

# **Statutory Instrument**

**S.I. No. 369 of 2006**

## **EUROPEAN COMMUNITIES (HYGIENE OF FOODSTUFFS) REGULATIONS 2006**

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## **S.I. No. 369 of 2006**

### **European Communities (Hygiene of Foodstuffs) Regulations 2006**

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 Regulation (EC) No. 852/2004<sup>1</sup> of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, as affected by the Corrigendum to Regulation (EC) No. 852/2004,<sup>2</sup> hereby make the following regulations:

#### **PART 1**

##### **Preliminary**

1. These Regulations may be cited as the European Communities (Hygiene of Foodstuffs) Regulations 2006.

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 Chief Medical Scientist located at an official laboratory,
  - (b) a Consultant Microbiologist located at an official laboratory,
  - (c) an Executive Analytical Chemist located at a Public Analyst’s Laboratory,
  - (d) a Deputy Public Analyst located at a Public Analyst’s Laboratory,
- or
- (e) a Public Analyst located at a Public Analyst’s Laboratory;

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<sup>1</sup> OJ L 139, 30.4.2004, p. 1.

<sup>2</sup> OJ L 226, 25.6.2004, p. 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;

“EC Regulation” means Regulation (EC) No. 852/2004<sup>1</sup> of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, as affected by the Corrigendum to Regulation (EC) No. 852/2004<sup>2</sup>;

“food business operator” means a food business operator as defined in the General Food Law 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, after those stages to which Article 4(1) of the EC Regulation applies;

“General Food Law Regulation” means Regulation (EC) No. 178/2002<sup>3</sup> 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;

“official agency” means the Health Service Executive established under section 6 of the Health Act 2004 (No. 42 of 2004), carrying out functions

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<sup>3</sup> OJ L 31, 1.2.2002, p. 1.

pursuant to these Regulations under a service contract with, 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<sup>4</sup> 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 Public Analyst’s Laboratory, Cork,
- (b) the Public Analyst’s Laboratory, Dublin,
- (c) the Public Analyst’s Laboratory, Galway,
- (d) the Public Health Laboratory, Limerick,
- (e) the Public Health Laboratory, Sligo,
- (f) the Public Health Laboratory, Waterford,
- (g) the Public Health Microbiology Laboratory, Cork,
- (h) the Public Health Microbiology Laboratory, Dublin, or
- (i) the Public Health Microbiology Laboratory, Galway;

“Regulations of 1950” means the Food Hygiene Regulations 1950 (S.I. No. 205 of 1950), as amended;

“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 or in the General Food Law Regulation has, unless the context otherwise requires, the same meaning in these Regulations as it has in the EC Regulation or in the General Food Law Regulation.
- (3) (a) A reference in these Regulations to a Regulation is to a Regulation of these Regulations, unless it is indicated that reference to some other Regulations is intended.
- (b) A reference in these Regulations to a paragraph or subparagraph is to the paragraph or subparagraph of the provision in which the

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<sup>4</sup> OJ L 165, 30.4.2004, p. 1, as affected by the Corrigendum to Regulation (EC) No. 882/2004, OJ L 191, 28.5.2004, p. 1.

reference occurs, unless it is indicated that reference to some other provision is intended.

- (c) A reference in these Regulations to a Schedule is to a Schedule to these Regulations, unless it is indicated that reference to some other Regulations is intended.
- (d) A reference in these Regulations to an Annex is to an Annex to the EC Regulation, unless it is indicated that reference to some other instrument is intended.

## PART 2

### General Provisions

3. A food business operator who fails to comply with Article 3 of the EC Regulation is guilty of an offence.
4.
  - (1) A food business operator who fails to comply with the general hygiene requirements laid down in Annex II to the EC Regulation is guilty of an offence.
  - (2) Where a food business operator derogates from the general hygiene requirements referred to in paragraph (1) in accordance with the derogations set down in Commission Directive 96/3/EC<sup>5</sup> of 26 January 1996, as amended by Commission Directive 2004/4/EC<sup>6</sup> of 15 January 2004, and in Commission Directive 98/28/EC<sup>7</sup> of 29 April 1998, he or she is not guilty of an offence.
  - (3) A food business operator who fails to adopt any specific hygiene measures required in accordance with Article 4(3)(b), (c), (d) or (e) of the EC Regulation, where the criteria, requirements or targets referred to in Article 4(4) have been adopted in respect of that specific hygiene measure in accordance with Article 14(2) of the EC Regulation, is guilty of an offence.
  - (4) A food business operator who fails to carry out sampling and analysis methods laid down in accordance with Article 14(2), as referred to in Article 4(4) of the EC Regulation, is guilty of an offence.
5.
  - (1) A food business operator who fails to comply with the requirements of Article 5(1) and (2) of the EC Regulation is guilty of an offence.
  - (2) A food business operator is guilty of an offence if the operator -
    - (a) fails to provide the official agency with the evidence required by the official agency, in the manner that the official agency requires, taking account of the nature and size of the food business, of the operator's compliance with Article 5(1) of the EC Regulation,

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<sup>5</sup> Commission Directive 96/3/Euratom, ECSC, EC of 26 January 1996 granting a derogation from certain provisions of Council Directive 93/43/EEC on the hygiene of foodstuffs as regards the transport of bulk liquid oils and fats by sea, OJ L 21, 27.1.1996, p. 42.

<sup>6</sup> Commission Directive 2004/4/EC of 15 January 2004 amending Directive 96/3/EC granting a derogation from certain provisions of Council Directive 93/43/EEC on the hygiene of foodstuffs as regards the transport of bulk liquid oils and fats by sea, OJ L 15, 22.1.2004, p. 25, as affected by Corrigendum to Commission Directive 2004/4/EC, OJ L 81, 19.3.2004, p. 92.

<sup>7</sup> Commission Directive 98/28/EC of 29 April 1998 granting a derogation from certain provisions of Directive 93/43/EEC on the hygiene of foodstuffs as regards the transport by sea of bulk raw sugar, OJ L 140, 12.5.1998, p. 10.

(b) fails to ensure that the documents describing the procedures developed in accordance with Article 5 of the EC Regulation are up-to-date at all times, or

(c) fails to retain such documents and records, as the operator is obliged to retain pursuant to Article 5(4)(c) of the EC Regulation, for the periods specified in paragraphs (3), (4) and (5).

- (3) In the case of foodstuffs requiring the indication of a 'use by' date in accordance with Article 10 of Directive 2000/13/EC<sup>8</sup> of the European Parliament and of the Council of 20 March 2000, the documents and records shall be retained for three months after the expiry of the relevant 'use by' date.
  - (4) In the case of foodstuffs requiring the indication of a 'best before' or 'best before end' date in accordance with Article 9 of Directive 2000/13/EC<sup>8</sup> of the European Parliament and of the Council of 20 March 2000, the documents and records shall be retained for one year after the expiry of the relevant 'best before' or 'best before end' date, as the case may be.
  - (5) In the case of foodstuffs for immediate consumption, the documents and records shall be retained for three months after the sale of the foodstuff.
6. (1) A food business operator who fails to notify the official agency of each establishment under its control in the manner the official agency requires, with a view to the registration of each such establishment, is guilty of an offence.
- (2) A food business operator who fails to provide the official agency, with any or all up-to-date information on each establishment under its control, including by notifying any significant change in activities and any closure of an existing establishment, is guilty of an offence.
- (3) A food business operator who fails to ensure that each establishment under its control is approved by the official agency, when approval is required under Article 6(3) of the EC Regulation, is guilty of an offence.
- (4) Regulation 6(1) does not apply to a food business operator in respect of a food premises which was registered or provisionally registered, or in respect of a food stall which was licensed, on 31 December 2005 under the Regulations of 1950. Such premises and stalls shall be deemed to be registered for the purposes of Article 6 of the EC Regulation.

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<sup>8</sup> Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, OJ L 109, 6.5.2000, p. 29, as affected by Corrigendum to Commission Directive 2000/13/EC, OJ L 124, 25.5.2000, p. 66.

7. (1) A food business operator importing food of non-animal origin or food containing both products of plant origin and processed products of animal origin, who fails to comply with a requirement of the EC Regulation is not guilty of an offence, if conditions recognised by the Community to be at least equivalent to that requirement, or the requirements of a specific agreement between the Community and the exporting country, have been complied with in accordance with Article 11 of the General Food Law Regulation.
- (2) A food business operator exporting food of non-animal origin or food containing both products of plant origin and processed products of animal origin who fails to comply with a requirement of the EC Regulation is not guilty of an offence if the non-compliance with the relevant requirements of food law is permitted in accordance with Article 12 of the General Food Law Regulation.
8. (1) The competent authority for the purposes of the EC Regulation and 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 an agency.
- (2) These Regulations shall not apply to food businesses engaged in –
  - (a) activities which are subject to the European Communities (Food and Feed Hygiene) Regulations 2005 (S.I. No. 910 of 2005)
  - (b) the catching, harvesting or processing of fish, or
  - (c) the activities set out in Article 1(2) of the EC Regulation,to the extent that the food business engages in those activities.



## **PART 3**

### **Enforcement**

9.
  - (1) The enforcement of these Regulations, and 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 EC Regulation, shall be enforced by the Authority, or by the 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 and the EC Regulation.
  
10.
  - (1) An authorised officer may, for the purposes of these Regulations and for the purposes of enforcing the EC Regulation, purchase, or take without payment, a sample of foodstuffs, or of another relevant article, or substance, as the officer may reasonably require.
  - (2) An authorised officer may, for the purpose of taking a sample of foodstuffs, or of another relevant article or substance, open any receptacle.
  - (3) Where an authorised officer purchases or takes without payment a sample of foodstuffs or of another relevant article or substance, with the intention of having it analysed, he or she shall after purchasing or taking the sample forthwith notify the food business operator of his or her intention of having the sample analysed.
  - (4) Nothing in these Regulations shall authorise the examination or detention of foodstuffs or of another relevant article or substance without the consent of an officer of the Revenue Commissioners where the duties of such officer in relation to such item have not been wholly discharged.
  
11.
  - (1) Where a sample of foodstuffs or of another relevant article or substance 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 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 food business operator and retain the third part.

- (2) Where an authorised officer takes, for the purposes of official analysis, a sample consisting of foodstuffs or of another relevant article or substance, contained in unopened containers and its division into parts -
- (a) is not reasonably practicable, or
  - (b) might affect the composition or impede the proper analysis of the sample,
- the provisions of paragraph (1) as regards the division of samples into parts shall be deemed to be complied with if the authorised officer divides the containers into three lots and deals with each lot as if it were a sample as specified under paragraph (1).
- (3) In proceedings for an offence under these Regulations, the result of any analysis of, or report on a sample of foodstuffs or of another relevant article or substance, taken pursuant to these Regulations, shall not be adduced unless before the proceedings were instituted the sample was divided as specified in paragraphs (1) and (2). The part, package or container retained by the authorised officer shall be made available for inspection by the court if the court so requires.
12. (1) An approved examiner or a person under his or her direction shall analyse as soon as practicable any sample of foodstuffs or of another article or substance submitted to him or her in pursuance of these Regulations and the approved examiner shall certify to the person who submitted the sample to him or her the result of such analysis. The form of certificate set out in the Schedule to these Regulations 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.
13. Where a sample of foodstuffs or of another relevant article or substance is taken by an authorised officer in pursuance of these Regulations for analysis by an approved examiner, and where the certificate given in accordance with Regulation 12 indicates that there has been non-compliance with the EC Regulation, 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 shall provide the food business operator with a copy of the report.
14. (1) An authorised officer may, for the purposes of these Regulations, seize, remove, detain and/or direct the withdrawal from the market of any foodstuffs where he or she suspects that there has been a breach of the EC Regulation causing the foodstuffs to be unsafe.

- (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 such foodstuffs as to prevent them being used for human consumption.
  - (3) An authorised officer who has seized, removed, detained and/or directed the withdrawal from the market of, foodstuffs in pursuance of the provisions 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 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 there has been a breach of the EC Regulation, causing such foodstuffs to be unsafe, 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.
  - (5) Where the 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 foodstuffs in accordance with paragraph (2), he or she shall not detain, or direct the detention of, the foodstuffs for a period exceeding 40 days.
15. (1) A food business operator who fails to comply with these Regulations is guilty of an offence.
- (2) A person who -
- (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 requirement under these Regulations,
  - (c) fails to comply with a request 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 requirement under these Regulations a name, address or corroborative evidence which is false or misleading,
- is guilty of an offence.

- (3) A person who is employed by a food business operator is guilty of an offence if he or she fails to comply with any relevant requirement laid down in Annex II to the EC Regulation.
  - (4) Regulation 18(4) shall not apply to a person who is guilty of an offence under paragraph (3). A person who is guilty of an offence under paragraph (3) is liable on summary conviction to a fine not exceeding €5,000 or at the discretion of the Court to imprisonment for a term not exceeding 3 months or both.
16. 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 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.
17.
  - (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, knowing it to be a forged or altered document as the case may be is guilty of an offence.
  - (4) Any person who, with intent to defraud or deceive -
    - (a) tampers with anything 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 Regulations,is guilty of an offence.
  - (5) A person who falsely represents himself or herself to be an authorised officer is guilty of an offence.
18.
  - (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) For the purposes of these Regulations, every contravention of an Article of the EC Regulation, 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) For the purposes of these Regulations, every contravention of Annex II to the EC Regulation, shall be deemed a separate contravention, and every contravention of a paragraph or subparagraph of Annex II 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.
  - (4) A person who is guilty of an offence under these Regulations is liable on summary conviction to a fine not exceeding €5,000 or at the discretion of the Court to imprisonment for a term not exceeding 6 months or both.
19. An offence under these Regulations may be prosecuted by either –
- (a) the Authority, or
  - (b) the official agency,
- or both.

## **PART 4**

### **Revocations**

20. (1) The following are revoked:
- (a) the European Communities (Hygiene of Foodstuffs) Regulations 2000 (S.I. No. 165 of 2000),
  - (b) the European Communities (Hygiene of Foodstuffs) (Amendment) Regulations 2005 (S.I. No. 67 of 2005), and
  - (c) Regulations 26B, 26C, 26D and Part IV of the Regulations of 1950.
- (2) References in any other instrument to the Regulations revoked under paragraph (1) shall be construed as references to these Regulations, as appropriate.

# Schedule

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

## **European Communities (Hygiene of Foodstuffs) Regulations 2006**

### *Certificate of Analysis*

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

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

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

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

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

Date .....

Number .....

Weight or Measure .....

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

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

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

I further certify that the sample has undergone no change which would affect my opinion/observations expressed above.

Certified by me this ..... day of ..... 20.....

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

Name in BLOCK LETTERS .....

Status .....

Signature .....

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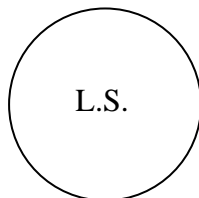
Official Stamp

*NOTES*

- (1) Insert the name and address of the person submitting the sample for analysis.
- (2) Insert description (e.g. Executive Analytical Chemist located at a Public Analyst's Laboratory).
- (3) Insert particulars of marking (e.g. name, date etc.) and the weight or measure (this may be left unanswered if the sample cannot be conveniently weighed or measured or if the weight or measurement is not material to the result of analysis).
- (4) Indicate whether the approved examiner carried out the analysis himself or herself or whether it was carried out by another under the direction of the approved examiner.
- (5) Here the approved examiner should specify the result of the analysis having regard to the provisions of the relevant legislation.
- (6) Here the approved examiner may insert, at his or her discretion, his or her opinion whether the analysis indicates any addition, abstraction, deficiency or the presence of foreign matter or other defect and whether the composition or quality is thereby affected; any physical, chemical or other properties bearing on the composition or quality of the article; whether the article is injurious to health or unfit for human consumption; whether and in what respect a label and description relating to the sample is incorrect or misleading; and he or she may add any other observations as he or she may consider relevant.
- (7) Insert the name and address of the laboratory carrying out the analysis/examination.

Given under my Official Seal this

12 day of July 2006.



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 give force to Regulation (EC) No. 853/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs. The Regulations impose obligations on food business operators in respect of the hygiene of foodstuffs including the general hygiene requirements, HACCP (Hazard Analysis and Critical Control Point) and registration.

These Regulations set out the penalties, enforcement and authorised officer provisions.

These Regulations may be cited as the European Communities (Hygiene of Foodstuffs) Regulations 2006.