

Statutory Instrument

S.I. No. 368 of 2005

European Communities (Sampling Methods and Methods of Analysis for the Official Control of the Levels of Certain Contaminants in Foodstuffs) (No. 2) Regulations 2005

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S.I. No. 368 of 2005

European Communities (Sampling Methods and Methods of Analysis for the Official Control of the Levels of Certain Contaminants in Foodstuffs) (No. 2) 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), having regard to Council Directive 85/591/EEC¹ of 20 December 1985 concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption, and for the purpose of giving further effect to Commission Directive 98/53/EC² of 16 July 1998 laying down the sampling methods and the methods of analysis for the official control of the levels for certain contaminants in foodstuffs, as amended by Commission Directive 2002/27/EC³ of 13 March 2002 and Commission Directive 2003/121/EC⁴ of 15 December 2003, and for the purpose of giving further effect to Commission Directive 2001/22/EC⁵ of 8 March 2001 laying down the sampling methods and the methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs, Commission Directive 2002/26/EC⁶ of 13 March 2002 laying down the sampling methods and methods of analysis for the official control of the levels of ochratoxin A in foodstuffs, Commission Directive 2002/69/EC⁷ of 30 July 2002 laying down the sampling methods and the methods of analysis for the official control of dioxins and the determination of dioxin-like PCBs in foodstuffs, Commission Directive 2003/78/EC⁸ of 11 August 2003 laying down the sampling methods and the methods of analysis for the official control of the levels of patulin in foodstuffs, and Commission Directive 2004/16/EC⁹ of 12 February 2004 laying down the sampling methods and the methods of analysis for the official control of the levels of tin in canned foods, and for the purpose of giving effect to Commission Directive 2004/43/EC¹⁰ of 13 April 2004 amending Directive 98/53/EC² and Directive 2002/26/EC⁶ as regards sampling methods and methods of analysis for the official control of the levels of aflatoxin and ochratoxin A in food for infants and young children, and Commission Directive 2004/44/EC¹¹ of 13 April 2004 amending Directive 2002/69/EC⁷ laying down the sampling methods and the methods of analysis for the official control of dioxins and the determination of dioxin-like PCBs in foodstuffs, hereby make the following regulations:

¹ OJ L 372, 31.12.1985, p. 50.

² OJ L 201, 17.7.1998, p. 93.

³ OJ L 75, 16.3.2002, p. 44.

⁴ OJ L 332, 19.12.2003, p.38.

⁵ OJ L 77, 16.3.2001, p. 14.

⁶ OJ L 75, 16.3.2002, p. 38.

⁷ OJ L 209, 6.8.2002, p. 5.

⁸ OJ L 203, 12.8.2003, p.40.

⁹ OJ L 42, 13.2.2004, p.16.

¹⁰ OJ L 113, 20.4.2004, p. 14.

¹¹ OJ L 113, 20.4.2004, p. 17.

PART 1

Preliminary

1. These Regulations may be cited as the European Communities (Sampling Methods and Methods of Analysis for the Official Control of the Levels of Certain Contaminants in Foodstuffs) (No. 2) 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) the State Chemist in the State Laboratory,
- (d) the Senior Chemist in the Institute, or
- (e) a person or class of persons designated by the Minister pursuant to Regulation 17;

"authorised officer" means:

- (a) an authorised officer appointed under section 49 of the Act of 1998,
- (b) a person appointed by the Minister for Agriculture and Food to be an authorised officer for the purposes of these Regulations,
- (c) a person appointed by the Minister for Communications, Marine and Natural Resources to be an authorised officer for the purposes of these Regulations,
- (d) a person appointed as an authorised officer under the European Communities (Sampling Methods and the Methods of Analysis for the Official Control of the Levels of Certain Contaminants in Foodstuffs) Regulations 2001 (S.I. No. 401 of 2001), or under the European Communities (Sampling Methods and Methods of Analysis for the Official Control of the Levels of Certain

Contaminants in Foodstuffs) Regulations 2003 (S.I. No. 267 of 2003), and holding office as an authorised officer under the said Regulations of 2003 immediately before the coming into effect of the European Communities (Sampling Methods and Methods of Analysis for the Official Control of the Levels of Certain Contaminants in Foodstuffs) Regulations 2005 (S.I. No. 68 of 2005), or

- (e) a person appointed as an authorised officer under the European Communities (Sampling Methods and Methods of Analysis for the Official Control of the Levels of Certain Contaminants in Foodstuffs) Regulations 2005, and holding office as an authorised officer immediately before the coming into operation of these Regulations;

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

"Directives" means Commission Directive 98/53/EC² of 16 July 1998 as amended by Commission Directive 2002/27/EC³ of 13 March 2002, Commission Directive 2003/121/EC⁴ of 15 December 2003 and Commission Directive 2004/43/EC¹⁰ of 13 April 2004, Commission Directive 2001/22/EC⁵ of 8 March 2001, Commission Directive 2002/26/EC⁶ of 13 March 2002 as amended by Commission Directive 2004/43/EC¹⁰ of 13 April 2004, Commission Directive 2002/69/EC⁷ of 30 July 2002 as amended by Commission Directive 2004/44/EC¹¹ of 13 April 2004, Commission Directive 2003/78/EC⁸ of 11 August 2003 and Commission Directive 2004/16/EC⁹ of 12 February 2004;

“foodstuff” means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. ‘Foodstuff’ 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/EC¹² and without prejudice to the requirements of Directives 80/778/EEC¹³ and 98/83/EC¹²;

“foodstuff” 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,

¹² OJ L 330, 5.12.1998, p. 32.

¹³ OJ L 229, 30.8.1980, p. 11.

- (d) medicinal products within the meaning of Council Directives 65/65/EEC¹⁴ and 92/73/EEC¹⁵,
- (e) cosmetics within the meaning of Council Directive 76/768/EEC¹⁶,
- (f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC¹⁷,
- (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;

"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 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 control of foodstuffs" means an inspection by authorised officers of the compliance of:

- (a) foodstuffs,
- (b) food additives, vitamins, mineral salts, trace elements and other additives intended to be sold as such, or
- (c) materials and articles intended to come into contact with food,

with provisions aimed at preventing risks to public health, guaranteeing fair commercial transactions or protecting consumer interests, including the provision of consumer information;

"official laboratory" means:

- (a) the Public Analyst's Laboratory, Cork,
- (b) the Public Analyst's Laboratory, Dublin,

¹⁴ OJ 22, 9.2.1965, p. 369.

¹⁵ OJ L 297, 13.10.1992, p.8.

¹⁶ OJ L 262, 27.9.1976, p.169.

¹⁷ OJ L 359, 8.12.1989, p.1.

- (c) the Public Analyst's Laboratory, Galway,
- (d) the State Laboratory,
- (e) the Institute, or
- (f) a laboratory designated by the Minister pursuant to Regulation 17;

“service contract” means a contract entered into between the Authority and an 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 Directives has, unless the context otherwise requires, the same meaning in these Regulations as it has in the Directives.
- (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) Sampling for the official control of the levels of aflatoxins in foodstuffs shall be carried out in accordance with the methods described in Annex I to Commission Directive 98/53/EC² as amended by Commission Directive 2002/27/EC,³ Commission Directive 2003/121/EC⁴ and Commission Directive 2004/43/EC¹⁰.
- (2) Sample preparation and methods of analysis used for the official control of the levels of aflatoxins in foodstuffs shall comply with the criteria described in Annex II to Commission Directive 98/53/EC² as amended by Commission Directive 2002/27/EC,³ Commission Directive 2003/121/EC⁴ and Commission Directive 2004/43/EC¹⁰.
4. (1) Sampling for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs shall be carried out in accordance with the methods described in Annex I to Commission Directive 2001/22/EC⁵.
- (2) Sample preparation and methods of analysis used for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs shall comply with the criteria described in Annex II to Commission Directive 2001/22/EC⁵.
5. (1) Sampling for the official control of the levels of ochratoxin A in foodstuffs shall be carried out in accordance with the methods described in Annex I to Commission Directive 2002/26/EC⁶ as amended by Commission Directive 2004/43/EC¹⁰.
- (2) Sample preparation and methods of analysis used for the official control of the levels of ochratoxin A in foodstuffs shall comply with the criteria described in Annex II to Commission Directive 2002/26/EC⁶, as amended by Commission Directive 2004/43/EC¹⁰.
6. (1) Sampling for the official control of the levels of dioxins and furans and the determination of the levels of dioxin-like PCBs in foodstuffs shall be carried out in accordance with the methods described in Annex I to Commission Directive 2002/69/EC⁷ as amended by Commission Directive 2004/44/EC¹¹.
- (2) Sample preparation and methods of analysis used for the official control of the levels of dioxins and furans and the determination of the levels of

dioxin-like PCBs in foodstuffs shall comply with the criteria described in Annex II to Commission Directive 2002/69/EC⁷, as amended by Directive 2004/44/EC¹¹.

7. (1) Sampling for the official control of the levels of patulin in foodstuffs shall be carried out in accordance with the methods described in Annex I to Commission Directive 2003/78/EC⁸.
- (2) Sample preparation and methods of analysis used for the official control of the levels of patulin in foodstuffs shall comply with the criteria described in Annex II to Commission Directive 2003/78/EC⁸.
8. (1) Sampling for the official control of the levels of tin in foodstuffs shall be carried out in accordance with the methods described in Annex I to Commission Directive 2004/16/EC⁹.
- (2) Sample preparation and methods of analysis used for the official control of the levels of tin in foodstuffs shall comply with the criteria described in Annex II to Commission Directive 2004/16/EC⁹.

PART 3

Enforcement

9. 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.
10. These Regulations shall be deemed to be food legislation for the purposes of the Act of 1998.
11. 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 9, the enforcement provisions contained in the Act of 1998 shall apply for the purposes of ensuring compliance with these Regulations.
12.
 - (1) Without prejudice to Regulations 9 and 11, and save insofar as they are inconsistent with the requirements of these Regulations, the provisions of the European Communities (Official Control of Foodstuffs) Regulations 1998 (S.I. No. 85 of 1998), as amended, shall apply for the purpose of ensuring compliance with these Regulations.
 - (2) In particular, authorised officers and approved examiners acting under these Regulations shall have the same powers as authorised officers and approved examiners acting under the said Regulations of 1998, save insofar as such powers are inconsistent with the requirements of these Regulations.
 - (3) Without prejudice to the generality of paragraph (1), Regulations 13 and 14 of the said Regulations of 1998 shall not apply for the purposes of ensuring compliance with these Regulations.
 - (4) The authorised officer may exercise such other powers as may be reasonably necessary to ensure that these Regulations are being complied with.
13. For the purposes of these Regulations, sampling shall be carried out by an authorised officer and analysis shall be carried out by an approved examiner, or by a person acting under his or her direction, in an official laboratory.
14. Where a sample of a foodstuff is taken pursuant to these Regulations:

- (a) the authorised officer shall, in the presence of the owner or person in apparent charge or control of such foodstuff, mark, seal and fasten the sample in such a manner as its nature will permit and in such a way that the integrity of the sample cannot be compromised and forward it to an approved examiner in an official laboratory for analysis;
 - (b) as soon as is reasonably practicable after he or she has received such a sample, the approved examiner or a person acting under his or her direction shall issue to the owner or person in apparent charge or control of the foodstuff, a certificate in the form set out in Schedule 2, or a certificate in like form, confirming that the integrity of the sample had been preserved;
 - (c) the approved examiner or a person acting under his or her direction shall prepare and sub-divide the sample in accordance with Regulations 3, 4, 5, 6, 7 and 8;
 - (d) the trade (defence) sample shall be marked in such a way as to identify it as a part of the sample taken by the authorised officer and shall be forwarded to the owner or person in apparent charge or control of the foodstuff in such a way that the integrity of the sample cannot be compromised.
15. (1) The approved examiner, or a person acting under his or her direction, shall analyse as soon as possible a sub-sample of the sample 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.
- (2) After the sub-sample has been analysed by the approved examiner, or a person acting under his or her direction, a certificate in the form set out in Schedule 1, or a certificate in like form, shall be completed.
- (3) An official certificate given in accordance with this Regulation may be adduced in evidence in a prosecution and shall be *prima facie* evidence of the matters contained therein, until the contrary is proved.
16. Where a sample of a foodstuff is taken by an authorised officer in pursuance of these Regulations for analysis by an approved examiner, and where the owner or person in apparent charge or control of the foodstuff requests in writing the results of such analysis, the request shall be made to -
- (a) the Authority, where the officer was appointed by the Authority,
 - (b) the official agency, where the officer was appointed by an official agency, or

- (c) where the officer was appointed by another person or body, such other person or body,

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

17. 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
- (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 and Schedule 2.

18. 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, an address or corroborative evidence which is false or misleading

shall be guilty of an offence.

19. (1) Any person who forges, or utters knowing it to be forged, a certificate or other document purporting to be issued, granted or given under 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 or other document issued, granted or given under 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.
20. 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 6 months, or both.
21. 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.
22. An offence under these Regulations may be prosecuted by -
- (a) the Authority, or
 - (b) an official agency.

PART 4

Revocation

23. (1) The European Communities (Sampling Methods and Methods of Analysis for the Official Control of the Levels of Certain Contaminants in Foodstuffs) Regulations 2005 (S.I. No. 68 of 2005) 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

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

European Communities (Sampling Methods and Methods of Analysis for the Official Control of the Levels of Certain Contaminants in Foodstuffs) (No. 2) 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 ⁽⁴⁾

was submitted to me by you and I certify that the sample 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 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. Senior Chemist in the Institute).
- (3) Insert particulars of marking (e.g. name, date etc.).
- (4) This may be left unanswered if the sample cannot be conveniently weighed or measured or the weight or measurement is not material to the result of analysis.
- (5) Here the approved examiner should specify the result of the analysis having regard to the provisions of 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.

Schedule 2

Form of official certificate to be issued by an approved examiner, or by a person acting under his or her direction, to the owner or person in apparent charge or control of a foodstuff in respect of which a sample was taken pursuant to these Regulations

European Communities (Sampling Methods and Methods of Analysis for the Official Control of the Levels of Certain Contaminants in Foodstuffs) (No. 2) Regulations 2005

Certificate of Integrity of Sample

To ⁽¹⁾

I, the undersigned ⁽²⁾

being an Approved Examiner for the purposes of the above Regulations, or a person acting under the direction of an Approved Examiner⁽³⁾, certify that on

theday of 20.....

a sample marked ⁽⁴⁾

Date

Numbers

Weight or Measure ⁽⁵⁾

was submitted to me by an authorised officer⁽⁶⁾ and I certify that the sample has not been tampered with and that it was delivered to this laboratory with its integrity preserved.

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

at ⁽⁷⁾

Name in BLOCK LETTERS

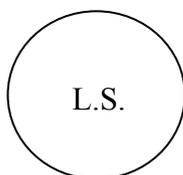
Status

Signature

Official Stamp

NOTES

- (1) Insert the name and address of the owner or person in apparent charge or control of the foodstuff.
- (2) Insert description (e.g. Senior Chemist in the Institute).
- (3) Delete as appropriate.
- (4) Insert particulars of marking (e.g. name, date etc.).
- (5) This may be left unanswered if the sample cannot be conveniently weighed or measured.
- (6) Insert the name of the authorised officer who submitted the sample.
- (7) Insert the name and address of the laboratory carrying out the analysis/examination.



Given under my Official Seal
this 15 day of July, 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 give further effect to Commission Directive 98/53/EC² of 16 July 1998 laying down the sampling methods and the methods of analysis for the official control of the levels for certain contaminants in foodstuffs, as amended by Commission Directive 2002/27/EC³ of 13 March 2002 and Commission Directive 2003/121/EC⁴ of 15 December 2003, Commission Directive 2001/22/EC⁵ of 8 March 2001 laying down the sampling methods and the methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs, Commission Directive 2002/26/EC⁶ of 13 March 2002 laying down the sampling methods and methods of analysis for the official control of the levels of ochratoxin A in foodstuffs, Commission Directive 2002/69/EC⁷ of 30 July 2002 laying down the sampling methods and the methods of analysis for the official control of dioxins and the determination of dioxin-like PCBs in foodstuffs, Commission Directive 2003/78/EC⁸ of 11 August 2003 laying down the sampling methods and the methods of analysis for the official control of the levels of patulin in foodstuffs and Commission Directive 2004/16/EC⁹ of 12 February 2004 laying down the sampling methods and the methods of analysis for the official control of the levels of tin in canned foods. These Directives were previously transposed by the European Communities (Sampling Methods and Methods of Analysis for the Official Control of the Levels of Certain Contaminants in Foodstuffs) Regulations 2005 (S.I. No. 68 of 2005).

These Regulations also give effect to two new Directives: Commission Directive 2004/43/EC¹⁰ of 13 April 2004 amending Directive 98/53/EC² and Directive 2002/26/EC⁶ as regards sampling methods and methods of analysis for the official control of the levels of aflatoxin and ochratoxin A in food for infants and young children, and Commission Directive 2004/44/EC¹¹ of 13 April 2004 amending Directive 2002/69/EC⁷ laying down the sampling methods and the methods of analysis for the official control of dioxins and the determination of dioxin-like PCBs in foodstuffs

The principal effect of these Regulations is to provide for the methods of sampling, and for the sample preparation and methods of analysis for the official control of the levels of certain contaminants in foodstuffs in accordance with the methods described in the Annexes to the Directives.

These Regulations may be cited as the European Communities (Sampling Methods and Methods of Analysis for the Official Control of the Levels of Certain Contaminants in Foodstuffs) (No. 2) Regulations 2005

DEPARTMENT OF HEALTH AND CHILDREN.
July, 2005