S.I. No. 747 of 2007

EUROPEAN COMMUNITIES (GENERAL FOOD LAW) REGULATIONS 2007

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 specific provisions relating to food of Regulation (EC) No. 178/20021 of the European Parliament and of the Council of 28 January 2002 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, hereby make the following regulations:

PART 1

PRELIMINARY

1. These Regulations may be cited as the European Communities (General Food Law) Regulations 2007.

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 Chemist at the State Laboratory,

   (b) a Chief Medical Scientist located at an official laboratory,

   (c) a Consultant Microbiologist located at an official laboratory,

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

   (e) an Executive Analytical Chemist located at a Public Analyst’s Laboratory,

   (f) an officer at or above the grade of Senior Scientific Officer of the Radiological Protection Institute of Ireland,

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

   (h) a Section Manager or Team Leader at the Marine Institute with responsibility for testing of food or food products,

Notice of the making of this Statutory Instrument was published in “Iris Oifigiúil” of 13th November, 2007.

(i) a Senior Chemist at the Marine Institute,

(j) a Senior Chemist at the State Laboratory,

(k) the State Chemist at the State Laboratory, or

(l) a person, or member of a class of persons, designated by the Minister pursuant to Regulation 3;

“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;


“food business operator” means a food business operator as defined in the EC Regulation, insofar as such operator has responsibility for—

(a) any stage of production, processing or distribution of—

(i) food of non-animal origin,

(ii) food of animal origin sold directly to the final consumer,

(iii) food of animal origin, insofar as the food business supplies such food from a retail establishment to other retail establishments where such supply is a marginal, localised and restricted activity as defined in national law, or

(iv) food containing both products of plant origin and processed products of animal origin, or

(b) the import or export of foods of non-animal origin or food containing both products of plant origin and processed products of animal origin,

or any related activities;

“Health Service Executive” (HSE) means the Health Service Executive, established under section 6 of the Health Act 2004 (No. 42 of 2004);

“Marine Institute” means the Marine Institute, established under section 3 of the Marine Institute Act 1991 (No. 2 of 1991);

“Minister” means the Minister for Health and Children;
“official agency” means the Health Service Executive, 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\(^2\) of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;

“official laboratory” means—

(a) the Marine Institute,

(b) the Public Analyst’s Laboratory, Cork,

(c) the Public Analyst’s Laboratory, Dublin,

(d) the Public Analyst’s Laboratory, Galway,

(e) the Public Health Laboratory, HSE, Dublin Mid-Leinster,

(f) the Public Health Laboratory, Sligo,

(g) the Public Health Laboratory, Waterford,

(h) the Public Health Microbiology Laboratory, Cork,

(i) the Public Health Microbiology Laboratory, Galway,

(j) the Public Health Microbiology Laboratory, Limerick,

(k) the Radiological Protection Institute of Ireland,

(l) the State Laboratory, or

(m) a laboratory designated by the Minister pursuant to Regulation 3;

“Radiological Protection Institute of Ireland” means the Radiological Protection Institute of Ireland, established under section 6 of the Radiological Protection Act 1991 (No. 9 of 1991);

“relevant provisions of the EC Regulation” means Articles 12, 14, 16, 17, 18 and 19 of the EC Regulation, insofar as they relate to food or another relevant article or substance and cognate terms shall be construed accordingly;

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

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

PART 2

GENERAL PROVISIONS

3. 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, or

(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 for the purposes of these Regulations and complete certificates in the form set out in Schedule 1.

4. (1) These Regulations shall not apply to food businesses engaged in activities which are subject to—

(a) the European Communities (Food and Feed Hygiene) Regulations 2005 (S.I. No. 910 of 2005), or

(b) the European Communities (Hygiene of Fishery Products and Fish Feed) Regulations 2006 (S.I. No. 335 of 2006),

only to the extent that the food business engages in those activities.

(2) The competent authority for the purposes of the relevant provisions of the EC Regulation, and for the purposes of these Regulations shall be—

(a) the Authority, or

(b) the official agency where these Regulations provide for the execution of a competent authority function under the EC Regulation by such agency.
(3) The public authority for the purposes of Article 10 of the EC Regulation, and for the purposes of these Regulations, shall be the Authority or the official agency, as appropriate.

5. (1) A food business operator is guilty of an offence if the food business operator places unsafe food on the market or otherwise contravenes Article 14 of the EC Regulation.

(2) Where the Authority or the official agency suspects that food is unsafe, although it conforms with specific provisions applicable to that food, the Authority, or the official agency, may take appropriate measures to impose restrictions on such food being placed on the market, or require its withdrawal from the market, in accordance with Article 14 of the EC Regulation.

(3) In proceedings for an offence under paragraph (1), it is a defence for a person charged with the offence to prove both of the following—

(a) commission of the offence was due to a mistake or the reliance on information supplied to him or her, or to the act or default of another person, an accident or some other cause beyond his or her control, and

(b) he or she exercised due diligence and took all reasonable precautions to avoid commission of the offence.

(4) If reliance on the defence provided by paragraph (3) involves the allegation that the commission of the offence was due to reliance on information supplied by another person or to the act or default of another person, the person charged with the offence shall not, without leave of the court, be entitled to rely on that defence unless, not less than 7 working days before the hearing, he or she has served on the prosecutor written notice providing information identifying, or assisting in the identification of, that other person.

6. A food business operator is guilty of an offence if the food business operator fails to comply with Article 16 of the EC Regulation in the labelling, advertising or presentation of food.

7. A food business operator is guilty of an offence if—

(a) the food business operator fails to ensure (in accordance with Article 17 of the EC Regulation) that a food satisfies the relevant requirements of food law, or

(b) the food business operator fails to carry out the necessary verification in accordance with Article 17 of the EC Regulation.

8. A food business operator is guilty of an offence if the food business operator fails—

(a) to identify a person who has supplied the food business operator with food,
(b) to identify another business to which the food business operator has supplied food,

(c) to have in place systems and procedures (including documentation) which allow for information on provenance and destination of foods to be made available to the official agency on demand,

(d) to provide the official agency with information on provenance or destination of a food, on demand,

(e) to adequately label or identify food for the purposes of traceability, through relevant documentation or information,

(f) to maintain records in accordance with Schedule 2,

(g) to maintain records for the duration prescribed in Schedule 2, or

(h) in any other way to comply with Article 18 of the EC Regulation.

9. (1) A food business operator is guilty of an offence if the food business operator fails to—

(a) initiate procedures to withdraw a food,

(b) ensure that a food is withdrawn,

(c) inform the Authority or the official agency of the initiation of procedures to withdraw a food,

(d) effectively and accurately inform consumers of the reasons for withdrawal of a food, or

(e) recall products from consumers,

in accordance with Article 19(1) of the EC Regulation.

(2) A food business operator responsible for retail or distribution activities that do not affect the packaging, labelling, safety or integrity of a food, is guilty of an offence, if the food business operator fails to—

(a) initiate procedures to withdraw a food,

(b) ensure that a food is withdrawn,

(c) pass on relevant information necessary to trace a food, or

(d) cooperate in action taken by producers, processors, manufacturers, and/or the Authority or the official agency,

in accordance with Article 19(2) of the EC Regulation.
(3) A food business operator is guilty of an offence if the food business operator—

(a) fails to immediately inform the Authority or the official agency of any grounds for believing that a food which it has placed on the market may be injurious to human health,

(b) fails to inform the Authority or the official agency of the action taken to prevent risks to the final consumer, or

(c) prevents or discourages any person from cooperating with the Authority or the official agency,

in accordance with Article 19(3) of the EC Regulation.

(4) A food business operator is guilty of an offence if the food business operator fails or refuses to collaborate with the Authority or the official agency, or both, on action taken to avoid or reduce risks posed by a food, in accordance with Article 19(4) of the EC Regulation.

(5) A food business operator is guilty of an offence if the food business operator fails in any other way to respond to an actual or potential breach of food safety requirements in accordance with the provisions of Article 19 of the EC Regulation.

(6) Where the Authority or the official agency forms the view that a food business operator should be taking measures pursuant to Article 19, but is failing to do so, the Authority, or the official agency, or both, may take action pursuant to Regulation 20.

10. (1) A food business operator is guilty of an offence if the food business operator exports or re-exports food which does not comply with the relevant requirements of food law, unless the non-compliance is permitted in accordance with Article 12 of the EC Regulation.

(2) A food business operator exporting or re-exporting food which does not comply with the relevant requirements of food law is not guilty of any offence under these Regulations or under other food law, if the non-compliance is permitted in accordance with Article 12 of the EC Regulation.

11. The Minister, after consultation with the Authority, and taking account of the precautionary principle set out in Article 7 of the EC Regulation, may, by order, put in place interim protective measures with regard to food, as provided for in Article 54 of the EC Regulation.
PART 3

ENFORCEMENT

12. (1) The enforcement of these Regulations and of the relevant provisions of 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 and the relevant provisions of the EC Regulation shall be enforced by the Authority or by the official agency acting pursuant to a service contract with the Authority and, without prejudice to paragraph (1), the enforcement provisions contained in the Act of 1998 shall apply for the purpose of ensuring compliance with the requirements of these Regulations and with the relevant provisions of the EC Regulation.

13. An authorised officer may, for the purposes of these Regulations, and for the purposes of enforcing the relevant provisions of the EC Regulation, at all reasonable times and subject to Section 50 of the Act of 1998, enter any premises in which he or she has reasonable grounds for believing that any food is being produced, manufactured, imported, processed, stored, transported, distributed or traded, and do all or any of the following—

(a) take the reading of values recorded by measuring instruments installed on the premises,

(b) make such other examinations, tests and inspections, including the opening of a receptacle, as may be necessary,

(c) there, or at any other place, interview the food business operator concerned or any relevant staff,

(d) require the food business operator or any relevant staff to produce any documents and to provide such assistance and information in relation to the documents as may be necessary, or

(e) inspect and take copies or extracts from records (including, in the case of information in a non-legible form, a copy of or an extract from such information in a legible form).

14. (1) An authorised officer may, for the purposes of these Regulations and for the purposes of enforcing the relevant provisions of the EC Regulation, purchase or take without payment a sample of a food.

(2) An authorised officer may, for the purpose of taking a sample of a food, open any receptacle.
(3) Where an authorised officer purchases or takes without payment a sample of a 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 such 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 a food, which is suspected by him or her—

(a) to be unsafe, or

(b) to fail to comply with the provisions of these or any other Regulations applicable to such a food, or with the relevant provisions of the EC Regulation,

he or she may, by notice in writing to the food business operator, or person in apparent charge or control of such food, prohibit the removal of the food 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 taking of the sample.

15. (1) Where a sample of a food is taken pursuant to these Regulations for the purpose of official analysis, and where the division of the sample is reasonably practicable, the authorised officer concerned may 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. The authorised officer shall, in the presence of the food business operator, or 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, for the purposes of official analysis, a sample consisting of food contained in unopened containers and its division into parts—

(a) is not reasonably practicable, or

(b) might affect the composition or impede the proper analysis of the sample,
the provisions of paragraph (1) 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, a food 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). 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 a food 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 or a certificate in like form shall be used.

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

17. Where a sample of a food is taken by an authorised officer in pursuance of these Regulations for analysis by an approved examiner, the Authority, or the official agency, as the case may be, shall draw up a report in accordance with Article 9 of the Official Controls Regulation, and where the certificate given in accordance with Regulation 16 indicates that there has been non-compliance with the relevant provisions of the EC Regulation, the Authority or the official agency, as the case may be, shall provide the food business operator with a copy of the report.

18. (1) An authorised officer may, for the purposes of these Regulations and the relevant provisions of the EC Regulation, inspect and take copies, or samples, of—

(a) labels used on food,

(b) packaging of a food, or

(c) any other materials used in the advertising or presentation of food.

(2) An authorised officer may request a food business operator to produce the information referred to in Article 18 of the EC Regulation and he or she may inspect, and take copies of, any such information.

19. (1) An authorised officer may, for the purposes of these Regulations, seize, remove, detain or direct the withdrawal from the market of any food where he or she suspects that the food fails to comply with the relevant provisions of the EC Regulation, or where a food business operator has failed to take measures pursuant to Article 19 of the EC Regulation, which in the view of the Authority or the official agency, or both, should have been taken.
(2) An authorised officer may, with the consent in writing of the food business operator, or in accordance with an order of a judge of the District Court under paragraph (4), destroy or otherwise dispose of a food so as to prevent the food being used for human consumption.

(3) An authorised officer who has seized, removed, detained or directed the withdrawal from the market of a food in pursuance of the provisions of this Regulation may, on giving notice in writing to the food business operator of his or her intention to do so, apply to a judge of the District Court for an order directing that such food 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—

(a) such food fails to comply with the relevant provisions of the EC Regulation, or

(b) the food business operator has failed to take measures in respect of the food which it ought to have taken pursuant to Article 19 of the EC Regulation,

order that it 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 it accordingly.

(5) Where an authorised officer has neither applied for an order of the District Court pursuant to paragraph (3), nor obtained the consent of the food business operator to the destruction or disposal of the food in accordance with paragraph (2), he or she shall not detain, or direct the detention of, the food for a period exceeding 40 days.

20. (1) A food business operator, or the owner or person in charge of the premises and any person employed there shall—

(a) afford to an authorised officer such facilities and assistance as are reasonably necessary to enable the officer to perform his or her functions under these Regulations and under the relevant provisions of the EC Regulation,

(b) produce to an authorised officer any books, documents, computerised data, written material as to verification systems or other records which he or she may reasonably require, or

(c) give to an authorised officer any information which he or she may reasonably require regarding—

(i) any food on the premises,

(ii) any books, documents, computerised data, or written material as to verification systems or other records produced by him or her pursuant to these Regulations, or
(iii) the composition of any food.

(2) An authorised officer, when exercising any powers under these Regulations, may be accompanied by other persons and may take with him or her, or those persons may take with them, any equipment or materials necessary to assist the officer in the exercise of those powers.

21. Where an authorised officer has reasonable grounds for believing that a person has contravened any provision of these Regulations or any relevant provision of the EC Regulation, and so informs that person, the authorised officer may require that person to state his or her name and address and, if the authorised officer thinks it necessary, to produce corroborative evidence of same.

22. (1) A person is guilty of an offence if he or she fails to comply with these Regulations, or with the relevant provisions of the EC Regulation.

(2) Paragraph (1) shall not apply to an authorised officer or an approved examiner 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 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 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 in this Regulation 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 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) For the purposes of these Regulations, every contravention of any of the relevant provisions shall be deemed a separate contravention, and every contravention of a paragraph or subparagraph of these Articles 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.

(3) A person who is guilty of an offence under these Regulations is liable—

(a) on summary conviction, to a fine not exceeding €5,000, or 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.

26. Notwithstanding Section 57 of the Act of 1998, a summary offence under these Regulations may be prosecuted by—

(a) the Authority, or

(b) the official agency,

or both.
PART 4

REVOCATIONS

27. Regulations 9, 10 and 11 of the Food Hygiene Regulations 1950 (S.I. No. 205 of 1950) are revoked.
SCHEDULE 1

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

**European Communities (General Food Law) Regulations 2007**

**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.) 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; or whether and in what respect a label and description relating to the sample is incorrect or misleading; and he or she may add such other observations as he or she may consider relevant.

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

SCHEDULE 2

TRACEABILITY INFORMATION

1. The food business operator shall, as a minimum, maintain records of the following:

   (a) in relation to food supplied to the food business operator—

      (i) name of supplier,

      (ii) address of supplier,

      (iii) nature of products supplied, and

      (iv) date of transaction/delivery;

   (b) in relation to food supplied by the food business operator to another business—
(i) name of customer,
(ii) address of customer,
(iii) nature of products supplied, and
(iv) date of transaction/delivery.

2. The food business operator shall maintain the records referred to in paragraph 1 for the following periods:

(a) for 6 months beyond the shelf-life in the case of a food having a shelf-life of more than 5 years,

(b) for 6 months from the date of delivery in the case of highly-perishable food having no ‘use by’ date, or having a ‘use by’ date of less than 3 months, where such food is destined for distribution to the final consumer, or

(c) for 5 years in all other cases.

GIVEN under my Official Seal,
8 November 2007

L.S.

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 are intended to give further effect to Articles 10, 12, 14, 16, 17, 18, 19 and 54 of Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 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, insofar as those provisions relate to food.

These Regulations may be cited as the European Communities (General Food Law) Regulations 2007.