025, 2.2.2016, p. 1.

⁵ OJ No. L 137, 23.5.2019, p. 12.

⁶ OJ No. L 104, 1.4.2022, p. 58.

⁷ OJ No. L 79, 17.3.2023, p. 40.

⁸ OJ No. L 94, 12.4.2018, p. 1.

⁹ OJ No. L 120, 8.4.2021, p. 4.

¹⁰ OJ No. L 225, 25.6.2021, p. 4.

Regulation (EU) 2023/589 of 10 January 2023⁷ and Commission Delegated Regulation (EU) 2024/2684 of 2 February 2024²,”

- (e) 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 2013¹ as amended by Commission Delegated Regulation (EU) 2017/1091 of 10 April 2017¹¹, Commission Delegated Regulation (EU) 2021/571 of 20 January 2021¹², Commission Delegated Regulation (EU) 2023/439 of 16 December 2022¹³ and Commission Delegated Regulation (EU) 2024/2791 of 29 January 2024³,” and

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

““Union list” means the Union list annexed to EU Regulation 609/2013 as amended by Commission Delegated Regulation (EU) 2017/1091 of 10 April 2017¹¹, Commission Delegated Regulation (EU) 2021/571 of 20 January 2021¹², Commission Delegated Regulation (EU) 2023/439 of 16 December 2022¹³ and Commission Delegated Regulation (EU) 2024/2791 of 29 January 2024³ 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,
9 April, 2025.

JENNIFER CARROLL MACNEILL,
Minister for Health.

¹¹ OJ No. L 158, 21.6.2017, p. 5.

¹² OJ No. L 120, 8.4.2021, p. 1.

¹³ OJ No. L 64, 1.3.2023, 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) 2024/2684 of 2 February 2024 amending Delegated Regulation (EU) 2016/127 as regards the minimum protein requirements for infant and follow-on formula manufactured from hydrolysed protein, and Commission Delegated Regulation (EU) 2024/2791 of 29 January 2024 amending the Annex to Regulation (EU) No 609/2013 of the European Parliament and of the Council to allow the use of iron milk caseinate as a source of iron in food for special medical purposes, excluding food for infants and young children and in total diet replacement for weight control.

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 2025.

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