



STATUTORY INSTRUMENTS.

**S.I. No. 169 of 2012**

---

EUROPEAN UNION (FOODSTUFFS INTENDED FOR PARTICULAR  
NUTRITIONAL USES) REGULATIONS 2012

**(Prn. A12/0833)**

## EUROPEAN UNION (FOODSTUFFS INTENDED FOR PARTICULAR NUTRITIONAL USES) REGULATIONS 2012

I, JAMES REILLY, 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 Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009<sup>1</sup> on foodstuffs intended for particular nutritional uses and Commission Regulation (EC) No. 953/2009 of 13 October 2009<sup>2</sup> as amended by Commission Regulation (EU) No. 1161/2011 of 14 November 2011<sup>3</sup> on substances that may be added for specific nutritional purposes in foods for particular nutritional uses, hereby make the following regulations:

**PART 1****Preliminary**

1. These Regulations may be cited as the European Union (Foodstuffs Intended for Particular Nutritional Uses) Regulations 2012.

2. (1) In these Regulations—

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

“approved examiner” means—

- (a) a Deputy Public Analyst located at a Public Analyst’s Laboratory,
- (b) an Executive Analytical Chemist located at a Public Analyst’s Laboratory,
- (c) a Public Analyst located at a Public Analyst’s Laboratory, or
- (d) a person, or member of a class of persons, designated by the Minister pursuant to Regulation 21;

“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;

<sup>1</sup>OJ No. L 124, 20.5.2009, p. 21.

<sup>2</sup>OJ No. L 269, 14.10.2009, p. 9.

<sup>3</sup>OJ No. L 296, 15.11.2011, p. 29

*Notice of the making of this Statutory Instrument was published in  
“Iris Oifigiúil” of 29th May, 2012.*

“Directive” means Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009<sup>1</sup> on foodstuffs intended for particular nutritional uses;

“EC Regulation” means Commission Regulation (EC) No. 953/2009 of 13 October 2009<sup>2</sup>, as amended by Commission Regulation (EU) No. 1161/2011 of 14 November 2011<sup>3</sup> on substances that may be added for specific nutritional purposes in foods for particular nutritional uses;

“foodstuffs for particular nutritional uses” has the meaning assigned to it by Regulation 3(2);

“General Food Law Regulation” means Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002<sup>4</sup> laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety;

“manufacture” includes the production and processing of food, other than primary production for private domestic use and domestic preparation, handling and storage of food for private domestic consumption, and cognate words shall be construed accordingly;

“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<sup>5</sup>, as affected by the Corrigendum to Regulation (EC) No. 882/2004 of 28 May 2004<sup>6</sup>, as amended by Council Regulation (EC) No. 301/2008 of 17 March 2008<sup>7</sup>, Commission Regulation (EC) No. 1029/2008 of 20 October 2008<sup>8</sup>, Regulation (EC) No. 596/2009 of 18 June 2009<sup>9</sup> and Commission Regulation (EU) No 208/2011 of 2 March 2011<sup>10</sup>;

“official laboratory” means—

- (a) the Public Analyst’s Laboratory, Cork,
- (b) the Public Analyst’s Laboratory, Dublin,
- (c) the Public Analyst’s Laboratory, Galway, or
- (d) a laboratory designated by the Minister pursuant to Regulation 21;

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

<sup>4</sup>OJ No. L 31, 1.2.2002, p. 1

<sup>5</sup>OJ No. L 165, 30.4.2004, p. 1

<sup>6</sup>OJ No. L 191, 28.5.2004, p. 1

<sup>7</sup>OJ No. L 97, 9.4.2008, p. 85

<sup>8</sup>OJ No. L 278, 21.10.2008, p. 6

<sup>9</sup>OJ No. L 188, 18.7.2009, p. 14

<sup>10</sup>OJ No. L 58, 3.3.2011, p. 29

“specific Directive” means a Directive adopted pursuant to Article 4 of Directive 2009/39/EC of 6 May 2009<sup>1</sup> for the purposes of setting down specific provisions applicable to the groups of foods for particular nutritional uses listed in Annex I to that Directive.

(2) A word or expression which is used in these Regulations and which is also used in the Directive, the EC Regulation or in the General Food Law Regulation has, unless the context otherwise requires, the same meaning in these Regulations as it has in the Directive, the EC Regulation or in the General Food Law Regulation.

- (3) (a) A reference in these Regulations to a Regulation is to a Regulation of these Regulations, unless it is indicated that reference to some other Regulations is intended.
- (b) A reference in these Regulations to a paragraph or subparagraph is to the paragraph or subparagraph of the provision in which the reference occurs, unless it is indicated that reference to some other provision is intended.
- (c) A reference in these Regulations to a Schedule is to a Schedule to these Regulations, unless it is indicated that reference to some other Regulations is intended.
- (d) A reference in these Regulations to an Article is to an Article of the Directive, unless it is indicated that reference to some other instrument is intended.

## **PART 2**

### **General Provisions**

3. (1) These Regulations concern foodstuffs intended for particular nutritional uses.

- (2) “Foodstuffs for particular nutritional uses” are those foodstuffs which—
- (a) are clearly distinguishable from foodstuffs for normal consumption, owing to their special composition or manufacturing process, and
- (b) are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability.

(3) A particular nutritional use must fulfil the particular nutritional requirements of—

- (a) certain categories of persons whose digestive processes or metabolism are disturbed, or
- (b) certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs, or

(c) infants or young children in good health.

4. A person shall not manufacture or place on the market foodstuffs intended for particular nutritional uses unless that person complies with the provisions laid down in these Regulations, the Directive and the EC Regulation.

5. (1) Foodstuffs for particular nutritional uses referred to in subparagraphs (a) and (b) of Regulation 3(3) may be characterised as “dietetic” or “dietary”.

(2) The following shall be prohibited in the labelling, presentation and advertising of foodstuffs for normal consumption—

(a) the use of the adjectives “dietetic” or “dietary”, either alone or in conjunction with other words, to designate those foodstuffs;

(b) all other markings or any presentation likely to give the impression that such foodstuffs referred to in Regulation 3 are involved.

6. (1) The nature or composition of the foodstuffs for particular nutritional uses referred to in Regulation 3 must be such that the foodstuffs are appropriate for the particular nutritional use intended.

(2) The foodstuffs for particular nutritional uses referred to in Regulation 3 must also comply with any mandatory provisions applicable to foodstuffs for normal consumption, save as regards changes made to them to ensure their conformity with the requirements of Regulation 3.

7. (1) The labelling, and the labelling methods used, the presentation and the advertising of the foodstuffs for particular nutritional uses referred to in Regulation 3 must not attribute properties for the prevention, treatment or cure of human disease to such foodstuffs or imply such properties.

(2) Paragraph (1) shall not prevent the dissemination of any useful information or recommendations exclusively intended for persons having qualifications in medicine, nutrition or pharmacy.

8. Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000<sup>11</sup> on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, shall apply to the foodstuffs for particular nutritional uses referred to in Regulation 3, subject to the additional requirements set out below—

(a) the designation under which any such foodstuff is sold shall be accompanied by an indication of its particular nutritional characteristics, save in the case of foodstuffs which fulfil the particular nutritional requirements referred to at Regulation 3 (3) (c), in which case that reference shall be replaced by a reference to the purpose for which they are intended;

<sup>11</sup>OJ No. L 109, 6.5.2000, p. 29, as affected by Corrigendum to Directive 2000/13/EC, OJ No. L 124, 25.5.2000, p. 66

- (b) in the case of the labelling of foodstuffs for particular nutritional uses for which no specific Directive has been adopted in accordance with Article 4 of the Directive, the labelling of such foodstuffs shall also include—
- (i) the particular elements of the qualitative and quantitative composition or the special manufacturing process which gives the foodstuff its particular nutritional characteristics;
  - (ii) the available energy value expressed in kilojoules and kilocalories and the carbohydrate, protein and fat content per 100 grams or 100 millilitres of the foodstuff as marketed, and where appropriate, per specified quantity of the foodstuff as proposed for consumption;
  - (iii) where the energy value is less than 50 kilojoules (12 kilocalories) per 100 grams or 100 millilitres of the foodstuff as marketed, these particulars may be replaced either by the words ‘energy value less than 50 kilojoules (12 kilocalories) per 100 grams’ or by the words ‘energy value less than 50 kilojoules (12 kilocalories) per 100 millilitres’.

9. (1) The foodstuffs for particular nutritional uses referred to at Regulation 3 shall only be allowed on the retail market in pre-packaged form, and the packaging shall completely cover the foodstuffs.

(2) Without prejudice to paragraph (1), the Minister, after consultation with the Authority, may permit derogations from the requirements of paragraph (1) for the purposes of the retail trade provided that the foodstuff is accompanied by the particulars provided for in Regulation 8 at the time when it is put on sale.

10. (1) Where a foodstuff for a particular nutritional use, which does not belong to one of the groups listed in Annex I to the Directive, is to be placed on the market for the first time in the State, the manufacturer, or where the foodstuff is manufactured in a third country, the importer, shall notify the Authority before the foodstuff is placed on the market. Such notification shall be accompanied by—

- (i) a model of the label used for the foodstuff, and
- (ii) an indication as to whether or not the foodstuff has been on the market in another Member State and, if so, the name of such Member State and the name of the competent authority which first received a notification pursuant to Article 11 of the Directive and a copy of all information provided to that competent authority.

(2) Where necessary, the Authority may require the manufacturer or, where appropriate, the importer, to produce the scientific work and the data establishing the foodstuff’s compliance with paragraphs (2) and (3) of Regulation 3 together with the information provided for in Regulation 8 (b) (i). If such work

is contained in a readily available publication, a mere reference to this publication shall suffice.

11. (1) The Minister, after consultation with the Authority, may by order impose temporary suspensions or restrictions on trade in a foodstuff intended for a particular nutritional use where he or she has detailed grounds for establishing that the foodstuff, not belonging to any of the groups listed in Annex I of the Directive, does not comply with paragraph (2) or (3) of Regulation 3 or endangers human health, albeit freely circulating in one or more of the Member States.

(2) The Minister, after consultation with the Authority, may by order temporarily suspend or restrict the application of the provisions of a specific Directive, where, as a result of new information or of a reassessment of existing information made since the relevant specific Directive was adopted, he or she has detailed grounds for establishing that foodstuffs intended for particular nutritional uses endanger human health even though they comply with the relevant specific Directive.

12. (1) This Regulation shall apply to foods for particular nutritional uses, excluding those foodstuffs covered by Commission Directive 2006/125/EC of 5 December 2006<sup>12</sup> on processed cereal-based foods and baby foods for infants and young children and Commission Directive 2006/141/EC of 22 December 2006<sup>13</sup> on infant formulae and follow-on formulae and amending Directive 1999/21/EC.

(2) Of the substances belonging to the categories appearing in the Annex to the EC Regulation, only those listed in that Annex complying with the relevant specifications as necessary may be added for specific nutritional purposes in the manufacture of foodstuffs for particular nutritional uses referred to in Regulation 3(3).

(3) Without prejudice to Regulation (EC) No. 258/97 of the European Parliament and of the Council of 27 January 1997<sup>14</sup>, other substances not belonging to the categories in the Annex to the EC Regulation may also be added for specific nutritional purposes in the manufacture of foods for particular nutritional uses.

(4) The use of substances added for specific nutritional purposes shall result in the manufacture of safe products that fulfil the particular nutritional requirements of the persons for whom they are intended, as established by generally accepted scientific data.

(5) Purity criteria for substances listed in the Annex to the EC Regulation, and specified by Community legislation for their use in the manufacture of foodstuffs for purposes other than those covered by the EC Regulation, shall apply to those substances when used for purposes covered by this Regulation.

<sup>12</sup>OJ No. L339, 6.12.2006, p. 16

<sup>13</sup>OJ No. L401, 30.12.2006, p. 1

<sup>14</sup>OJ No. L 43, 14.2.1997, p. 1

(6) For those substances listed in the Annex to the EC Regulation, for which purity criteria are not specified by Community legislation, and until the adoption of such specifications, generally acceptable purity criteria recommended by international bodies shall apply.

### **PART 3**

#### **Enforcement**

13. (1) The enforcement of these Regulations, the Directive and the EC Regulation shall be carried out in accordance with the provisions of these Regulations.

(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.

14. (1) An authorised officer may, for the purposes of these Regulations, purchase or take without payment a sample of foodstuffs or a sample of any other relevant substance.

(2) An authorised officer may, for the purpose of taking a sample of foodstuffs or a sample of any other relevant substance, open any receptacle.

(3) Where an authorised officer purchases or takes without payment a sample of foodstuffs or a sample of any other relevant substance, with the intention of having it analysed, he or she shall after purchasing or taking the sample forthwith notify the food business operator, or the person in apparent charge or control of such foodstuffs or of any other relevant substance, of his or her intention of having the sample analysed.

(4) Where an authorised officer purchases or takes without payment, with the intention of having it analysed, a sample of foodstuffs or a sample of any other relevant substance which is suspected by him or her to fail to comply with the provisions of these Regulations, he or she may, by notice in writing to the food business operator, or the person in apparent charge or control of such foodstuffs or other substances, prohibit their 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.

15. (1) Where a sample of foodstuffs or a sample of any other relevant substance, is taken pursuant to these Regulations for the purposes of analysis and where the division of the sample is reasonably practicable, the authorised officer concerned shall 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. The



authorised officer shall, in the presence of the food business operator, or the person in apparent charge or control of such food:

- (a) 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, and
- (d) retain the third part.

(2) Where an authorised officer takes a sample consisting of foodstuffs or a sample of any other relevant substance, 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) 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).

(3) In proceedings for an offence under these Regulations, the result of any test, examination or analysis of, or report on a sample of foodstuffs or a sample of any other relevant substance, taken pursuant to these Regulations, shall not be adduced unless before the proceedings were instituted the sample was divided as specified in paragraphs (1) and (2) of this Regulation. The part, package or container retained by the authorised officer shall be produced at the hearing.

16. (1) The approved examiner or a person under his or her direction shall analyse as soon as possible any sample of foodstuffs or a sample of any other relevant substance submitted to him or her in pursuance of these Regulations and the approved examiner shall certify to the person who submitted the sample to him or her the result of such analysis. The form of certificate set out in Schedule 1 to these Regulations or a certificate in like form shall be used.

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

17. (1) Where a sample of foodstuffs or a sample of any other relevant substance is taken by an authorised officer in pursuance of these Regulations for analysis by an approved examiner, 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 16 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 person in apparent control of such food, with a copy of the report referred to in paragraph (1).

18. (1) An authorised officer may, for the purposes of these Regulations, inspect and take copies, or samples, of labels used on any food or samples of any other relevant substance.

(2) An authorised officer may examine any procedure connected with the manufacture of a food.

19. (1) An authorised officer may, for the purposes of these Regulations, seize, remove or detain any foodstuffs or other products which are suspected by him or her to fail to comply with the provisions of these Regulations.

(2) An authorised officer may, with the consent in writing of the food business operator, or person in apparent charge or control of such foodstuffs or other products, or in accordance with an order of a judge of the District Court under paragraph (4) of this Regulation, destroy or otherwise dispose of same so as to prevent them being used for human consumption.

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

(4) A judge of the District Court, to whom an application is made for an order under paragraph (3), may, if satisfied that such foodstuffs or products fail to comply with these Regulations, order that they 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 them accordingly.

20. In the course of his or her duties, an authorised officer may 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.

21. 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.

22. (1) A person is guilty of an offence if he or she fails to comply with these Regulations.

(2) Paragraph (1) 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.

(3) 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 to an authorised officer which the person knows is false or misleading, or
- (e) gives, in purported compliance with a request under these Regulations, a name, address or corroborative evidence which is false or misleading.

23. 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.

24. (1) A person is guilty of an offence if he or she 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").

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

(3) A person is guilty of an offence if he or she, without lawful authority, has in his or her possession a forged document or an altered document, knowing it to be a forged or altered document as the case may be.

(4) A person is guilty of an offence if he or she with the intent to defraud or deceive:

(a) tampers with any substance or thing with the result that a sample taken pursuant to these Regulations does not correctly represent the substance sampled, or

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

(5) A person is guilty of an offence if he or she falsely represents himself or herself to be an authorised officer.

25. (1) 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.

(2) 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 3 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.

(3) No prosecution on indictment shall be taken on foot of these Regulations in respect of an offence that occurred before the entry into force of these Regulations.

(4) 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.

(5) An order for costs and expenses under paragraph (4) is in addition to, and not instead of, any fine or penalty the court may impose under paragraph (2).

26. 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 4**

### **Revocations**

27. (1) The following are revoked:

- (a) the European Communities (Foodstuffs Intended for Particular Nutritional Uses) Regulations 2006 (S.I. No. 579 of 2006), and
- (b) the European Communities (Foodstuffs Intended for Particular Nutritional Uses) (Amendment) Regulations 2007 (S.I. No. 554 of 2007).

(2) References in any other instrument to the Regulations revoked under paragraph (1) shall be construed as references to these Regulations, as appropriate.

**Schedule 1**

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

**European Union**

**(Foodstuffs Intended for Particular Nutritional Uses) Regulations 2012**

*Certificate of Analysis*

To<sup>(1)</sup> .....

I, the undersigned<sup>(2)</sup> .....

being an Approved Examiner for the purpose of the above Regulations certify that on

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

a sample marked<sup>(3)</sup> .....

Date.....

Number.....

Weight or Measure.....

was submitted to me by you and I certify that the sample was prepared and analysed/examined by me or under my direction<sup>(4)</sup>

and as a result I am of the opinion that<sup>(5)</sup>

Observations:<sup>(6)</sup>

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<sup>(7)</sup> .....

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.) and the weight or measure (this may be left unanswered if the sample cannot be conveniently weighed or measured or if the weight or measurement is not material to the result of analysis).
- (4) 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.
- (5) Here the approved examiner should specify the result of the analysis having regard to the provisions of the relevant legislation.
- (6) 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.
- (7) Insert the name and address of the laboratory carrying out the analysis/examination.



GIVEN under my Official Seal,  
24 May 2012.

JAMES REILLY,  
Minister for Health.

## EXPLANATORY NOTE

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

These Regulations concern foodstuffs intended for particular nutritional uses. They revoke both the European Communities (Foodstuffs Intended for Particular Nutritional Uses) Regulations 2006 (S.I. No. 579 of 2006) and the European Communities (Foodstuffs Intended for Particular Nutritional Uses) (Amendment) Regulations 2007 (S.I. No. 554 of 2007) and bring into effect new Regulations.

These Regulations give effect to Directive 2009/39/EC of 6 May 2009 on foodstuffs intended for particular nutritional uses and to Commission Regulation (EC) No. 953/2009 of 13 October 2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses as amended by Commission Regulation (EU) No. 1161/2011 of 14 November 2011.

These Regulations may be cited as the European Union (Foodstuffs Intended for Particular Nutritional Uses) Regulations 2012.



BAILE ÁTHA CLIATH  
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR  
Le ceannach díreach ón  
OIFIG DHÍOLTA FOILSEACHÁN RIALTAIS,  
TEACH SUN ALLIANCE, SRÁID THEACH LAIGHEAN, BAILE ÁTHA CLIATH 2,  
nó tríd an bpost ó  
FOILSEACHÁIN RIALTAIS, AN RANNÓG POST-TRÁCHTA,  
AONAD 20 PÁIRC MIONDÍOLA COIS LOCHA, CLÁR CHLAINNE MHUIRIS,  
CONTAE MHAIGH EO,  
(Teil: 01 - 6476834 nó 1890 213434; Fax: 094 - 9378964 nó 01 - 6476843)  
nó trí aon díoltóir leabhar.

---

DUBLIN  
PUBLISHED BY THE STATIONERY OFFICE  
To be purchased directly from the  
GOVERNMENT PUBLICATIONS SALE OFFICE  
SUN ALLIANCE HOUSE, MOLESWORTH STREET, DUBLIN 2,  
or by mail order from  
GOVERNMENT PUBLICATIONS, POSTAL TRADE SECTION,  
UNIT 20 LAKESIDE RETAIL PARK, CLAREMORRIS, CO. MAYO,  
(Tel: 01 - 6476834 or 1890 213434; Fax: 094 - 9378964 or 01 - 6476843)  
or through any bookseller.

---

€4.06

