STATUTORY INSTRUMENTS.

S.I. No. 425 of 2019

EUROPEAN UNION (FOOD INTENDED FOR INFANTS AND YOUNG CHILDREN, FOOD FOR SPECIAL MEDICAL PURPOSES, AND TOTAL DIET REPLACEMENT FOR WEIGHT CONTROL) REGULATIONS 2019

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I, SIMON HARRIS, 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 Regulation (EU) No. 609/2013 of the European Parliament and of the Council of 12 June 2013[1], Commission Delegated Regulation (EU) 2016/128 of 25 September 2015[2] and Commission Delegated Regulation (EU) 2017/1091 of 10 April 2017[3], hereby make the following regulations:

PART I

PRELIMINARY

Citation

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) Regulations 2019.

Interpretation

2. (1) In these Regulations—

"Act of 1998" means the Food Safety Authority of Ireland Act 1998 (No. 29 of 1998);

"Annex I to EU Regulation 2016/128" means Annex I to Commission Delegated Regulation (EU) 2016/128 of 25 September 2015[2];

"Annex II to EU Regulation 2016/128" means Annex II to Commission Delegated Regulation (EU) 2016/128 of 25 September 2015[2];

"Annex III to EU Regulation 2016/128" means Annex III to Commission Delegated Regulation (EU) 2016/128 of 25 September 2015[2];

[1] OJ No. L 181, 29.6.2013, p. 35.
[2] OJ No. L 25, 2.2.2016, p. 30.
[3] OJ No. L 158, 21.6.2017, p. 5.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 16*th August*, 2019.

"Annex IV to EU Regulation 2016/128" means Annex IV to Commission Delegated Regulation (EU) 2016/128 of 25 September 2015[2];

"approved examiner" means—

(*a*) an Agricultural Inspector in the Department of Agriculture, Food and the Marine,

(*b*) an Assistant Agricultural Inspector in the Department of Agriculture, Food and the Marine,

(*c*) a Deputy Public Analyst located at a Public Analyst's Laboratory,

(*d*) an Executive Analytical Chemist located at a Public Analyst's Laboratory,

(*e*) a Public Analyst located at a Public Analyst's Laboratory, or

(*f*) a person, or member of a class of persons, designated by the Minister pursuant to Regulation 27;

"authorised officer" means an authorised officer appointed under section 49 of the Act of 1998;

"Authority" means the Food Safety Authority of Ireland, established under section 9 of the Act of 1998;

"EC Regulation 1924/2006" means Regulation (EC) No. 1924/2006 of the European Parliament and of the Council of 20 December 2006[4] as affected by Corrigendum to Regulation (EC) No. 1924/2006 of the European Parliament and of the Council of 20 December 2006[5] and as amended by Regulation (EC) No. 107/2008 of the European Parliament and of the Council of 15 January 2008[6], Regulation (EC) No. 109/2008 of the European Parliament and of the Council of 15 January 2008[7], Commission Regulation (EU) No. 116/2010 of 9 February 2010[8] and Commission Regulation (EU) No. 1047/2012 of 8 November 2012[9];

"EU Regulation 1169/2011" means Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011[10], as affected by Corrigendum to Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011[11], and as amended by Commission Delegated Regulation (EU) No. 1155/2013 of 21 August 2013[12], Commission Delegated Regulation (EU) No. 78/2014 of 22 November 2013[13],

[4] OJ No. L 404, 30.12.2006, p. 9.
[5] OJ No. L 12, 18.1.2007, p. 3.
[6] OJ No. L 39, 13.2.2008, p. 8.
[7] OJ No. L 39, 13.2.2008, p. 14.
[8] OJ No. L 37, 10.2.2010, p. 16.
[9] OJ No. L 310, 9.11.2012, p. 36.
[10] OJ No. L 304, 22.11.2011, p.18.
[11] OJ No. L 247, 13.9.2012, p. 17.
[12] OJ No. L 306, 16.11.2013, p. 7.
[13] OJ No. L 27, 30.1.2014, p. 7.

and EU Regulation 2015/2283 of the European Parliament and of the Council of 25 November 2015[14];

"EU Regulation 609/2013" means Regulation (EU) No. 609/2013 of the European Parliament and of the Council of 12 June 2013[1] as amended by Commission Delegated Regulation (EU) 2017/1091 of 10 April 2017[3];

"EU Regulation 2016/128" means Commission Delegated Regulation (EU) 2016/128 of 25 September 2015[2] supplementing EU Regulation 609/2013;

"food for special medical purposes" means food specially processed or formulated and intended for the dietary management of patients, including infants, to be used under medical supervision; it is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone;

"General Food Law Regulation" means Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002[15], as amended by Regulation (EC) No. 1642/2003 of the European Parliament and of the Council of 22 July 2003[16], Commission Regulation (EC) No. 575/2006 of 7 April 2006[17], Commission Regulation (EC) No. 202/2008 of 4 March 2008[18], Regulation (EU) No. 652/2014 of the European Parliament and of the Council of 15 May 2014[19] and Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017[20];

"Minister" means the Minister for Health;

"Official Agency" means an official agency carrying out functions under a service contract and acting on behalf of the Authority pursuant to section 48 of the Act of 1998;

"Official Controls Regulation" means Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 29 April 2004[21], as affected by the Corrigendum to Regulation (EC) No. 882/2004 of 28 May 2004[22], as amended by Commission Regulation (EC) No. 1029/2008 of 20 October 2008[23], Regulation (EC) No. 596/2009 of the European Parliament and of the Council

[14] OJ No. L 327, 11.12.2015, p. 1.
[15] OJ No. L 31, 1.2.2002, p. 1.
[16] OJ No. L 245, 29.9.2003, p. 4.
[17] OJ No. L 100, 8.4.2006, p. 3.
[18] OJ No. L 60, 5.3.2008, p. 17.
[19] OJ No. L 189, 27.6.2014, p. 1.
[20] OJ No. L 117, 5.5.2017, p. 1.
[21] OJ No. L 165, 30.4.2004, p. 1.
[22] OJ No. L 191, 28.5.2004, p. 1.
[23] OJ No. L 278, 21.10.2008, p. 6.

of 18 June 2009[24], Commission Regulation (EU) No. 208/2011 of 2 March 2011[25] (as corrected by Commission Regulation (EU) No. 880/2011 of 2 September 2011[26]), Commission Regulation (EU) No. 563/2012 of 27 June 2012[27], Council Regulation (EU) No. 517/2013 of 13 May 2013[28] and Regulation (EU) No. 652/2014 of the European Parliament and of the Council of 15 May 2014[29];

"Official laboratory" means—

(*a*) Dairy Science Laboratory, Celbridge, Co Kildare,
(*b*) Pesticides Control Laboratory, Celbridge, Co Kildare,
(*c*) Public Analyst's Laboratory, Cork,
(*d*) Public Analyst's Laboratory, Dublin,

(*e*) Public Analyst's Laboratory, Galway, or

(*f*) a laboratory designated by the Minister pursuant to Regulation 27;

"relevant thing" means—

(*a*) a label, labelling, packaging or container used on food,
(*b*) materials used in the presentation or advertising of food or other accompanying material, or
(*c*) materials used in the dissemination of any useful information or recommendations on food exclusively intended for persons having qualifications in medicine, nutrition, pharmacy, or for other healthcare professionals responsible for maternal care and childcare, in accordance with Regulation 7(2);

"residue" means the residue of an active substance as referred to in Article 2(2) of Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of 21 October 2009[30] used in a plant protection product as referred to in Article 2(1) of that Regulation, including metabolites and products resulting from the degradation or reaction of that active substance;

"service contract" means a contract entered into between the Authority and an official agency pursuant to section 48 of the Act of 1998;

"Union list" means the Union list annexed to EU Regulation 609/2013 of 12 June 2013[1] as amended by Commission Delegated Regulation (EU) 2017/1091 of 10 April 2017[3] and which lists the

[24] OJ No. L 188, 18.7.2009, p. 14.
[25] OJ No. L 58, 3.3.2011, p. 29.
[26] OJ No. L 228, 3.9.2011, p. 8.
[27] OJ No. L 168, 28.6.2012, p. 24.
[28] OJ No. L 158, 10.6.2013, p. 1.
[29] OJ No. L 189, 27.6.2014, p. 1.
[30] OJ No. L 309, 24.11.2009, p 1.

various substances that may be added to one or more of the categories of food referred to in Regulation 3.

(2) A word or expression which is used in these Regulations and which is also used in EC Regulation 1924/2006, EU Regulation 1169/2011, EU Regulation 609/2013 or the General Food Law Regulation has, unless the context otherwise requires, the same meaning in these Regulations as it has in those Regulations.

Scope

3. These Regulations apply to the following foods—

(1) infant formula and follow-on formula,

(2) processed cereal-based food and baby food,

(3) food for special medical purposes, and

(4) total diet replacement for weight control.

PART 2

FOOD INTENDED FOR INFANTS AND YOUNG CHILDREN, FOOD FOR SPECIAL MEDICAL PURPOSES AND TOTAL DIET REPLACEMENT FOR WEIGHT CONTROL

Scope of this Part

4. Without prejudice to Part 3 which provides for additional offences in relation to the food referred to in Regulation 3(3), this Part applies to all food referred to in Regulation 3.

Requirements in relation to prepacked food

5. A food business operator who places on the retail market a food referred to in Regulation 3 other than in the form of prepacked food, is guilty of an offence.

General compositional requirements

6. A food business operator who places on the market a food referred to in Regulation 3—

(1) the composition of which is not appropriate for satisfying the nutritional requirements of and is not suitable for the persons for whom it is intended, in accordance with generally accepted scientific data,

(2) which contains a substance in such quantity as to endanger the health of the persons for whom it is intended,

(3) to which substances have been added for the purposes of meeting the requirements of paragraph (1) but which substances, on the basis of generally accepted scientific data—

(a) are not bio-available for use by the human body,

(*b*) do not have a nutritional or physiological effect, or

(*c*) are not suitable for the persons for whom the food is intended,

is guilty of an offence.

General information requirements

7. (1) Subject to paragraph (2), a food business operator who places on the market a food referred to in Regulation 3 and who fails to ensure that the labelling, presentation or advertising of that food—

(*a*) provides information for the appropriate use of that food,

(*b*) does not mislead, or

(*c*) does not attribute to that food the property of preventing, treating or curing a human disease, or imply such properties,

is guilty of an offence.

(2) Paragraph (1) shall not prevent the dissemination of any useful information or recommendations on food referred to in Regulation 3 exclusively intended for persons having qualifications in medicine, nutrition, pharmacy, or for other healthcare professionals responsible for maternal care and childcare.

Additional requirements relating to infant and follow-on formula

8. (1) A food business operator who places on the market infant formula or follow-on formula, and who fails to ensure that the labelling, presentation or advertising of that food is designed in a manner so as not to discourage breastfeeding, is guilty of an offence.

(2) Subject to paragraph (3), a food business operator who—

(*a*) places on the market infant formula where the labelling, presentation or advertising of such food includes pictures of infants, or other pictures or text which may idealise the use of such formulae, or

(*b*) places on the market follow-on formula where the label of such food includes pictures of infants, or other pictures or text which may idealise the use of such formulae,

is guilty of an offence.

(3) Paragraph (2) shall not prevent the use of graphic representations for easy identification of infant formula and follow-on formula and for illustrating methods of preparation.

Union list

9. (1) A food business operator who adds to a food referred to in Regulation 3, a substance belonging to one of the following categories of substances—

(*a*) vitamins,

(*b*) minerals,

(*c*) amino acids,

(*d*) carnitine and taurine,

(*e*) nucleotides, or

(*f*) choline and inositol

when—

(i) that substance is not included in the Union list, or

(ii) the particular requirements set out in the Union list for the addition of that substance are not complied with,

is guilty of an offence.

(2) A food business operator who adds to a food referred to in Regulation 3, a substance belonging to a category other than one listed in paragraph (1), where that substance does not satisfy the general requirements set out in Articles 6 and 9 of EU Regulation 609/2013, is guilty of an offence.

Part 3

SPECIFIC COMPOSITIONAL AND INFORMATION REQUIREMENTS FOR FOOD FOR SPECIAL MEDICAL PURPOSES

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

Compositional requirements

11. (1) A food business operator who places on the market a food referred to in Regulation 3(3) and who fails to ensure that—

(*a*) the food has been formulated based on sound medical and nutritional principles,

(*b*) the use of the food, in accordance with manufacturer's instructions, is safe, beneficial or effective in meeting the specific nutritional requirements of the persons for whom it is intended as demonstrated by generally accepted scientific data,

(*c*) subject to paragraph (2) and where the food has been developed to satisfy the nutritional requirements of infants, the food complies with the compositional requirements set down in Part A of Annex I to EU Regulation 2016/128, or

(*d*) subject to paragraph (2) and where the food has been developed other than to satisfy the nutritional requirements of infants, the food complies with the compositional requirements set out in Part B of Annex I to EU Regulation 2016/128,

is guilty of an offence.

(2) The compositional requirements referred to in paragraphs (1)(c) and (1)(d) shall apply to food referred to in Regulation 3(3) which is ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions.

Requirements on pesticides in food for special medical purposes developed to satisfy the nutritional requirements of infants and young children

12. (1) Subject to paragraph (3), a food business operator who places on the market a food referred to in Regulation 3(3) which has been developed to satisfy the nutritional requirements of infants and young children and who fails to ensure that such food—

(*a*) subject to subparagraph (b), does not contain residues exceeding 0.01 mg/kg per active substance,

(*b*) does not, in the case of the active substances listed in Annex II to EU Regulation 2016/128, contain residue levels exceeding those specified in that Annex, or

(*c*) subject to paragraph (2), has not been produced from agricultural products, for the production of which plant protection products containing the active substances listed in Annex III to EU Regulation 2016/128 have been used,

is guilty of an offence.

(2) For the purposes of paragraph 1(c), plant protection products containing the active substances listed in Annex III to EU Regulation 2016/128 shall be considered not to have been used in agricultural products, if their residues do not exceed 0.003mg/kg.

(3) The levels referred to in paragraphs (1) (a), (b) and (c) shall apply to the food referred to in Regulation 3(3) ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions.

Name of the food

13. A food business operator who places on the market a food referred to in Regulation 3(3) but which is not named "Food for special medical purposes", is guilty of an offence.

Specific requirements on food information

14. (1) A food business operator who places on the market a food referred to in Regulation 3(3) but who fails to ensure that the following mandatory particulars, preceded by the words 'important notice' or their equivalent, are included on the package or on a label attached thereto—

15. (*a*) a statement that the product must be used under medical supervision,

(*a*) a statement that the product must be used under medical supervision,

(*b*) a statement as to whether the product is suitable for use as the sole source of nourishment,

(*c*) a statement that the product is intended for a specific age group, as appropriate,

(*d*) where appropriate, a statement that the product poses a health hazard when consumed by persons who do not have the disease, disorder or medical condition for which the product is intended,

is guilty of an offence.

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

(*a*) the statement 'For the dietary management of…' where the blank shall be filled in with the disease, disorder or medical condition for which the product is intended,

(*b*) where appropriate, a statement concerning adequate precautions and contra-indications,

(*c*) a description of the properties and/or characteristics that make the product useful in relation to the disease, disorder or medical condition for the dietary management of which the product is intended, in particular, as the case may be, relating to the special processing and formulation, the nutrients which have been increased, reduced, eliminated or otherwise modified and the rationale of the use of the product,

(*d*) where appropriate, a warning that the product is not for parenteral use,

(*e*) instructions for appropriate preparation, use and storage of the product after the opening of the container, as appropriate,

is guilty of an offence.

(3) A food business operator who fails to ensure that the mandatory particulars listed in paragraphs (1) and (2) 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 of the 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^2,

is guilty of an offence.

Specific requirements on nutrition declaration

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

(*a*) 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 area of the packaging or container,

(*b*) fails to include in the mandatory nutrition declaration under paragraph 1(a), in addition to the information referred to in Article 30(1) of EU Regulation 1169/2011—

(i) the amount of each mineral substance and of each vitamin listed in Annex I to EU Regulation 2016/128 and present in the product,

(ii) the amount of components of protein, carbohydrate, fat or of other nutrients and their components, the declaration of which would be necessary for the appropriate intended use of the product,

(iii) information on the osmolality or the osmolarity of the product, where appropriate, or

(iv) information on the source and nature of the protein or protein hydrolysates contained in the product,

(*c*) fails to ensure that the nutrients in the nutrition declaration referred to in paragraph 1(a) comply with the calculation, expression and presentation and requirements under Articles 31 to 35 of EU Regulation 1169/2011,

(*d*) notwithstanding Article 30(3) of EU Regulation 1169/2011, repeats information included in the mandatory nutrition declaration under paragraph (1)(a), on the package or on the label attached to such a food,

(*e*) fails to present the particulars included in the nutrition declaration under paragraph (1)(a) 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,

(*f*) fails to position the indication for the amount of sodium with the other minerals, in the nutrition declaration under paragraph (1)(a), or

(*g*) repeats the amount of sodium next to the indication of salt content other than by stating 'Salt X g (of which sodium: Ymg)',

is guilty of an offence.

(2) Notwithstanding Article 31(3) of EU Regulation 1169/2011, the energy value and the amounts of nutrients of food referred to in Regulation 3(3) shall be those of the food as sold and, where appropriate, those of the food ready for use after preparation in accordance with the manufacturer's instructions.

(3) 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(3) shall not be expressed as a percentage of the reference intakes set out in Annex XIII to that Regulation.

Nutrition and health claims

16. A food business operator who makes a nutrition or health claim on a food referred to in Regulation 3(3), is guilty of an offence.

Specific requirements for food for special medical purposes developed to satisfy the nutritional requirements of infants

17. (1) A food business operator who places on the market a food referred to in Regulation 3(3) developed to satisfy the nutritional requirements of infants but who—

(*a*) fails to ensure that the mandatory particulars appear in a language easily understood by consumers,

(*b*) subject to paragraph (3) labels, presents or advertises that food with pictures of infants or other pictures or text which may idealise the use of the product,

(*c*) fails to ensure that the labelling, presentation and advertising of that food is designed in such a way that it enables consumers to make a clear distinction between such products and infant formula and follow-on formula, in particular as to the text, images and colours used, so as to avoid any risk of confusion,

(*d*) subject to paragraph (4), advertises that food—

(i) in publications other than those specialising in baby care and scientific publications, or

(ii) in such a way that the advertisement, in publications specialising in baby care and scientific publications, contains information other than of a scientific and factual nature,

(*e*) provides directly to the consumer at retail level—

(i) point-of-sale advertising,

(ii) samples, or

(iii) any other promotional devices

to induce sales of that food,

is guilty of an offence.

(2) A manufacturer or distributor of a food referred to in Regulation 3(3) developed to satisfy the nutritional requirements of infants, who directly provides to the general public or to pregnant women, mothers or members of their families—

(a) free or low-priced products,

(b) samples, or

(c) any other promotional gifts,

is guilty of an offence.

(3) A food business operator who labels, presents or advertises a food referred to in Regulation 3(3) developed to satisfy the nutritional requirements of infants with graphic representations for easy identification of the product and for illustrating methods of preparation is not guilty of an offence.

(4) A food business operator who disseminates information exclusively intended for health care professionals is not guilty of an offence under paragraph (1)(d).

Offences arising from failure to notify the Authority

18. A food business operator who places on the market in the State a food referred to in Regulation 3(3) but who fails who notify the Authority of the information appearing on the label by sending to it a model of the label used for the product and any other information which the Authority may reasonably request to establish compliance with these Regulations or EU Regulation 2016/128, is guilty of an offence.

Part 4

ENFORCEMENT, OFFENCES AND PENALTIES

Enforcement generally

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

(2) These Regulations shall be deemed to be food legislation for the purposes of the Act of 1998.

(3) These Regulations shall be enforced by the Authority or by an official agency acting pursuant to a service contract with the Authority, or by both and, without prejudice to paragraph (1), the enforcement provisions contained in the Act of 1998 shall apply for the purposes of ensuring compliance with the requirements of these Regulations.

Taking of food samples

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

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

(3) An authorised officer who purchases or takes without payment a sample of food with the intention of having it analysed, shall, after purchasing or taking the sample, forthwith notify the food business operator, or the person in apparent charge or control of the food of his or her intention of having the sample analysed.

(4) An authorised officer who suspects that a food fails to comply with the provisions of these Regulations and who purchases or takes a sample of that food without payment, with the intention of having it analysed, may, by notice in writing to the food business operator, or the person in apparent charge or control of such food, 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.

Division of food samples

21. (1) An authorised officer who takes a sample of food pursuant to these Regulations, for the purposes of official analysis shall, where the division of the sample is reasonably practicable, divide the sample into three approximately equal parts (enforcement, trade (defence) and referee) and mark each, 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 in accordance with paragraph (1), shall—

(a) in the presence of the food business operator, or the person in apparent charge or control of the food mark, seal and fasten 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 the approved examiner in an official laboratory for analysis,
(*c*) give or send one part to the food business operator or the person in apparent charge or control of such food, and
(*d*) retain the third part.

(3) Where an authorised officer 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 or impede the proper analysis of the sample,

the provisions of paragraph (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).

(4) In proceedings for an offence under these Regulations, the result of any test, examination or analysis of, or report on, a sample of food taken pursuant to these Regulations, shall not be adduced unless before the proceedings were instituted the sample was divided as specified in this Regulation and the part, package or container retained by the authorised officer shall be produced at the hearing.

Taking of relevant things

22. (1) 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.

(2) An authorised officer who takes a sample of a relevant thing related to a food sample taken in accordance with Regulations 20 and 21, for the purposes of official analysis, shall obtain three identical such relevant things, or take three copies or photographs thereof.

(3) An authorised officer who takes a relevant thing related to a food sample taken in accordance with Regulations 20 and 21, or a copy or photograph thereof, with the intention of having it analysed, shall—

(*a*) forthwith notify the food business operator or the person in apparent charge or control of the relevant thing, of his or her intention of having the relevant thing, copy or photograph analysed,

(*b*) mark, seal and fasten each relevant thing, or copy or photograph of the relevant thing, in such a manner as its nature will permit, and in such a way that the integrity of the sample is not compromised,

(*c*) forward one of the relevant things, or one of the copies or photographs of the relevant thing, to the approved examiner in an official laboratory for analysis,

(*d*) give or send one of the relevant things, or one of the copies or photographs of the relevant thing, to the food business operator or the person in apparent charge or control of such relevant thing, and

(*e*) retain the third relevant thing, or the third copy or photograph of the relevant thing.

(4) An authorised officer who takes a sample of a relevant thing pursuant to these Regulations, for the purpose of inspection, shall obtain three identical such relevant things, or takes three copies or photographs of such relevant thing.

(5) An authorised officer who takes a relevant thing, or a copy or photograph thereof, with the intention of having it inspected, shall—

(*a*) forthwith notify the food business operator or the person in apparent charge or control of the relevant thing, of his or her intention of having the relevant thing, copy or photograph inspected,

(*b*) mark, seal and fasten each relevant thing, or copy or photograph of the relevant thing, in such a manner as its nature will permit, and in such a way that the integrity of the sample is not compromised,

(*c*) give or send one of the relevant things, or one of the copies or photographs of the relevant thing, to the food business operator or the person in apparent charge or control of such relevant thing,

(*d*) retain one of the relevant things, or one of the copies or photographs of the relevant thing, for the purpose of inspection, and

(*e*) retain the third relevant thing, or the third copy or photograph of the relevant thing.

(6) In proceedings for an offence under these Regulations, the result of any analysis or inspection of, or report on, a sample of a relevant thing taken pursuant to these Regulations shall not be adduced unless before the proceedings were instituted three identical relevant things, copies or photographs were taken as specified in this Regulation and the relevant thing or the copy or photograph of the relevant thing retained by the authorised officer is produced at the hearing.

Analysis of food samples and relevant things

23. (1) The approved examiner or a person under his or her direction, shall analyse as soon as possible any sample of food, relevant thing or copy or photograph of a relevant thing submitted to him or her in pursuance of these Regulations and the approved examiner shall certify to the person who submitted same to him or her the result of such analysis.

(2) For the purposes of paragraph (1), the form of certificate set out in the Schedule to these Regulations or a certificate in like form shall be used.

(3) An official certificate given in accordance with paragraph (1) shall be evidence of the matters contained therein until the contrary is shown.

Report on official controls

24. (1) Where a sample is taken by an authorised officer in pursuance of these Regulations for inspection or analysis, the Authority, or an official agency as the case may be, shall draw up a report in accordance with Article 9 of the Official Controls Regulation.

(2) Where the certificate given in accordance with Regulation 23(1) indicates that there has been non-compliance with these Regulations, the Authority, or the official agency, as the case may be, shall provide the food business operator or the person in apparent charge or control of such food or relevant thing, with a copy of the report referred to in paragraph (1).

Powers of authorised officers

25. An authorised officer may, for the purposes of these Regulations—

(*a*) examine any procedure connected with the manufacture of food, and

(*b*) require a person to state his or her name and address and, if the authorised officer thinks it necessary, to produce corroborative evidence of same.

Seizure, removal, detention and destruction

26. (1) An authorised officer may seize, remove or detain food or a relevant thing which is suspected by him or her of failing to comply with the provisions of these Regulations.

(2) An authorised officer may, with the consent in writing of the food business operator or the person in apparent charge or control of such food or in accordance with an order of a judge of the District Court under paragraph (5), destroy or otherwise dispose of food so as to prevent the food being used for human consumption.

(3) An authorised officer may, with the consent in writing of the food business operator or the person in apparent charge or control of such relevant thing or in accordance with an order of a judge of the District Court under paragraph (5), destroy or otherwise dispose of a relevant thing so as to prevent consumers from being misled or a risk to human health.

(4) An authorised officer who has seized, removed or detained food or a relevant thing in pursuance of the provisions of this Regulation may, on giving notice in writing to the food business operator, or the person in apparent charge or control of such food or relevant thing, of his or her intention to do so, apply to a judge of the District Court for an order directing that such food or relevant thing be destroyed or otherwise disposed of.

(5) A judge of the District Court, to whom an application is made for an order under paragraph (4), may, if satisfied that the food or relevant thing fail to comply with these Regulations, order that same be destroyed or otherwise disposed of, after such period, not exceeding 14 days, as may be specified in such order, and an authorised officer shall destroy or dispose of the food or relevant thing accordingly.

Designation of official laboratories and approved examiners

27. The Minister may, for the purposes of these Regulations designate, by notice in writing published in *Iris Oifigiúil*—

(*a*) a laboratory as a laboratory at which samples taken under these Regulations may be analysed and testing and verification may be carried out, and

(*b*) a person as being a person who, or a class of persons the members of which, may, at a designated laboratory engage in analysis, testing and verification for the purposes of these Regulations.

Enforcement

28. (1) The offences provided for in these Regulations shall not apply to an authorised officer or an approved examiner, or to a person acting under such an officer's or examiner's express direction, acting in the course of his or her duties pursuant to these Regulations.

(2) A person is guilty of an offence if he or she—

(*a*) obstructs or interferes with an authorised officer in the exercise of the officer's powers under these Regulations,

(*b*) fails or refuses to state his or her name or address in compliance with a request under these Regulations,

(*c*) fails to comply with a request or notice from an authorised officer under these Regulations,

(*d*) makes a statement or provides information to an authorised officer which the person knows is false or misleading,

(*e*) provides records or documents, or copies thereof, which the person knows to be false or misleading in content, or

(*f*) gives, in purported compliance with a request under these Regulations, a name, an address or corroborative evidence which is false or misleading.

(3) A person who forges, or utters knowing it to be forged, a certificate of analysis or other document purporting to be issued, granted or given under these Regulations or required for the purposes of these Regulations (hereafter referred to as "a forged document"), is guilty of an offence.

(4) A person who alters with intent to defraud or deceive, or utters knowing it to be so altered, a certificate of analysis or other document issued, granted or given under these Regulations, or required for the purposes of these Regulations (hereafter referred to as "an altered document"), is guilty of an offence.

(5) A person who, without lawful authority, has in his or her possession a forged document or an altered document, is guilty of an offence.

(6) A person who, with the intent to defraud or deceive—

(*a*) tampers with any food or relevant thing, or

(*b*) tampers or interferes with any sample taken under these Regulations,

is guilty of an offence.

(7) A person who falsely represents himself or herself to be an authorised officer, is guilty of an offence.

(8) For the purposes of these Regulations, every contravention of a Regulation shall be deemed a separate contravention and every contravention of a paragraph or a subparagraph shall also be deemed to be a separate contravention and shall carry the same penalty as for a single contravention of any Regulation.

Bodies corporate

29. Where a body corporate, or a person acting on behalf of a body corporate, commits an offence under these Regulations and the offence is committed with the consent, connivance or approval of, or is attributable to any neglect or default on the part of, any director, manager, secretary or any other officer of such body, or a person purporting to act in any such capacity, such person is also guilty of an offence and is liable to be proceeded against and punished as if he or she were guilty of the first-mentioned offence.

Prosecution of offences

30. (1) A person who is guilty of an offence under these Regulations is liable—

(*a*) on summary conviction, to a class A fine or at the discretion of the Court to imprisonment for a term not exceeding 6 months, or both, or

(*b*) on conviction on indictment, to a fine not exceeding €500,000, or imprisonment for a term not exceeding 3 years, or both.

(2) Where a person is convicted of an offence under these Regulations, the court shall, unless it is satisfied that there are special and substantial reasons for

not so doing, order the person to pay to the Authority or the official agency, as the case may be, the costs and expenses, measured by the court, incurred by the Authority or official agency in relation to the investigation, detection and prosecution of the offence, including costs and expenses incurred in the taking of samples, the carrying out of tests, examinations and analyses and in respect of the remuneration and other expenses of employees, consultants and advisors engaged by the Authority or official agency.

(3) An order for costs and expenses under paragraph (2) is in addition to, and not instead of, any fine or penalty the court may impose under paragraph (1).

(4) Notwithstanding section 57 of the Act of 1998, a summary offence under these Regulations may be prosecuted by—

(*a*) the Authority, or

(*b*) an official agency.

PART 5

TRANSITIONAL MEASURES, AMENDMENTS AND REVOCATIONS

Transitional measures

31. (1) Notwithstanding the provisions of Part 2, a food business operator is not guilty of an offence under these Regulations for failure to comply with EU Regulation 609/2013 in respect of a food referred to in Regulation 3 and which, before 20 July 2016, was placed on the market or labelled in accordance with the European Union (Foodstuffs Intended for Particular Nutritional Uses) Regulations 2012 (S.I. No. 169 of 2012).

(2) Notwithstanding Regulation 34, the European Union (Foodstuffs Intended for Particular Nutritional Uses) Regulations 2012 (S.I. No. 169 of 2012) and as applicable—

(*a*) the European Communities (Processed Cereal-Based Foods and Baby Foods for Infants and Young Children) Regulations 2007 (S.I. No. 776 of 2007),

(*b*) the European Communities (Foods Intended for Use in Energy-Restricted Diets for Weight Reduction) Regulations 2007 (S.I. No. 784 of 2007),

(*c*) the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2007 (S.I. No. 852 of 2007), or

(*d*) the European Communities (Dietary Foods for Special Medical Purposes) Regulations 2009 (S.I. No. 187 of 2009)

shall continue to apply, in respect of a food referred to in Regulation 3 which was placed on the market or labelled before 20 July 2016, until the stocks of such food are exhausted.

(3) Notwithstanding the provisions of Part 2, a food business operator is not guilty of an offence under these Regulations for failure to comply with EU Regulation 609/2013 in respect of a food which is not referred to in Regulation 3 and which, before 20 July 2016, was placed on the market or labelled in accordance with the European Union (Foodstuffs Intended for Particular Nutritional Uses) Regulations 2012 (S.I. No. 169 of 2012) and as applicable—

(*a*) the European Communities (Foods Intended for Use in Energy-Restricted Diets for Weight Reduction) Regulations 2007 (S.I. No. 784 of 2007), or

(*b*) Commission Regulation (EC) No. 41/2009 of 20 January 2009[31].

(4) Notwithstanding Regulations 33 and 34, the European Union (Foodstuffs Intended for Particular Nutritional Uses) Regulations 2012 (S.I. No. 169 of 2012) and as applicable—

(*a*) the European Communities (Foods Intended for Use in Energy-Restricted Diets for Weight Reduction) Regulations 2007 (S.I. No. 784 of 2007), or

(*b*) Commission Regulation (EC) No. 41/2009 of 20 January 2009[31]

shall continue to apply, in respect of a food which is not referred to in Regulation 3 which was placed on the market or labelled before 20 July 2016, until the stocks of such food are exhausted.

(5) Notwithstanding the provisions of Part 3, a food business operator is not guilty of an offence under these Regulations for failure to comply with EU Regulation 2016/128 in respect of a food which is referred to in Regulation 3(3) and which, before 22 February 2019, was placed on the market or labelled in accordance with the European Communities (Dietary Foods for Special Medical Purposes) Regulations 2009 (S.I. No. 187 of 2009), as amended by the European Communities (Dietary Foods for Special Medical Purposes) (Amendment) Regulations 2013 (S.I. No. 382 of 2013).

(6) Notwithstanding Regulation 34, the European Communities (Dietary Foods for Special Medical Purposes) Regulations 2009 (S.I. No. 187 of 2009), as amended by the European Communities (Dietary Foods for Special Medical Purposes) (Amendment) Regulations 2013 (S.I. No. 382 of 2013), shall continue to apply, in respect of a food referred to in Regulation 3(3) which was placed on the market or labelled before 22 February 2019, until the stocks of such food are exhausted.

(7) Notwithstanding the provisions of Part 3, a food business operator is not guilty of an offence under these Regulations for failure to comply with EU Regulation 2016/128 in respect of a food which is referred to in Regulation 3(3) developed to satisfy the nutritional requirements of infants and which, before 22 February 2020, was placed on the market or labelled in accordance with the European Communities (Dietary Foods for Special Medical Purposes) Regulations 2009 (S.I. No. 187 of 2009), as amended by the European

[31] OJ No. L 16, 21.1.2009, p. 3.

Communities (Dietary Foods for Special Medical Purposes) (Amendment) Regulations 2013 (S.I. No. 382 of 2013).

(8) Notwithstanding Regulation 34, the European Communities (Dietary Foods for Special Medical Purposes) Regulations 2009 (S.I. No. 187 of 2009), as amended by the European Communities (Dietary Foods for Special Medical Purposes) (Amendment) Regulations 2013 (S.I. No. 382 of 2013), shall continue to apply, in respect of a food referred to in Regulation 3(3) developed to satisfy the nutritional requirements of infants which was placed on the market or labelled before 22 February 2020, until the stocks of such food are exhausted.

Amendment of European Communities (Infant Formulae and Follow-On Formulae) Regulations 2007 (S.I. No. 852 of 2007)

32. The European Communities (Infant Formulae and Follow-On Formulae) Regulations 2007 (S.I. No. 852 of 2007) are amended —

(1) in Regulation 2(1) —

(*a*) by deleting the definition of "Directive 92/52/EEC",

(*b*) by deleting the definition of "Directives",

(2) in Regulation 2(2) by substituting "Directive 2006/141/EC" for "the Directives" in both places where it occurs,

(3) in Regulation 2(3)(d) by substituting "Directive 2006/141/EC" for "the Directives",

(4) in Part 3 by deleting regulations 11, 12, 13 and 14, and

(5) in Regulation 15(1) by substituting "Directive 2006/141/EC" for "the Directives".

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

33. The European Communities (Foods Intended for Use in Energy-Restricted Diets for Weight Reduction) Regulations 2007 (S.I. No. 784 of 2007) are amended—

(1) in Regulation 2(1), by substituting for the definition of "foods for use in energy-restricted diets for weight reduction" with the following:

> "foods for use in energy-restricted diets for weight reduction" means specially formulated foods which, when used as instructed by the manufacturer, replace the whole of the total daily diet;

(2) in Regulation 3—

(*a*) by substituting "foods for use in energy-restricted diets for weight reduction means products presented as a replacement for the whole of the daily diet." for "foods for use in energy-

restricted diets for weight reduction are divided into two categories:", and

(*b*) by deleting paragraphs (a) and (b),

(3) in Regulation 5—

(*a*) in paragraph (2), by substituting "in Regulation 3" for "in Regulation 3(a)",

(*b*) in paragraph (3)—

(i) by substituting "shall be "Total diet replacement for weight control"." for "shall be—", and

(ii) by deleting paragraphs (a) and (b),

(4) in Regulation 6—

(*a*) by substituting for paragraph (f), "(f) a statement that the product provides adequate amounts of all essential nutrients for the day;", and

(*b*) by substituting for paragraph (g), "(g) a statement that the product should not be used for more than three weeks without medical advice".

(5) in Schedule 1,

(*a*) at point 1, by substituting for points 1.1 and 1.2, the following:

"The energy provided shall not be less than 3,360 kJ (800kcal) and shall not exceed 5,040 kJ (1,200 kcal) for the total daily ration.".,

(*b*) at point 2, by substituting for point 2.1, the following:

"2.1 The protein shall provide not less than 25% and not more than 50% of the total energy of the product. In any case the amount of protein shall not exceed 125g".,

(*c*) at point 3, by substituting for points 3.2 and 3.3, the following:

"3.2 The linoleic acid (in the form of glycerides) shall not be less than 4.5g",

(*d*) at point 4, by deleting the words "of products mentioned in Regulation 3(a)",

(*e*) at point 5, by substituting for points 5.1 and 5.2 excluding the table, the following:

"The products shall provide for the whole of the daily diet at least: 100% of the amounts of vitamins and minerals specified in the Table".

Revocations

34. (1) The following Regulations are revoked—

(*a*) The European Communities (Dietary Foods for Special Medical Purposes) Regulations 2009 (S.I. No. 187 of 2009),

(*b*) The European Union (Foodstuffs Intended for Particular Nutritional Uses) Regulations 2012 (S.I. No. 169 of 2012), and

(*c*) The European Communities (Dietary Foods for Special Medical Purposes) (Amendment) Regulations 2013 (S.I. No. 382 of 2013).

(2) References in other enactments to Regulations revoked under paragraph (1) shall, where the context so admits, be construed as references to these Regulations.

Schedule

Form of official certificate to be given by an approved examiner to an authorised officer.

European Union (Food Intended for Infants and Young Children, Food for Special Medical Purposes, and Total Diet Replacement for Weight Control) Regulations 2019

Certificate of Analysis

To [(1)] .....

I, the undersigned [(2)] .....

being an approved examiner for the purpose of the above Regulations certify that on

the .....day of ..... 20.....

a sample marked [(3)] .....

Date .....

Number .....

Weight or Measure [(4)] .....

was submitted to me by you and I certify that the sample / relevant thing/ copy/photograph of relevant thing was prepared and analysed/examined by me or under my direction [(5)]

and as a result I am of the opinion that [(6)]

Observations: [(7)]

I further certify that the sample has undergone no change which would affect my opinion/observations expressed above.

Certified by me this ..... day of ..... 20.....

At [8] .....

Name in BLOCK LETTERS .....

Status .....

Signature .....

_____

Official Stamp

NOTES

(1) Insert the name and address of the person submitting the sample for analysis.

(2) Insert description (e.g. Executive Analytical Chemist located at a Public Analyst's Laboratory).

(3) Insert particulars of marking (e.g. name, date etc.).

(4) This may be left unanswered if the sample cannot be conveniently weighed or measured or the weight or measurement is not material to the result of analysis.

(5) Indicate whether the approved examiner carried out the analysis himself or herself or whether it was carried out by another under the direction of the approved examiner.

(6) Here the approved examiner should specify the result of the analysis having regard to the provisions of the relevant legislation.

(7) Here the approved examiner may insert, at his or her discretion, his or her opinion whether the analysis indicates any addition, abstraction, deficiency or the presence of foreign matter or other defect and whether the composition or quality is thereby affected; any physical, chemical or other properties bearing on the composition or quality of the article; whether the article is injurious to health or unfit for human consumption; whether and in what respect a label and description relating to the sample is incorrect or misleading; and he or she may add any other observations as he or she may consider relevant. In the case of analysis or examination of a relevant thing, or a copy or photograph thereof, the approved examiner may insert, at his or her discretion, any observations in relation to the relevant thing that he or she may consider relevant.

(8) Insert the name and address of the laboratory carrying out the analysis/examination.

L.S.

GIVEN under my Official Seal
14 August, 2019.

SIMON HARRIS,
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 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, as amended by Commission Delegated Regulation (EU) 2017/1091 of the European Parliament and of the Council of 10 April 2017. They also give effect to Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing European (EU) No 609/2013 as regards the specific compositional and information requirements for food for special medical purposes.

These Regulations also make provision for transitional arrangements and revoke the European Communities (Dietary Foods for Special Medical Purposes) Regulations 2009 (S.I. No. 187 of 2009), the European Union (Foodstuffs Intended for Particular Nutritional Uses) Regulations 2012 (S.I. No. 169 of 2012), and the European Communities (Dietary Foods for Special Medical Purposes) (Amendment) Regulations 2013 (S.I. No. 382 of 2013).

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) Regulations 2019.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ó
FOILSEACHÁIN RIALTAIS,
52 FAICHE STIABHNA, BAILE ÁTHA CLIATH 2
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