

# STATUTORY INSTRUMENTS.

S.I. No. 411 of 2024

EUROPEAN UNION (FOOD INTENDED FOR INFANTS AND YOUNG CHILDREN, FOOD FOR SPECIAL MEDICAL PURPOSES, AND TOTAL DIET REPLACEMENT FOR WEIGHT CONTROL) (AMENDMENT) REGULATIONS 2024

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# EUROPEAN UNION (FOOD INTENDED FOR INFANTS AND YOUNG CHILDREN, FOOD FOR SPECIAL MEDICAL PURPOSES, AND TOTAL DIET REPLACEMENT FOR WEIGHT CONTROL) (AMENDMENT) REGULATIONS 2024

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 further effect to Regulation (EU) No. 609/2013 of the European Parliament and of the Council of 12 June 2013<sup>1</sup> and Commission Delegated Regulation (EU) 2017/1798 of 2 June 2017<sup>2</sup>, as amended by Commission Delegated Regulation (EU) 2022/2182 of 30 August 2022<sup>3</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 2024.

(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 Regulations of 2023 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 2024.

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 2023" 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 2023 (S.I. No. 490 of 2023).

3. Regulation 2(1) of the Principal Regulations (as last amended by Regulation 3 of the Regulations of 2023) is hereby amended by inserting the following definitions:

<sup>&</sup>lt;sup>1</sup> OJ No. L 181, 29.6.2013, p. 35.

<sup>&</sup>lt;sup>2</sup> OJ No. L 259, 7.10.2017, p. 2.

<sup>&</sup>lt;sup>3</sup> OJ No. L 288, 9.11.2022, p. 18.

"Annex I to EU Regulation 2017/1798' means Annex I to Commission Delegated Regulation (EU) 2017/1798 of 2 June 2017<sup>2</sup> as amended by Commission Delegated Regulation (EU) 2022/2182 of 30 August 2022<sup>3</sup>;

'Annex II to EU Regulation 2017/1798' means Annex II to Commission Delegated Regulation (EU) 2017/1798 of 2 June 2017<sup>2</sup>;

'EU Regulation 2017/1798' means Commission Delegated Regulation (EU) 2017/1798 of 2 June 2017<sup>2</sup> as amended by Commission Delegated Regulation (EU) 2022/2182 of 30 August 2022<sup>3</sup>;

'total diet replacement for weight control' means food specially formulated for use in energy restricted diets for weight reduction which, when used as instructed by the food business operator, replaces the whole daily diet.".

4. The Principal Regulations are amended by inserting after Part 3A the following:

#### "PART 3B

# SPECIFIC COMPOSITIONAL AND INFORMATION REQUIREMENTS FOR TOTAL DIET REPLACEMENT FOR WEIGHT CONTROL

18N. This Part only applies to food referred to in Regulation 3(4) and supplements Part 2 insofar as it applies to such food.

## Placing on the market

18O. A food business operator who places on the market a food referred to in Regulation 3(4) and who fails to use the product name 'total diet replacement for weight control' is guilty of an offence.

### Compositional requirements

18P. (1) A food business operator who places on the market a food referred to in Regulation 3(4) and who fails to ensure that the food complies with the compositional requirements set out in Annex I to EU Regulation 2017/1798, taking into account the specifications set out in Annex II to EU Regulation 2017/1798 is guilty of an offence.

(2) The compositional requirements set out in Annex I to EU Regulation 2017/1798 shall apply to a food referred to in Regulation 3(4), ready for use, marketed as such, or after preparation in accordance with the manufacturer's instructions.

(3) A food business operator who places on the market a food referred to in Regulation 3(4) which contains ingredients other than the substances listed in Annex I to EU Regulation 2017/1798 whose suitability has not been established by generally accepted scientific data, is guilty of an offence.

# Specific requirements concerning food information

18Q. (1) A food business operator who places on the market a food referred to in Regulation 3(4) but who fails to ensure that the following mandatory particulars are included on the package or on a label attached thereto

- (a) a statement that the product is only intended for healthy overweight or obese adults who intend to achieve weight reduction,
- (b) a statement that the product should be not used by pregnant or lactating women, adolescents or by individuals suffering from a medical condition without the advice of a healthcare professional,
- (c) a statement on the importance of maintaining an adequate daily fluid intake,
- (d) a statement that the product provides adequate daily amounts of all essential nutrients when used in accordance with the instructions for use,
- (e) a statement that the product should not be used for more than 8 weeks, or repeatedly for shorter periods than this, by healthy overweight or obese adults without the advice of a healthcare professional,
- (f) instructions for appropriate preparation, where necessary, and a statement as to the importance of following those instructions,
- (g) a statement that the food may have a laxative effect, if a product when used as instructed by the manufacturer, provides a daily intake of polyols in excess of 20g per day, or
- (h) a statement that the advice of a healthcare professional must be sought regarding the possibility of supplementing the product with dietary fibre, if dietary fibre is not added to the product,

is guilty of an offence.

(2) A food business operator who fails to ensure that the mandatory particulars listed in paragraph (1) are printed on the package or on the label attached thereto—

- (a) in such a way as to ensure clear legibility, and
- (b) in characters using a font size where the x-height, as defined in Annex IV to EU Regulation 1169/2011, is—
  - (i) equal to or greater than 1.2 mm, or
  - (ii) equal to or greater than 0.9 mm, in the case of packaging or containers the largest surface of which has an area of less than 80cm<sup>2</sup>,

is guilty of an offence.

(3) A person who makes any reference to the rate or amount of weight reduction which may result from use of a food referred to in Regulation 3(4) in the labelling, presentation and advertising of such food is guilty of an offence.

## Specific requirements on the nutrition declaration

18R. (1) A food business operator who places on the market a food referred to in Regulation 3(4) but who—

- (a) fails to include in the mandatory nutrition declaration, in addition to the information referred to in Article 30(1) of EU Regulation 1169/2011, the amount of each mineral substance and of each vitamin listed in Annex I to EU Regulation 2017/1798 that are present in the product,
- (b) fails to include in the mandatory nutrition declaration, in addition to the information referred to in Article 30(1) of EU Regulation 1169/2011, the amount of choline present, and if added, of dietary fibre,
- (c) notwithstanding Article 30(3) of EU Regulation 1169/2011, repeats information included in the mandatory nutrition declaration, on the label attached to such a food,
- (d) fails to include a nutrition declaration on the package or on the label attached to such food, irrespective of the size of the largest surface of the packaging or container,
- (e) fails to ensure that the nutrients in the nutrition declaration referred to in sub-paragraphs (a) and (b) comply with the calculation, expression and presentation and requirements under Articles 31 to 35 of EU Regulation 1169/2011,
- (f) fails to present the particulars included in the nutrition declaration that are not listed in Annex XV to EU Regulation 1169/2011 after—
  - (i) the most relevant entry of that Annex to which they belong or of which they are components, or
  - (ii) the last entry of that Annex, where they do not belong to or are not components of any of the entries of that Annex,
- (g) fails to ensure that the indication of the amount of sodium appears together with the other minerals,
- (h) uses the statement 'very low calorie diet' where the energy content of the product is not below 3360 kJ/day (800 kcal/day), or
- uses the statement 'low calorie diet' where the energy content of the product is not between 3360 kJ/day (800 kcal/day) and 5040 kJ/day (1200 kcal/day),

is guilty of an offence.

(2) In addition to the information referred to in Article 30(2)(a) to (e) of EU Regulation 1169/2011, the content of the mandatory nutrition declaration for a food referred to in Regulation 3(4) may be supplemented with one or more of the following:

(a) the amounts of components of fat and carbohydrates;

- (b) the amount of any of the substances listed in the Annex to EU Regulation 609/2013, where the indication of any of those substances is not covered by sub-paragraph (1)(a) or (1)(b); or
- (c) the amount of any of the substances added to the product pursuant to Article 3(3) of EU Regulation 2017/1798.

(3) Notwithstanding Article 31(3), 32(2) and 33(1) of EU Regulation 1169/2011, the energy value and the amounts of nutrients of a food referred to in Regulation 3(4) shall be expressed per total daily ration as well as, per portion and/or per consumption unit of the food ready for use after preparation in accordance with the manufacturer's instructions. Where appropriate, information may in addition refer to 100g or 100ml of the food as sold.

(4) Notwithstanding Article 32(3) and (4) of EU Regulation 1169/2011, the energy value and the amount of nutrients of food referred to in Regulation 3(4) shall not be expressed as a percentage of the reference intakes set out in Annex XIII to that Regulation.

(5) A food business operator who places on the market a food referred to in Regulation 3(4) may repeat the indication of the amount of sodium included in the nutrition declaration next to the indication of the salt content as follows: 'Salt: X g (of which sodium: Y mg)'.

## Nutrition and Health Claims

18S. (1) Subject to paragraph (2), a food business operator who makes a nutrition or health claim on a food referred to in Regulation 3(4) is guilty of an offence.

(2) Notwithstanding paragraph (1), the nutrition claim 'added fibre' may be used for a food referred to in Regulation 3(4) provided that the dietary fibre content of the product is not less than 10g.

#### Offences arising from failure to notify the Authority

18T. A food business operator who places on the market in the State a food referred to in Regulation 3(4) but who fails to notify the Authority of the information appearing on the label, or labels, by sending to it a model of the label, or labels, used for the product, in a manner to be specified by the Authority, and any other information which the Authority may reasonably request to establish compliance with these Regulations or EU Regulation 2017/1798, is guilty of an offence.".

5. Regulation 19 of the Principal Regulations is hereby amended by substituting for paragraph (1) the following:

"(1) The enforcement of these Regulations, of EU Regulation 609/2013, EU Regulation 2016/127, EU Regulation 2016/128 and EU Regulation 2017/1798, shall be carried out in accordance with this Part.".

6. The Principal Regulations are hereby amended by substituting for Regulation 20 the following:

## "Taking of Samples

20. (1) An authorised officer may, for the purposes of these Regulations, purchase or take without payment a sample of food or relevant thing.

(2) An authorised officer may, for the purpose of taking a sample of food open any receptacle.

(3) An authorised officer may, for the purposes of these Regulations, inspect, take or make copies, whether in writing, by photography, electronically or otherwise, of a relevant thing.

(4) Subject to paragraphs (5) and (6), an authorised officer who purchases or takes without payment a sample of food or any relevant thing, with the intention of having it analysed, tested or inspected, shall, at the time of such purchasing or taking, notify the food business operator or the person in apparent charge or control of the food or relevant thing of his or her intention of having the sample analysed, tested or inspected.

(5) In the case of food or a relevant thing offered for sale by means of distance communication, an authorised officer may order samples without identifying himself or herself.

(6) Where a sample is obtained under paragraph (5), the authorised officer shall take all reasonable steps to ensure that the person from whom the sample is ordered—

- (a) is informed that such sample has been taken and where appropriate, is analysed, tested or inspected for the purposes of these Regulations, and
- (b) where the sample is analysed or tested, is able to exercise his or her right to a second expert opinion under Article 35(1) of the Official Controls Regulation and Regulation 20A.

(7) An authorised officer who suspects that food or a relevant thing fails to comply with these Regulations, and who purchases or takes a sample of that food or relevant thing without payment, with the intention of having it analysed, tested or inspected, may, by notice in writing to the food business operator, or the person in apparent charge or control of such food or relevant thing, prohibit its removal except to any place which may be specified in the notice, during such period as may be specified in the notice, but not exceeding 15 working days from the date of the taking of the sample.

(8) An authorised officer who serves a notice under paragraph (7) may, by further notice in writing to the recipient of the first notice, extend the period during which the removal of the food or relevant thing is prohibited for a further period specified in the second notice not exceeding 10 working days, provided that such extension is necessary for the purposes of completing analysis, testing or inspection of the food or relevant thing.". 7. The Principal Regulations are hereby amended by inserting after Regulation 20 the following Regulation:

## "Second expert opinion

20A. (1) Where a sample of food or any relevant thing is purchased or taken pursuant to Regulation 20, the authorised officer shall ensure that the food business operator whose food or relevant thing is being analysed, tested or inspected has the right to a second expert opinion, at the expense of the food business operator, in accordance with Article 35 of the Official Controls Regulation ('a second expert opinion'), provided that the second expert opinion is requested by notice in writing to the authorised officer within a period of 7 working days after the food business operator is notified of the results of the analysis, testing or inspection.

(2) Following receipt of a request pursuant to paragraph (1), the authorised officer shall issue a written acknowledgement of the request.

(3) A food business operator who makes a request pursuant to paragraph (1) shall provide to the authorised officer, in writing within 7 working days of the date of the acknowledgement issued pursuant to paragraph (2), written details of the recognised and appropriately qualified expert who shall be giving the second expert opinion and a written list of documents and records relating to the sampling, analysis, or test required for the purpose of the documentary review under Article 35 of the Official Controls Regulation.

(4) The documentary review under Article 35 of the Official Controls Regulation shall be completed within 15 working days of the date on which the documents and records required for the purpose of the review are issued to the food business operator.

(5) Where a sample of food or any relevant thing is purchased or taken pursuant to Regulation 20, and where relevant, appropriate and technically feasible having regard in particular to—

- (a) the prevalence and distribution of the hazard in the food or relevant thing,
- (b) the perishability of the sample of food or relevant thing, and
- (c) the amount of available substrate,

the authorised officer shall—

- (i) when purchasing or taking the sample, and if so requested by the food business operator or the person in apparent charge or control of the food or relevant thing, ensure that a sufficient quantity is taken to allow for a second expert opinion referred to in Article 35(3) of the Official Controls Regulation, or
- (ii) where it is not possible to take a sufficient quantity as referred to in subparagraph (i), inform the food business operator or person in charge or control thereof.

(6) The Authority shall publish guidelines in relation to the recognition of appropriately qualified experts for the purposes of a documentary review.

(7) Where there is a dispute between the Authority or the official agency and the food business operator that is based on a second expert opinion, the food business operator may, by notice in writing delivered to the authorised officer no more than 10 working days after the issuance of the opinion, request pursuant to Article 35(3) of the Official Controls Regulation and at his or her own expense, a documentary review of the initial analysis or test or another analysis, test or inspection by another official laboratory.

(8) The official laboratory, official agency or the Authority, as the case may be, shall grant reasonable access, in such manner as it prescribes, for a recognised and appropriately qualified expert appointed by a food business operator to the records required for a documentary review.".

8. The Principal Regulations are hereby amended by substituting for Regulation 21 the following:

## "Division of food samples

21. (1) An authorised officer who purchases or takes a sample of food pursuant to Regulation 20 for the purpose of proceedings for an offence under these Regulations may, where the division of the sample is reasonably practicable, divide the sample into three approximately equal parts (enforcement, trade (defence) and referee), each of which he or she shall mark in such a way as to identify it as a part of the sample taken by the officer.

(2) An authorised officer who divides a sample pursuant to paragraph (1) shall—

- (a) in the presence of the food business operator, or the person in apparent charge or control of the food mark, close and seal each part in such a manner as its nature will permit, and in such a way that the integrity of the sample is not compromised,
- (b) forward one part to an approved examiner in an official laboratory for analysis, test or inspection,
- (c) give or send one part to such food business operator or person, or where necessary retain such part in his or her possession on behalf of the food business operator or person, and
- (d) retain the third part.

(3) Notwithstanding paragraph (2)(a), an authorised officer may mark, close and seal a part of a sample, as appropriate, in the absence of the food business operator, or the person in apparent charge or control of the food, where no such person agrees to be present or it is not technically feasible for such person to be present during such marking, closing and sealing.

(4) Where an authorised officer purchases or takes a sample of food contained in unopened containers and its division into parts—

(a) is not reasonably practicable, or

(b) might affect the composition, integrity or impede the proper analysis of the sample,

the provisions of paragraphs (1) and (2) as regards the division of samples into parts shall be deemed to be complied with if the authorised officer divides the containers into three lots and deals with each lot as if it were a sample as specified under paragraph (1) and (2).

(5) Where a sample is obtained pursuant to Regulation 20(5), the requirement in paragraph (2) to carry out the actions referred to therein in the presence of the food business operator or the person in apparent charge or control of the food shall not apply.

(6) In proceedings for an offence under these Regulations, the result of any analysis, test or inspection of, or report on, a sample of food purchased or taken pursuant to these Regulations shall not be adduced unless before the proceedings were instituted the sample was divided as specified in this Regulation, or the food business operator concerned availed of its right to a second expert opinion under Article 35 of the Official Controls Regulation and Regulation 20A.

(7) Notwithstanding paragraph (6), in proceedings for an offence under these Regulations arising out of a consumer complaint in relation to a single sample of food which was not—

- (a) divided into parts in accordance with paragraph (1), or
- (b) divided into lots in accordance with paragraph (3),

the result of any analysis, test or inspection of the sample may be adduced where the sample has, before trial of the proceedings been made reasonably available to the accused person, or his or her agent, for inspection and second expert opinion and, where requested, the person who carried out the documentary review pursuant to Article 35 of the Official Controls Regulation.

(8) The Authority or the official agency, as the case may be, may, where it considers that it is necessary to eliminate or contain the risks to human, animal or plant health, animal welfare, or, as regards GMOs and plant protection products, also to the environment, take immediate action notwithstanding that the sampling procedures set out in this Regulation have not been carried out and notwithstanding any application by the food business operator for a second expert opinion under Article 35 of the Official Controls Regulation and Regulation 20A.".

9. The Principal Regulations are hereby amended by substituting for Regulation 22 the following:

## "Samples of relevant things

22. (1) An authorised officer who purchases or takes a sample of a relevant thing pursuant to Regulation 20 shall, where possible, obtain three identical such relevant things, or take three copies or photographs thereof.

(2) An authorised officer who purchases or takes three relevant things, copies or photographs pursuant to paragraph (1) shall—

- (a) in the presence of the food business operator, or the person in apparent charge or control of the relevant thing, mark, close and seal each relevant thing, copy or photograph, in such a manner as its nature will permit, and in such a way that the integrity of the sample is not compromised,
- (b) forward one of the relevant things, copies or photographs, to an approved examiner in an official laboratory for analysis or test, or retain it for the purpose of inspection, as appropriate,
- (c) give or send one of the relevant things, copies or photographs, to the food business operator or the person in apparent charge or control of the relevant thing, or where necessary retain such relevant thing, copy or photograph in his or her possession on behalf of the food business operator or person, and
- (d) retain the third relevant thing, copy or photograph.

(3) Notwithstanding paragraph (2)(a), an authorised officer may mark, close and seal a part of a sample, as appropriate, in the absence of the food business operator, or the person in apparent charge or control of the relevant thing, where no such person agrees to be present or it is not technically feasible for such person to be present during such marking, closing and sealing.

(4) In proceedings for an offence under food legislation, where three relevant things, copies or photographs were purchased or taken pursuant to paragraph (1), or the food business operator concerned availed of its right to a second expert opinion under Article 35 of the Official Controls Regulation and Regulation 20A, the result of any analysis, test or inspection of, or report on, the relevant thing, copy or photograph shall not be adduced unless the relevant thing, copy or photograph retained by the authorised officer is produced at the hearing.

(5) Where it is not possible to purchase or take three identical relevant things, copies or photographs pursuant to paragraph (1), the result of any analysis, test or inspection of the sample of the relevant thing may be adduced where the sample has, before trial of the proceedings, been made reasonably available to the accused person, or his or her agent, for inspection and, where requested, the person who carried out the documentary review pursuant to Article 35 of the Official Controls Regulation.

(6) The Authority or the official agency, as the case may be, may, where it considers that it is necessary to eliminate or contain the risks to human, animal or plant health, animal welfare, or, as regards GMOs and plant protection products, also to the environment, take immediate action notwithstanding that the sampling procedures set out in this Regulation have not been carried out and notwithstanding any application by the food business operator for a second expert opinion under Article 35 of the Official Controls Regulation and Regulation 20A.".

10. The Principal Regulations are amended by inserting after Regulation 26 the following:

# *"Compliance notice"*

26A. (1) Where an authorised officer is of the opinion that there is noncompliance with a requirement of these Regulations, he or she may, following consultation with the chief executive or such other officer of the Authority or an official agency designated in that behalf by the Board of the Authority, serve, or arrange to have served, on the food business operator concerned or the person in charge a notice ('compliance notice') in accordance with paragraph (2).

- (2) A compliance notice shall—
  - (a) be signed by the authorised officer issuing it, or the officer consulted in accordance with paragraph (1),
  - (b) identify the requirement(s) of these Regulations with which there has not been compliance,
  - (c) where appropriate, direct the person on whom the compliance notice is served to ensure that the food is not placed or made available on the market until such time as all appropriate measures, including corrective measures, have been taken to bring the food into conformity with these Regulations,
  - (d) where appropriate, direct the person on whom the compliance notice is served to recall and withdraw from the market any food which fails to comply with these Regulations,
  - (e) specify a date, commensurate with the nature of the noncompliance, within which the food business operator must take such corrective action as is required to bring the non-compliance to an end, and
  - (f) contain information regarding the bringing of an appeal under paragraph (5) against the notice, including the manner in which an appeal shall be brought.

(3) A compliance notice shall not specify a date in accordance with paragraph (2)(e) that falls on or before the date by which an appeal under paragraph (5) must be brought.

(4) The chief executive of the Authority or an official agency or another officer of the Authority or an official agency designated by the Board of the Authority for that purpose may, for stated reasons, revoke or vary a compliance notice issued by an authorised officer appointed by the Authority or an official agency.

(5) A person may appeal a compliance notice served on him or her to the District Court not later than 7 days after the service of the compliance notice concerned.

(6) A person who appeals against a compliance notice shall at the same time notify the Authority or official agency of the appeal and the grounds for the appeal and the Authority or official agency shall be entitled to appear, be heard and adduce evidence on the hearing of the appeal.

(7) In the event of non-compliance or delay by the person on whom a compliance notice has been served, an authorised officer may, with the approval of the chief executive of the Authority or official agency, or another officer thereof designated by the Board of the Authority for that purpose, take whatever measures are considered necessary to ensure compliance with the compliance notice, including the seizure and destruction of the food in question or the making of any arrangements for such seizure or destruction or both.

(8) The District Court shall, upon an appeal under this Regulation, do one of the following:

- (a) affirm the compliance notice concerned;
- (b) direct the authorised officer to withdraw the compliance notice concerned; or
- (c) direct the authorised officer to modify the compliance notice concerned.

(9) An authorised officer shall comply with a direction under paragraph (8)(b) or (c).

(10) A person who fails to comply with a compliance notice by the specified date shall be guilty of an offence and shall be liable on summary conviction to a class A fine or to imprisonment for a term not exceeding 6 months, or to both.

- (11) This Regulation shall not operate to prevent or restrict—
  - (a) the entitlement of the Authority or an official agency to bring proceedings for the purpose of securing compliance with these Regulations by a person, or
  - (b) the bringing or prosecuting of any proceedings for an offence under these Regulations.

(12) In this Regulation, 'specified date' means, in relation to a compliance notice—

- (a) the date specified in the notice in accordance with paragraph (2)(e), where no appeal against the notice is brought under this Regulation, or
- (b) the day falling immediately after the expiration of the period of 7 days from the date on which the District Court so affirms the notice, where an appeal against the notice is brought under paragraph (5) and the District Court affirms the notice in accordance with paragraph (8)(a).

(13) Nothing in this Regulation shall prevent the Authority or an official agency from serving a prohibition order or closure order at any time in respect of any business which is subject to a compliance notice if, in the opinion of an authorised officer, the circumstances require the service of such order.

## Service of notices

26B. (1) A notice served or given by or under these Regulations shall be addressed to the person concerned and served or given in one of the following:

- (a) by addressing it to the person by name and delivering it to him or her;
- (b) by leaving it at the address at which the person ordinarily resides or carries on business;
- (c) by sending it by post in a prepaid registered letter addressed to the person at the address at which he or she ordinarily resides or carries on business;
- (d) if an address for the service of notices has been furnished by the person, by leaving it at, or sending it by prepaid registered post addressed to him or her to, that address;
- (e) where the address at which the person ordinarily resides or carries on business cannot be ascertained by reasonable inquiry and notice is required to be served on, or given to, him or her in respect of any premises by delivering it to a person over the age of 16 years resident in or employed on the premises, or by affixing it in a conspicuous position on or near the premises; or
- (f) by sending it by means of electronic mail to a device or facility for the reception of electronic mail where such an electronic mail address has been furnished by the person, but only if the sender's facility for the reception of electronic mail generates a message confirming a receipt of the electronic mail confirming successful transmission of the notice.

(2) Where the name of the person concerned cannot be ascertained by reasonable inquiry, a notice under these Regulations may be addressed to 'the occupier', 'the owner' or 'the person in charge', as the case may be.

(3) For the purposes of this Regulation, a company within the meaning of the Companies Act 2014 (No. 38 of 2014) shall be deemed to be ordinarily resident at its registered office, and every other body corporate and every unincorporated body shall be deemed to be ordinarily resident at its principal office or place of business.

(4) A person shall not at any time during the period of 3 months after a notice is affixed under paragraph (1)(e) remove, damage or deface the notice without lawful authority.".

11. Regulation 31 of the Principal Regulations is amended by inserting after subparagraph (12) the following:

"(13) Notwithstanding the provisions of Part 3B, a food business operator is not guilty of an offence under these Regulations for failure to comply with EU Regulation 2017/1798 in respect of a food which is referred to in Regulation 3(4) and which, before 27 October 2022, was placed on the market or labelled in accordance with the European Communities (Foods Intended for Use in Energy-Restricted Diets for Weight Reduction) Regulations 2007 (S.I. No. 784 of 2007).

(14) Notwithstanding Regulation 34, the European Communities (Foods Intended for Use in Energy-Restricted Diets for Weight Reduction) Regulations 2007 (S.I. No. 784 of 2007) shall continue to apply, in respect of a food referred to in Regulation 3(4) which was placed on the market or labelled before 27 October 2022, until the stocks of such food are exhausted.".

- 12. Regulation 34(1) of the Principal Regulations is amended
  - (a) by substituting "(g) European Communities (Infant Formulae and Follow-on Formulae) (Amendment) Regulations 2014 (S.I. No. 92 of 2014)," for "(f) European Communities (Infant Formulae and Follow-on Formulae) (Amendment) Regulations 2014 (S.I. No. 92 of 2014).", and
  - (b) by inserting after subparagraph (g) the following:

"(h) European Communities (Foods Intended for Use in Energy-Restricted Diets for Weight Reduction) Regulations 2007 (S.I. No. 784 of 2007).".



GIVEN under my Official Seal, 20 August, 2024.

STEPHEN DONNELLY, Minister for Health.

# 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) 2017/1798 of 2 June 2017 supplementing Regulation (EU) No. 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for total diet replacement for weight control, as amended by Commission Delegated Regulation (EU) 2022/2182 of 30 August 2022 amending Delegated Regulation (EU) 2017/1798 as regards the lipid and magnesium requirements for total diet replacement for weight control.

These Regulations also give further effect to 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.

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 2024. 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

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