

STATUTORY INSTRUMENTS.

S.I. No. 11 of 2014

EUROPEAN UNION (NUTRITION AND HEALTH CLAIMS MADE ON FOODS) REGULATIONS 2014

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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 Regulation (EC) No. 1924/2006 of the European Parliament and of the Council of 20 December 2006¹ on nutrition and health claims made on foods, as affected by Corrigendum to Regulation (EC) No. 1924/2006 of the European Parliament and of the Council of 20 December 2006^2 and as amended by Regulation (EC) No. 107/2008 of the European Parliament and of the Council of 15 January 2008³, Regulation (EC) No. 109/2008 of the European Parliament and of the Council of 15 January 2008⁴, Commission Regulation (EU) No. 116/2010 of 9 February 2010⁵ and Commission Regulation (EU) No. 1047/2012 of 8 November 2012⁶ and for the purpose of giving effect to Commission Decision 2009/980/EC of 17 December 2009⁷ as amended by Commission Decision 2010/770/EU of 13 December 2010⁸ and for the purpose of giving effect to Commission Regulation (EC) No. 983/2009 of 21 October 2009⁹ as amended by Commission Regulation (EU) No. 376/2010 of 3 May 2010¹⁰, and for the purpose of giving effect to Commission Regulation (EC) No. 1024/2009 of 29 October 200911, Commission Regulation (EU) No. 384/2010 of 5 May 2010¹², Commission Regulation (EU) No. 957/2010 of 22 October 2010¹³, Commission Regulation (EU) No. 440/2011 of 6 May 2011¹⁴, Commission Regulation (EU) No. 665/2011 of 11 July 2011¹⁵, Commission Regulation (EU) No. 1160/2011 of 14 November 2011¹⁶ and Commission Regulation (EU) No. 1048/2012 of 8 November 2012¹⁷ and for the purpose of giving effect to Commission Regulation (EU) No. 432/2012 of 16 May 2012¹⁸ as amended by Commission Regulation (EU) No. 536/2013 of 11 June 2013¹⁹ and Commission Regulation (EU) No. 851/2013 of 3 September 2013²⁰ hereby make the following regulations:

¹OJ No. L. 404, 30.12.2006, p. 9. ²OJ No. L. 12, 18.1.2007, p. 3. ³OJ No. L. 39, 13.2.2008, p. 8. ⁴OJ No. L. 39, 13.2.2008, p. 14. ⁵OJ No. L. 37, 10.2.2010, p. 16. ⁶OJ No. L. 310, 9.11.2012, p. 36. ⁷OJ No. L. 336, 18.12.2009, p. 55. ⁸OJ No. L. 328, 14.12.2010, p. 18. ⁹OJ No. L. 277, 22.10.2009, p. 3. ¹⁰OJ No. L. 111, 4.5.2010, p. 3. ¹¹OJ No. L. 283, 30.10.2009, p. 22. ¹²OJ No. L. 113, 6.5.2010, p. 6. ¹³OJ No. L. 279, 23.10.2010, p. 13. ¹⁴OJ No. L. 119, 7.5.2011, p. 4. ¹⁵OJ No. L. 182, 12.7.2011, p. 5. ¹⁶OJ No. L. 296, 15.11.2011, p. 26. ¹⁷OJ No. L. 310, 9.11.2012, p. 38. ¹⁸OJ No. L. 136, 25.5.2012, p. 1. ¹⁹OJ No. L. 160, 12.6.2013, p. 4. ²⁰OJ No. L. 235, 4.9.2013, p. 3.

> Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 24th January, 2014.

PART I

PRELIMINARY

1. These Regulations may be cited as the European Union (Nutrition and Health Claims made on Foods) Regulations 2014.

2. (1) In these Regulations—

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

"Annex" means the Annex to Regulation (EC) No. 1924/2006 of the European Parliament and of the Council of 20 December 2006¹, as affected by Corrigendum to Regulation (EC) No. 1924/2006 of the European Parliament and of the Council of 20 December 2006² and as amended by Commission Regulation (EU) No. 116/2010 of 9 February 2010⁵ and Commission Regulation (EU) No. 1047/2012 of 8 November 2012⁶;

"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,
- (d) a person, or member of a class of persons, designated by the Minister pursuant to Regulation 29(b);

"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;

"claim" means any message or representation, which is not mandatory under European Union or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics;

"EC Regulation 1924/2006" means Regulation (EC) No. 1924/2006 of the European Parliament and of the Council of 20 December 2006¹ as affected by Corrigendum to Regulation (EC) No. 1924/2006 of the European Parliament and of the Council of 20 December 2006² and as amended by Regulation (EC) No. 107/2008 of the European Parliament and of the Council of 15 January 2008³, Regulation (EC) No. 109/2008 of the European Parliament and of the Council of 15 January 2008⁴, Commission Regulation (EU) No. 116/2010 of 9 February 2010⁵ and Commission Regulation (EU) No. 1047/2012 of 8 November 2012⁶;

"General Food Law Regulation" means Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002²¹;

"health claim" means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health;

"list of permitted claims which may be made on foods, as provided for in Article 13(3) of EC Regulation 1924/2006" means the list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health, which may be made on foods listed in the Annex to Commission Decision 2009/980/EC of 17 December 2009⁷ as amended by Commission Decision 2010/770/EU of 13 December 2010⁸ and the Annex to Commission Regulation (EU) No. 432/2012 of 16 May 2012¹⁸ as amended by Commission Regulation (EU) No. 536/2013 of 11 June 2013¹⁹ and Commission Regulation (EU) No. 851/2013 of 3 September 2013²⁰;

"list of permitted claims which may be made on foods, as provided for in Article 14(1) of EC Regulation 1924/2006" means the list of permitted reduction of disease risk claims and claims referring to children's development and health listed in Annex I to Commission Regulation (EC) No. 983/2009 of 21 October 2009⁹ as amended by Commission Regulation (EU) No. 376/2010 of 3 May 2010¹⁰, and Annex I to Commission Regulation (EC) No. 1024/2009 of 29 October 2009¹¹, Commission Regulation (EU) No. 384/2010 of 5 May 2010¹², Commission Regulation (EU) No. 957/2010 of 22 October 2010¹³, Commission Regulation (EU) No. 665/2011 of 11 July 2011¹⁵, Commission Regulation (EU) No. 1160/2011 of 14 November 2011¹⁶ and the Annex to Commission Regulation (EU) No. 1048/2012 of 8 November 2012¹⁷;

"Minister" means the Minister for Health;

"nutrient" means protein, carbohydrate, fat, fibre, sodium, vitamins and minerals listed in the Annex to Council Directive 90/496/EEC of 24 September 1990²², and substances which belong to or are components of one of those categories;

"nutrition claim" means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to:

- (a) the energy (calorific value) it—
 - (i) provides;
 - (ii) provides at a reduced or increased rate; or
 - (iii) does not provide; or
- (b) the nutrients or other substances it—

²¹OJ No. L. 31, 1.2.2002, p. 1.

²²OJ No. L. 276, 6.10.1990, p. 40.

- (i) contains;
- (ii) contains in reduced or increased proportions; or
- (iii) does not contain;

"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 2004²³, as affected by the Corrigendum to Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 28 May 2004²⁴, as amended by Council Regulation (EC) No. 301/2008 of 17 March 2008²⁵, Commission Regulation (EC) No. 1029/2008 of 20 October 2008²⁶, Regulation (EC) No. 596/2009 of the European Parliament and of the Council of 18 June 2009²⁷ and Commission Regulation (EU) No. 208/2011 of 2 March 2011²⁸;

"official laboratory" means-

- (a) Public Analyst's Laboratory, Cork,
- (b) Public Analyst's Laboratory, Dublin,
- (c) Public Analyst's Laboratory, Galway,
- (d) a laboratory designated by the Minister pursuant to Regulation 29(a);

"other substance" means a substance other than a nutrient that has a nutritional or physiological effect;

"relevant thing" means-

- (a) labels and packaging used on food,
- (b) materials used in the advertising or presentation of food, or
- (c) materials supporting health or nutritional claims;

"reduction of disease risk claim" means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease;

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

²³OJ No. L. 165, 30.4.2004, p. 1.
²⁴OJ No. L. 191, 28.5.2004, p. 1.
²⁵OJ No. L. 97, 9.4.2008, p. 85.
²⁶OJ No. L. 278, 21.10.2008, p. 6.
²⁷OJ No. L. 188, 18.7.2009, p. 14.
²⁸OJ No. L. 58, 3.3.2011, p. 29.

(2) A word or expression which is used in these Regulations and which is also used in EC Regulation 1924/2006 or in the General Food Law Regulation has, unless the context otherwise requires, the same meaning in these Regulations as it has in EC Regulation 1924/2006 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 the Schedule to these Regulations, unless it is indicated that reference to some other Regulations is intended.

PART 2

GENERAL PROVISIONS

3. (1) The requirements of these Regulations shall apply to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer.

(2) The requirements shall also apply to foods intended for supply to restaurants, hospitals, schools, canteens and similar mass caterers.

4. (1) The national competent authority for the purposes of EC Regulation 1924/2006 and for the purposes of these Regulations shall be the Authority.

(2) The functions of the State referred to in Article 24 of EC Regulation 1924/2006 shall be performed by the Authority in accordance with Regulation 20 of these Regulations.

- 5. A food business operator is guilty of an offence if-
 - (*a*) the labels used on food, the packaging of a food, or the advertising or presentation of food that he or she places on the market fails to comply with these Regulations and EC Regulation 1924/2006, or
 - (b) he or she fails to comply with the general principles for all claims in accordance with Article 3 of EC Regulation 1924/2006.

6. A food business operator is guilty of an offence if he or she fails to ensure that beverages containing more than 1.2% by volume of alcohol—

(a) do not carry health claims, and

(b) do not carry nutrition claims other than those referring to low alcohol levels, or the reduction of the alcohol content, or the reduction of the energy content,

in accordance with Article 4 of EC Regulation 1924/2006.

7. A food business operator is guilty of an offence if, in using a health or nutrition claim, he or she fails to—

- (a) fulfil the conditions set out in Article 5(1) of EC Regulation 1924/2006,
- (b) ensure that nutrition and health claims are only permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim, or
- (c) ensure that nutrition and health claims only refer to the food ready for consumption in accordance with the manufacturer's instructions,

in accordance with Article 5 of EC Regulation 1924/2006.

8. (1) A food business operator is guilty of an offence if, in making a health or nutrition claim, he or she fails to—

- (*a*) ensure that the nutrition and health claims are based on and substantiated by generally accepted scientific evidence, or
- (b) justify the use of a nutrition or health claim,

in accordance with Article 6(1) and 6(2) of EC Regulation 1924/2006.

(2) A food business operator or person placing food on the market is guilty of an offence if he or she fails to produce, when requested by the Authority or the official agency, all relevant elements and data establishing compliance with EC Regulation 1924/2006 in accordance with Article 6(3) of that Regulation.

9. (1) Subject to paragraph (2), a food business operator is guilty of an offence if he or she fails to provide nutrition information in accordance with Article 7 of EC Regulation 1924/2006.

(2) Paragraph (1) shall not apply in the case of non-prepackaged foodstuffs (including fresh products such as fruit, vegetables or bread) put up for sale to the final consumer or to mass caterers and foodstuffs packed at the point of sale at the request of the purchaser or pre-packaged with a view to immediate sale.

10. (1) Subject to paragraph (2), a food business operator is guilty of an offence if he or she fails to ensure that a nutrition claim is only used by him or her when it is listed in the Annex and conforms with the conditions set out in EC Regulation 1924/2006.

(2) Provided any additional nutritional claim complies with EC Regulation 1924/2006, paragraph (1) shall not apply in the case of products making nutrition claims laid down in the Annex to Commission Regulation (EU) No. 1047/2012

of 8 November 2012⁶ and such products which are placed on the market prior to 1 June 2014 may continue to be marketed until the stocks are exhausted.

11. A food business operator is guilty of an offence if he or she fails to ensure that a comparative nutrition claim made by him or her satisfies the relevant requirements of Article 9 of EC Regulation 1924/2006.

12. (1) Subject to paragraph (2), a trade mark, brand name or fancy name appearing in the labelling, presentation or advertising of a food which may be construed as a nutrition or health claim may be used without undergoing the authorisation procedures provided for in EC Regulation 1924/2006, provided that it is accompanied by a related nutrition or health claim in that labelling, presentation or advertising which complies with the provisions of these Regulations and EC Regulation 1924/2006.

(2) Paragraph (1) shall not apply in the case of products bearing trademarks or brand names existing before 1 January 2005 which do not comply with these Regulations and EC Regulation 1924/2006 and may continue to be marketed until 19 January 2022 after which time the provisions of these Regulations and EC Regulation 1924/2006 shall apply.

(3) A food business operator is guilty of an offence if he or she continues to market a product bearing a trademark or brand name after 19 January 2022 that does not comply with these Regulations and EC Regulation 1924/2006.

(4) Any manufacturer or person who places products bearing a new trademark or brand name which may be construed as a nutrition or health claim on the market after 1 January 2005 that does not comply with these Regulations and EC Regulation 1924/2006 is guilty of an offence.

13. (1) Subject to paragraph (2), a food business operator is guilty of an offence if, in using a health claim, he or she fails to provide in the labelling, or if no such labelling exists, in the presentation and advertising, all of the following information:

- (*a*) a statement indicating the importance of a varied and balanced diet and a healthy lifestyle;
- (b) the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect;
- (c) where appropriate, a statement addressed to persons who should avoid using the food;
- (*d*) an appropriate warning for products that are likely to present a health risk if consumed to excess,

in accordance with Article 10(2) of EC Regulation 1924/2006.

(2) Paragraph (1)(a) and (1)(b) shall not apply in the case of non-prepackaged foodstuffs (including fresh products such as fruit, vegetables or bread) put up

for sale to the final consumer or to mass caterers and foodstuffs packed at the point of sale at the request of the purchaser or prepackaged with a view to immediate sale.

14. A food business operator is guilty of an offence if he or she makes reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being unless it is accompanied by a specific health claim included in the list of permitted claims which may be made on foods, as provided for in Article 13(3) of EC Regulation 1924/2006 or the list of permitted claims which may be made on foods, as provided for in Article 14(1) of EC Regulation 1924/2006 in accordance with Article 10(3) of EC Regulation 1924/2006.

15. (1) A food business operator is guilty of an offence in using a health claim that—

- (a) suggests that health could be affected by not consuming the food,
- (b) makes reference to the rate or amount of weight loss, or
- (c) makes reference to recommendations of individual doctors or health professionals and associations,

in accordance with Article 12 of EC Regulation 1924/2006.

(2) A food business operator is guilty of an offence if he or she makes reference to recommendations of national associations of medical, nutrition or dietetic professionals and health-related charities, unless it is accompanied by a specific health claim included in the list of permitted claims which may be made on foods, as provided for in Article 13(3) of EC Regulation 1924/2006 or the list of permitted claims which may be made on foods, as provided for in Article 14(1) of EC Regulation 1924/2006 and complies with these Regulations and EC Regulation 1924/2006.

16. (1) Subject to paragraph (2), a food business operator is guilty of an offence, in using a health claim other than those referring to the reduction of disease risk and to children's development and health, where he or she fails to ensure that the claim is—

- (a) authorised in accordance with EC Regulation 1924/2006,
- (b) in compliance with the necessary conditions of use of the permitted claim, and
- (c) included in the list of permitted claims which may be made on foods, as provided for in Article 13(3) of EC Regulation 1924/2006.

(2) Paragraph (1) shall not apply in the case of health claims describing or referring to the role of a nutrient or other substance in growth, development and the functions of the body whose evaluation by the European Food Safety

Authority or whose consideration by the Commission has not yet been completed and such claims may continue to be made provided that they comply with these Regulations and EC Regulation 1924/2006.

17. A food business operator is guilty of an offence, in using a health claim relating to reduction of disease risk claims and claims referring to children's development and health, where he or she fails to ensure that the claim is—

- (a) authorised in accordance with EC Regulation 1924/2006,
- (b) in compliance with the necessary conditions of use of the permitted claim, and
- (c) included in the list of permitted claims which may be made on foods, as provided for in Article 14(1) of EC Regulation 1924/2006.

18. A food business operator is guilty of an offence if in using a reduction of disease risk claim he or she fails to ensure that the labelling or, if no such labelling exists, the presentation or advertising shall also bear a statement indicating that the disease to which the claim is referring has multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect in accordance with Article 14(2) of EC Regulation 1924/2006.

- 19. (1) A person who-
 - (a) has issued or displayed or caused to be issued or displayed, or
 - (b) proposes to issue or display or causes to be issued or displayed,

any commercial communication which fails to comply with these Regulations and EC Regulation 1924/2006 shall, if so requested, notified or directed by the Authority, ensure that the commercial communication or proposed commercial communication is withdrawn and he or she shall in the case of a commercial communication which has been issued or displayed, if further directed by the Authority, publish a corrective statement in a form and by a means acceptable to the Authority.

(2) Any direction given under paragraph (1) shall state in detail the reasons on which it is based.

20. (1) Where the Authority considers that serious grounds exist that a claim does not comply with EC Regulation 1924/2006 or that the scientific substantiation required by Article 6 of EC Regulation 1924/2006 is insufficient, the Authority may direct a user of a claim to temporarily suspend the use of that claim.

(2) Any direction given under paragraph (1) shall state in detail the reasons on which it is based.

PART 3

ENFORCEMENT

21. (1) The enforcement of these Regulations and of EC Regulation 1924/2006, 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.

22. (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 or relevant thing, open any receptacle.

(3) Where an authorised officer purchases or takes without payment a sample of food or relevant thing 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 the food or relevant thing 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 food or relevant thing which is suspected by him or her of failing 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 food or relevant thing, 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.

23. (1) Where a sample of food or relevant thing is taken pursuant to these Regulations, for the purposes of official 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 or relevant thing:

(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 food or relevant thing 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 food or relevant thing taken pursuant to these Regulations shall not be adduced unless before the proceedings were instituted the sample was divided as specified in paragraphs (1) or (2) of this Regulation. The part, package or container retained by the authorised officer shall be produced at the hearing.

24. (1) The approved examiner or a person under his or her direction shall analyse as soon as possible any sample of food or relevant thing 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 the Schedule 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 proved.

25. (1) Where a sample of food or relevant thing 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 24(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 person in apparent control of such food or relevant thing, with a copy of the report referred to in paragraph (1).

26. (1) An authorised officer may, for the purposes of these Regulations, inspect and take copies, or samples of a relevant thing.

(2) An authorised officer may request a food business operator or person placing food on the market to produce the information referred to in Article 6 of EC Regulation 1924/2006 and he or she may inspect, and take copies of, any such information.

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

27. (1) An authorised officer may, for the purposes of these Regulations, seize, remove or detain food or relevant thing 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 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) of this Regulation, destroy or otherwise dispose of same 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) of this Regulation, destroy or otherwise dispose of same so as to prevent a risk to human health.

(4) An authorised officer who has seized, removed or detained food or 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 products 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 such food or relevant thing fails 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 the food or relevant thing accordingly.

28. 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.

29. 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.

30. (1) Subject to paragraph (2), 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 or provides information 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, an address or corroborative evidence which is false or misleading.

31. 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.

32. (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.

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

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

33. (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 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.

(3) 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.

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

34. 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.

Schedule

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

European Union (Nutrition and Health Claims made on Foods) Regulations 2014.

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

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

and as a result I am of the opinion that⁽⁵⁾

Observations:(6)

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⁽⁷⁾

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) 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, 21 January 2014.

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 give effect to Regulation (EC) No. 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, as affected by Corrigendum to Regulation (EC) No. 1924/2006 and as amended.

These Regulations also give effect to Commission Regulation (EU) No. 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health as amended by Commission Regulation (EU) No. 536/2013 of 11 June 2013 and Commission Regulation (EU) No. 851/2013 of 3 September 2013 and effect to Commission Decision 2009/980/EC of 17 December 2009 as amended by Commission Decision 2010/770/EU of 13 December 2010.

These Regulations also give effect to the following Regulations on the authorisation of certain health claims made on foods and referring to the reduction of disease risk and to children's development and health: Commission Regulation (EC) No. 983/2009 of 21 October 2009 (as amended by Commission Regulation (EU) No. 376/2010 of 3 May 2010), Commission Regulation (EC) No. 1024/2009 of 29 October 2009, Commission Regulation (EU) No. 384/2010 of 5 May 2010, Commission Regulation (EU) No. 957/2010 of 22 October 2010, Commission Regulation (EU) No. 440/2011 of 6 May 2011, Commission Regulation (EU) No. 665/2011 of 11 July 2011, Commission Regulation (EU) No. 1160/2011 of 14 November 2011 and Commission Regulation (EU) No. 1048/2012 of 8 November 2012.

These Regulations may be cited as the European Union (Nutrition and Health Claims made on Foods) Regulations 2014 and they come into effect on the date they were signed.

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