



STATUTORY INSTRUMENTS.

S.I. No. 489 of 2014

HEALTH (PROVISION OF FOOD ALLERGEN INFORMATION TO
CONSUMERS IN RESPECT OF NON-PREPACKED FOOD)
REGULATIONS 2014

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I, LEO VARADKAR, Minister for Health, in exercise of the powers conferred on me by section 54 (inserted by section 25 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006)) of the Health Act 1947 (No. 28 of 1947) (as adapted by the Enterprise, Trade and Innovation (Alteration of Name of Department and Title of Minister) Order 2011 (S.I. No. 245 of 2011) and Agriculture, Fisheries and Food (Alteration of Name of Department and Title of Minister) Order 2011 (S.I. No. 455 of 2011)), after consultation with the Minister for Jobs, Enterprise and Innovation and the Minister for Agriculture, Food and the Marine, hereby make the following regulations:

Part 1

PRELIMINARY

Citation and commencement

1. (1) These Regulations may be cited as the Health (Provision of Food Allergen Information to Consumers in respect of Non-Prepacked Food) Regulations 2014.

(2) These Regulations come into operation on 13 December 2014.

Interpretation

2. In these Regulations—

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

“allergen” means any ingredient or processing aid listed in Annex II of Regulation (EU) No. 1169/2011 of the European Parliament and Council of 25 October 2011¹, as amended by Commission Delegated Regulation (EU) No. 78/2014 of 22 November 2013², or derived from a substance or product listed in the said Annex, causing allergies or intolerances, used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form;

“approved examiner” means—

(a) a Deputy Public Analyst located at a Public Analyst’s Laboratory,

¹OJ No. L 304, 22.11.2011, p. 18.

²OJ No. L 27, 30.01.2014, p. 7.

*Notice of the making of this Statutory Instrument was published in
“Iris Oifigiúil” of 31st October, 2014.*

- (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 16;

“authorised officer” means an 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;

“Board” means the Board of the Authority;

“final consumer” means the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity;

“food business operator” means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control;

“mass caterer” means any establishment (including a vehicle or a fixed or mobile stall), such as restaurants, canteens, schools, hospitals and catering enterprises in which, in the course of a business, food is prepared to be ready for consumption by the final consumer;

“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 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 16;

“prepacked food” means any single item for presentation as such to the final consumer and to mass caterers, consisting of a food and the packaging into which it was put before being offered for sale, whether such packaging encloses the food completely or only partially, but in any event in such a way that the contents cannot be altered without opening or changing the packaging;

“relevant thing” means any medium through which food is presented or made available for sale or supply or through which food information is displayed;

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

Scope

3. These Regulations apply to all food which is not prepacked food and is offered for sale or supply, including supply free of charge, to the final consumer or to a mass caterer, including—

- (a) food packed at a food business operator’s premises at the consumer’s request, and
- (b) food packed for direct sale or supply.

Part 2

FOOD ALLERGEN INFORMATION

Prohibition in respect of presentation, sale and supply

4. A food business operator shall not present or make available food for sale or supply, or sell or supply food, unless written particulars of any allergen in the food are indicated at:

- (a) the point of presentation,
- (b) the point of sale, or
- (c) the point of supply,

in accordance with the applicable requirements of this Part.

Manner in which allergen information is to be provided

5. (1) Subject to paragraphs (2) and (3), a food business operator shall provide written particulars of any allergen in food presented or made available for sale or supply such that the information is—

- (a) freely and easily accessible before the sale or supply of the food,
- (b) at least in the English or in the Irish language and in the English language,
- (c) in a conspicuous place, such that it is easily visible and available to the final consumer or mass caterer,
- (d) in clear legible script, and
- (e) presented in a manner such that there is no possibility of confusion as to which food the information relates.

(2) Subject to paragraph (3), in the case of food presented or made available for sale or supply by means of distance selling, the food business operator shall provide particulars of any allergen in such food—

- (a) before the purchase is concluded, on the material supporting the distance selling or through other appropriate means clearly identified by the food business operator which do not involve charging consumers supplementary costs, and
- (b) at the moment of delivery,

and such particulars shall be provided in writing at at least one of the stages referred to in subparagraphs (a) and (b).

(3) Paragraph (2)(a) shall not apply to foods presented or made available for sale or supply by means of automatic vending machines or automated commercial premises.

Exemption where allergen referred to in name of food

6. Notwithstanding Regulation 5, where the name of the food clearly refers to the allergen concerned, the food business operator is not obliged to separately provide particulars of the allergen.

Part 3

ENFORCEMENT, OFFENCES AND PENALTIES

Enforcement generally

7. (1) 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 the enforcement provisions contained in the Act of 1998 shall apply for the purposes of ensuring compliance with the requirements of these Regulations.

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

Taking of food samples

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

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

(3) Where an authorised officer purchases or takes without payment a sample of food 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 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 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, 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.

Division of food samples

9. (1) Where a sample of food 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.

(2) Where an authorised officer divides a sample in accordance with paragraph (1), he or she 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.

(3) Where an authorised officer takes a sample of food 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 paragraphs (1) and (2) as regards the division of samples into parts shall be deemed to be complied with if the authorised officer obtains three samples and deals with each as if it were a sample as specified under paragraphs (1) and (2).

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

Taking of relevant things

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

(2) Where a sample of a relevant thing is taken pursuant to these Regulations, for the purposes of official analysis, the authorised officer shall obtain three identical such relevant things, or takes three copies or photographs of such relevant thing.

(3) Where an authorised officer takes a relevant thing, or a copy or photograph thereof, with the intention of having it analysed, he or she shall—

- (a) forthwith notify the food business operator of his or her intention of having the relevant thing, copy or photograph analysed,
- (b) forward one of the relevant things, or one of the copies or photographs of the relevant thing, to the approved examiner in an official laboratory for analysis,
- (c) give or send one of the relevant things, or one of the copies or photographs of the relevant thing, to the food business operator, and
- (d) retain the third relevant thing, or the third copy or photograph of the relevant thing.

Analysis of food samples and relevant things

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

(2) The form of certificate set out in the Schedule to these Regulations or a certificate in like form shall be used for the purpose of paragraph (1).

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

Report on official controls

12. (1) Where a sample of food 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 Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 29 April 2004³.

(2) Where the certificate given in accordance with Regulation 11(1) indicates that a sample of food is not in 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 charge or control of such food, with a copy of the report referred to in paragraph (1).

Powers of authorised officers

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

³OJ No. L. 165, 30.4.2004, p. 1.

- (a) examine any procedure connected with the manufacture of food, and
- (b) require a person to state his or her name and address and, if the authorised officer thinks it necessary, to produce corroborative evidence of same.

Seizure, removal, detention and destruction

14. (1) An authorised officer may seize, remove or detain food or a relevant thing which is 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), destroy or otherwise dispose of food so as to prevent the food being used for human consumption.

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

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

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

Compliance Notice

15. (1) Where an authorised officer is of the opinion that there is non-compliance with a requirement of these Regulations, the authorised officer may, following consultations with the chief executive or such other officer of the Authority or an official agency designated in that behalf by the Board, serve, or arrange to have served, on the food business operator concerned a notice (“compliance notice”) in accordance with paragraph (2).

(2) A compliance notice shall—

- (a) be signed by the authorised officer issuing it, or the officer consulted in accordance with paragraph (1),

- (b) identify the requirement(s) of these Regulations with which there has not been compliance,
 - (c) identify the corrective actions to be taken,
 - (d) where appropriate, direct the food business operator on whom the compliance notice is served to ensure that the food is not offered for sale or supply to the final consumer or to a mass caterer until such time as all appropriate measures, including corrective measures, have been taken to bring the food and relevant thing into conformity with these Regulations,
 - (e) where appropriate, direct the food business operator on whom the compliance notice is served to recall and withdraw from the market any food which the authorised officer suspects fails to comply with Regulation 5,
 - (f) specify a time period, commensurate with the nature of the risk, within which the food business operator must take the corrective actions identified in subparagraph (c), and
 - (g) state that if a food business operator to whom the notice is addressed fails to take such measures as are specified in the notice within the time period specified in that notice, that food business operator commits an offence.
- (3) A compliance notice shall give the person on whom it is served information on the right of appeal against such notice.
- (4) The chief executive of the Authority or another officer of the Authority designated for that purpose, may, for stated reasons, revoke or vary a compliance notice issued by an authorised officer appointed by the Authority.
- (5) The chief executive of an official agency, or another officer of an official agency designated for that purpose, may, for stated reasons, revoke or vary a compliance notice issued by an authorised officer appointed by the official agency.
- (6) A copy of every compliance notice, and every revocation or variation of a compliance notice, shall be provided within three working days to the Authority and to the official agency.
- (7) In the event of non-compliance or delay by the person on whom a compliance notice has been served, an authorised officer shall, with the approval of the chief executive of the Authority or official agency, or another officer thereof designated for that purpose, take whatever measures are considered necessary to ensure compliance with the compliance notice, including the seizure and destruction of the products in question or the making of any arrangements for such seizure or destruction or both.

Designation of official laboratories and approved examiners

16. 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.

Offences

17. (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,
- (e) provides records or documents, or copies thereof, which the food business operator knows to be false or misleading in content, or
- (f) gives, in purported compliance with a request under these Regulations, a name, an address or corroborative evidence which is false or misleading.

(4) 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").

(5) 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").

(6) 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.

(7) 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.

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

(9) 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.

(10) 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.

Prosecution of offences

18. (1) An offence under these Regulations may be prosecuted by either—

(a) the Authority, or

(b) an official agency.

(2) Where a person is convicted of an offence under these Regulations, the court shall, unless it is satisfied that there are special and substantial reasons for not so doing, order the person to pay to the Authority or the official agency, as the case may be, the costs and expenses, measured by the court, incurred by the Authority or official agency in relation to the investigation, detection and prosecution of the offence, including costs and expenses incurred in the taking of samples, the carrying out of tests, examinations and analyses and in respect of the remuneration and other expenses of employees, consultants and advisors engaged by the Authority or official agency.

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

Schedule

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

Health (Provision of Food Allergen Information to Consumers in respect of Non-prepacked Food) 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 / relevant thing / copy of relevant thing / photograph of relevant thing marked ⁽³⁾

.....

Date.....

Number.....

Weight or Measure ⁽⁴⁾.....

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

Observations:⁽⁶⁾

I further certify that the sample / relevant thing / copy / photograph 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.....

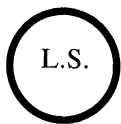
Status.....

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. It may also be left unanswered in the case of analysis or examination of a relevant thing, or a copy or photograph thereof.
- (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 any allergen 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 food information relating to the sample is incorrect or misleading; and he or she may add any other observations as he or she may consider relevant. In the case of analysis or examination of a relevant thing, or a copy or photograph thereof, the approved examiner may insert, at his or discretion, any observations in relation to the relevant thing that 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,
23 October 2014.

LEO VARADKAR,
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 the provision of food allergen information to consumers in respect of non-prepacked food. They provide for the means, expression and presentation through which allergen particulars are to be made available on non-prepacked food, as provided for under Article 44 of Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers.

These Regulations may be cited as the Health (Provision of Food Allergen Information to Consumers in respect of Non-Prepacked Food) Regulations 2014.

BAILE ÁTHA CLIATH
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