

Statutory Instrument

S.I. No. 65 of 2005

EUROPEAN COMMUNITIES (NUTRITION LABELLING FOR FOODSTUFFS) REGULATIONS 2005

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Prn. A5/0162

Price: €3.05

S.I. No. 65 of 2005

European Communities (Nutrition Labelling for Foodstuffs) Regulations 2005

I, Mary Harney, Minister for Health and Children, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving further effect to Council Directive 90/496/EEC¹ of 24 September 1990 on nutrition labelling for foodstuffs and for the purpose of giving effect to Commission Directive 2003/120/EC² of 5 December 2003 amending Directive 90/496/EEC¹, hereby make the following regulations:

PART 1

Preliminary

1. These Regulations may be cited as the European Communities (Nutrition Labelling for Foodstuffs) Regulations 2005.

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 Public Analyst located at a Public Analyst's Laboratory,
- (b) a Deputy Public Analyst located at a Public Analyst's Laboratory,
- (c) an Executive Analytical Chemist located at a Public Analyst's Laboratory;

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

¹ OJ L 276, 6.10.1990, p. 40.

² OJ L 333, 20.12.2003, p. 51.

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

"average value" means the value which best represents the amount of the nutrient which a given food contains, and reflects allowances for seasonal variability, patterns of consumption and other factors which may cause the actual value to vary;

"carbohydrate" means any carbohydrate which is metabolised in man, and includes polyols;

"Directive" means Council Directive 90/496/EEC¹ of 24 September 1990 on nutrition labelling for foodstuffs, as amended by Commission Directive 2003/120/EC² of 5 December 2003;

"export" means exportation to a third country;

"fat" means total lipids, and includes phospholipids;

"fibre" means the material to be defined in accordance with the procedure laid down in Article 10 of the Directive and measured by the method of analysis to be determined in accordance with that procedure;

"food" or "foodstuff" means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be, ingested by humans;

"food" includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC³ and without prejudice to the requirements of Directives 80/778/EEC⁴ and 98/83/EC³;

"food" shall not include –

- (a) feed,
- (b) live animals unless they are prepared for placing on the market for human consumption,
- (c) plants prior to harvesting,
- (d) medicinal products within the meaning of Council Directives 65/65/EEC⁵ and 92/73/EEC⁶,

³OJ L 330, 5.12.1998, p. 32.

⁴OJ L 229, 30.8.1980, p. 11.

⁵OJ 22, 9.2.1965, p. 369.

⁶OJ L 297, 13.10.1992, p. 8.

- (e) cosmetics within the meaning of Council Directive 76/768/EEC⁷,
- (f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC⁸,
- (g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971, or
- (h) residues and contaminants;

"import" means importation from a country other than a Member State, except in the context of paragraphs (6) and (7) of Regulation 3, where "import" means importation from a Member State into a third country;

"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;

"Member State" means a Member State of the European Community and shall be construed as including reference to those States that are Contracting Parties to the EEA Agreement;

"mono-unsaturates" means fatty acids with one *cis* double bond;

"nutrition claim" means any representation and any advertising message which states, suggests or implies that a foodstuff has particular nutrition properties due to the energy (calorific value) it –

- (a) provides,
- (b) provides at a reduced or increased rate,
- (c) does not provide, or

due to the nutrients it

- (a) contains,
- (b) contains in reduced or increased proportions, or
- (c) does not contain,

⁷OJ L 262, 27.9.1976, p. 169.

⁸OJ L 359, 8.12.1989, p. 1.

or a claim to any combination of the above; however, a reference to qualities or quantities of a nutrient does not constitute a nutrition claim in so far as it is required by legislation;

“nutrition labelling” means any information appearing on labelling and relating to —

- (a) energy value, or
- (b) the following nutrients:
 - (i) protein,
 - (ii) carbohydrate,
 - (iii) fat,
 - (iv) fibre,
 - (v) sodium, and
 - (vi) vitamins and minerals listed in Schedule 1, and present in significant amounts as defined in Schedule 1;

“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 laboratory" in these Regulations means —

- (a) the Public Analyst’s Laboratory, Cork,
- (b) the Public Analyst’s Laboratory, Dublin,
- (c) the Public Analyst’s Laboratory, Galway;

"place on the market" means —

- (a) import,
- (b) sell,
- (c) offer or expose for sale,
- (d) invite the making by a person of an offer to purchase,
- (e) distribute free of charge, or
- (f) supply for any of those purposes (whether or not for profit)

and cognate words shall be construed accordingly;

“polyunsaturates” means fatty acids with *cis*, *cis*-methylene interrupted double bonds;

“protein” means the protein content calculated by multiplying the total Kjeldahl nitrogen by 6.25;

“saturates” means fatty acids without double bonds;

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

“sugars” means all monosaccharides and disaccharides present in food, but excludes polyols;

“third country” means a country which is not a Member State.

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

PART 2

General Provisions

3. (1) Subject to paragraph (2), these Regulations shall apply to the nutrition labelling of foodstuffs to be delivered as such to the ultimate consumer and to foodstuffs intended for supply to restaurants, hospitals, canteens and other similar mass caterers (hereinafter referred to as "mass caterers"), and such foodstuffs shall not be placed on the market unless these Regulations are complied with, and any information required by these Regulations is set out accurately.
- (2) These Regulations shall not apply to –
 - (a) natural mineral waters or other waters intended for human consumption,
 - (b) diet integrators, or
 - (c) food supplements.
- (3) Subject to paragraph (4), nutrition labelling shall be optional.
- (4) Where a nutrition claim appears on labelling, in presentation or in advertising, with the exclusion of generic advertising, nutrition labelling shall be compulsory, and shall be carried out in accordance with these Regulations.
- (5) These Regulations shall apply without prejudice to the labelling provisions of Council Directive 89/398/EEC⁹ of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses, as amended, and without prejudice to the labelling provisions set down in specific Directives as referred to in Article 4 of Directive 89/398/EEC⁹, as amended.
- (6) Subject to paragraphs (7) and (8), these Regulations shall also apply in respect of foodstuffs intended for export, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country.
- (7) Notwithstanding paragraph (6), foodstuffs which are not in compliance with these Regulations may nonetheless be exported, provided that –
 - (a) the competent authorities of the importing country have expressly agreed to such importation, after having been fully informed of the

⁹ OJ L 186, 30.6.1989, p. 27.

reasons for which and the circumstances in which the foodstuffs concerned could not be placed on the market in the Community, and

(b) the foodstuffs in question are not injurious to health.

(8) Notwithstanding paragraph (6), where the provisions of a bilateral agreement concluded between the Community or the State and a third country are applicable, foodstuffs exported from the State to that third country shall comply with the said provisions.

4. The only nutrition claims permitted shall be those relating to-

(1) energy,

(2) the following nutrients: protein, carbohydrate, fat, fibre, sodium, and vitamins and minerals listed in Schedule 1 and present in significant amounts as defined in Schedule 1, and

(3) substances which belong to or which are components of a category of those nutrients.

5. (1) Where nutrition labelling is provided, the information to be given shall consist of the matters specified in either "Group 1" or "Group 2" in the following order -

Group 1

(a) energy value;

(b) the amounts of protein, carbohydrate and fat.

Group 2

(a) energy value;

(b) the amounts of protein, carbohydrate, sugars, fat, saturates, fibre and sodium.

(2) Where a nutrition claim is made for sugars, saturates, fibre or sodium, the information to be given shall consist of Group 2.

(3) Nutrition labelling may also include the amounts of one or more of the following:

— starch,

— polyols,

— mono-unsaturates,

— polyunsaturates,

— cholesterol,

— any of the minerals or vitamins listed in Schedule 1 and present in significant amounts as defined in Schedule 1.

- (4) The declaration of substances which belong to or are components of one of the categories of nutrients referred to in paragraph (1) and paragraph (3) shall be compulsory where a nutrition claim is made.

In addition, where the amount of polyunsaturates or mono-unsaturates or the cholesterol rate (or any combination of these) is given, the amount of saturates shall also be given, the declaration of the latter not constituting in this case a nutrition claim within the meaning of paragraph (2).

6. The energy value to be declared shall be calculated using the following conversion factors:

— carbohydrate (except polyols)	4 kcal/g — 17 kJ/g
— polyols	2.4 kcal/g — 10 kJ/g
— protein	4 kcal/g — 17 kJ/g
— fat	9 kcal/g — 37 kJ/g
— alcohol (ethanol)	7 kcal/g — 29 kJ/g
— organic acid	3 kcal/g — 13 kJ/g
— salatrims	6 kcal/g — 25 kJ/g.

7. (1) The declaration of the energy value and of the proportion of nutrients or their components shall be numerical. The units to be used are the following:

— energy:	kJ and kcal
— protein:	grams (g)
— carbohydrate:	grams (g)
— fat:	grams (g)
— fibre:	grams (g)
— sodium:	grams (g)
— cholesterol:	milligrams (mg)
— vitamins and minerals:	the units specified in Schedule 1.

- (2) Information shall be expressed per 100g or per 100ml. In addition, this information may be given per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated.

- (3) The amounts mentioned shall be those of the food as placed on the market. Where appropriate, this information may relate to the foodstuff after preparation, provided that sufficiently detailed preparation instructions are given and the information relates to the food as prepared for consumption.
- (4) (a) Information on vitamins and minerals must also be expressed as a percentage of the recommended daily allowance (RDA) given in Schedule 1 for the amounts as specified in paragraph (2).
- (b) The percentage of the recommended daily allowance (RDA) for vitamins and minerals may also be given in graphical form.
- (5) Where sugars or polyols or starch (or any combination of these) are declared, this declaration shall immediately follow the declaration of the carbohydrate content in the following manner -

— carbohydrate	g
of which:	
— sugars	g
— polyols	g
— starch	g

- (6) Where the amount or type of fatty acid or the cholesterol rate (or any combination of these) is declared, this declaration shall immediately follow the declaration of total fats in the following manner -

— fat	g
of which:	
— saturates	g
— mono-unsaturates	g
— polyunsaturates	g
— cholesterol	mg

- (7) The declared values shall, according to the individual case, be average values based on –
- (a) the manufacturer's analysis of the food,
- (b) a calculation from the known or actual average values of the ingredients used, and
- (c) a calculation from generally established and accepted data.

8.
 - (1) The information covered by these Regulations must be presented together in one place in tabular form, with the numbers aligned if space permits. Where space does not permit, the information shall be presented in linear form. It shall be printed in legible and indelible characters in a conspicuous place.
 - (2) A person placing foodstuffs on the market shall ensure that the information covered by these Regulations appears in a language easily understood by purchasers, unless other measures have been taken to ensure that the purchaser is informed. This provision shall not prevent such information from being indicated in more than one language.
9. Non-prepackaged foodstuffs put up for sale to the ultimate 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, shall as far as practicable comply with the provisions of Regulation 5.

PART 3

Enforcement

10. Control of the foodstuffs affected by these Regulations and the enforcement of these Regulations shall be carried out in accordance with the provisions of these Regulations.
11. These Regulations shall be deemed to be food legislation for the purposes of the Act of 1998.
12. These Regulations shall be enforced by the Authority or by an official agency pursuant to a service contract with the Authority and, without prejudice to Regulation 10, the enforcement provisions contained in the Act of 1998 shall apply for the purposes of ensuring compliance with these Regulations.
13.
 - (1) An authorised officer may, for the purposes of these Regulations, purchase or take without payment a sample of foodstuffs.
 - (2) An authorised officer may, for the purpose of taking a sample of foodstuffs, open any receptacle.
 - (3) Where an authorised officer purchases or takes without payment, with the intention of having it analysed, a sample of foodstuffs which are 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 seller, owner or person in apparent charge or control of such foodstuffs, prohibit the removal of the foodstuffs 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 days from the date of the detention of the sample.
 - (4) Where an authorised officer purchases or takes without payment a sample of foodstuffs with the intention of having it analysed, he or she shall after purchasing or taking the sample forthwith notify the seller, owner or person in apparent charge or control of the foodstuffs of his or her intention of having the sample analysed.
14.
 - (1) Where a sample of foodstuffs is taken pursuant to these Regulations for the purpose of analysis, and where the division of the sample is reasonably practicable, the authorised officer concerned may divide the sample into not more than three approximately equal parts 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 mark, seal and fasten each part in such a manner as its nature will permit, forward one part to the approved examiner in an official laboratory for analysis, give or send one part to the seller, owner or person in apparent charge or control of the foodstuffs and retain the third part.

(2) Where an authorised officer takes a sample consisting of foodstuffs 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) of this Regulation 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) of this Regulation.

(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 taken for the purpose of analysis 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.

15. (1) The approved examiner or a person under his or her direction shall analyse as soon as possible any sample of foodstuffs 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 2 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 *prima facie* evidence of the matters contained therein until the contrary is proved.

16. Where a sample of foodstuffs is taken by an authorised officer in pursuance of these Regulations for analysis by an approved examiner, and where the seller, owner or person in apparent charge or control of the foodstuffs requests in writing the results of such analysis the request shall be made to –

(1) the Authority, where the officer was appointed by the Authority, or

(2) the official agency, where the officer was appointed by an official agency

and the Authority, or the official agency (as the case may be) shall comply with such request.

17. An authorised officer may, for the purposes of these Regulations, inspect and take copies, or samples, of –

(1) labels used on foodstuffs, or

- (2) any other materials used in the advertising or presentation of foodstuffs.
18. (1) An authorised officer may, for the purposes of these Regulations, seize, remove, detain or direct the withdrawal from the market of any foodstuffs 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 owner or person in apparent charge or control of such foodstuffs 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 as to prevent them being used for human consumption.
- (3) An authorised officer who has seized, removed, detained or directed the withdrawal from the market of, foodstuffs in pursuance of the provisions of this Regulation may, on giving notice in writing to the owner or person in apparent charge or control of such foodstuffs of his or her intention to do so, apply to a judge of the District Court for an order directing that such foodstuffs 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 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.
19. (1) A person who fails to comply with these Regulations shall be guilty of an offence.
- (2) Paragraph (1) shall not apply to an authorised officer acting in the course of his or her duties pursuant to these Regulations.
20. Where an offence under these Regulations is committed by a body corporate or by a person acting on behalf of a body corporate and is proved to have been so committed with the consent, connivance or approval of, or to be attributed to any neglect or default on the part of, any director, manager, secretary or any other officer of such body, or a person who was purporting to act in any such capacity, such person shall also be guilty of an offence and shall be liable to be proceeded against and punished as if he or she were guilty of the first-mentioned offence.
21. (1) Any 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 in this Regulation referred to as "a forged document"), is guilty of an offence.
- (2) Any person who alters with intent to defraud or deceive, or who 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 in this Regulation referred to as "an altered document"), is guilty of an offence.

- (3) Any person who, without lawful authority, has in his or her possession a forged document or an altered document is guilty of an offence.
 - (4) Any person who, with intent to defraud or deceive –
 - (a) tampers with any thing so as to procure that any sample taken pursuant to these Regulations does not correctly represent the substance sampled, or
 - (b) tampers or interferes with any sample taken under these Regulationsis guilty of an offence.
22. (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 of these Regulations.
- (2) A person who is guilty of an offence under these Regulations shall be liable on summary conviction to a fine not exceeding €3,000 or at the discretion of the Court to imprisonment for a term not exceeding 12 months or both.
23. An offence under these Regulations may be prosecuted by –
- (1) the Authority, or
 - (2) an official agency.

PART 4

Revocation

24. (1) The Health (Nutrition Labelling for Foodstuffs) Regulations 1993 (S.I. No. 388 of 1993) are revoked.
- (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

Vitamins and minerals which may be declared and their recommended daily allowances (RDAs).

Vitamin A	µg	800
Vitamin B ₆	mg	2
Vitamin B ₁₂	µg	1
Vitamin C	mg	60
Vitamin D	µg	5
Vitamin E	mg	10
Pantothenic acid	mg	6
Calcium	mg	800
Biotin	mg	0.15
Thiamin	mg	1.4
Phosphorus	mg	800
Riboflavin	mg	1.6
Iron	mg	14
Niacin	mg	18
Magnesium	mg	300
Zinc	mg	15
Folacin	µg	200
Iodine	µg	150

As a rule, 15% of the recommended allowance specified in this Schedule supplied by 100g or 100ml or per package (if the package contains only a single portion) should be taken into consideration in deciding what constitutes a significant amount.

Schedule 2

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

European Communities (Nutrition Labelling for Foodstuffs) Regulations 2005

Certificate of Analysis

To ⁽¹⁾

I, the undersigned ⁽²⁾

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

theday 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

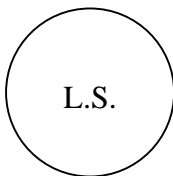
Official Stamp

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 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,

This 11 day of February 2005.



Mary Harney
Minister for Health and Children

Explanatory Note

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

These Regulations concern nutrition labelling of foodstuffs for the ultimate consumer and for mass caterers. They revoke the Health (Nutrition Labelling for Foodstuffs) Regulations 1993 (S.I. No. 388 of 1993).

These Regulations give further effect to Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs [previously transposed by the Health (Nutrition Labelling for Foodstuffs) Regulations 1993 (S.I. No. 388 of 1993)]. They also give effect to Commission Directive 2003/120/EC of 5 December 2003 amending Directive 90/496/EEC by the addition of an energy value conversion factor for salatrims.

These Regulations may be cited as the European Communities (Nutrition Labelling for Foodstuffs) Regulations 2005.