



STATUTORY INSTRUMENTS

S.I. No. 277 of 2009



EUROPEAN COMMUNITIES (PURITY CRITERIA ON FOOD
ADDITIVES OTHER THAN COLOURS AND SWEETENERS)
REGULATIONS 2009

(Prn. A9/1021)

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EUROPEAN COMMUNITIES (PURITY CRITERIA ON FOOD
ADDITIVES OTHER THAN COLOURS AND SWEETENERS)
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WHEREAS Commission Directive 2008/84/EC¹ of 27 August 2008 laying down specific purity criteria on food additives other than colours and sweeteners consolidates with amendments Commission Directive 96/77/EC² of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners, as amended by Commission Directives 98/86/EC³, 2000/63/EC⁴, 2001/30/EC⁵, 2002/82/EC⁶, 2003/95/EC⁷, 2004/45/EC⁸ and 2006/129/EC⁹;

Now I, MARY HARNEY, Minister for Health and Children, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972), and for the purpose of giving further effect to Council Directive 89/107/EEC¹⁰ of 21 December 1988 and effect to Commission Directive 2008/84/EC¹ of 27 August 2008, as amended by Commission Directive 2009/10/EC¹¹ of 13 February 2009, laying down specific purity criteria on food additives other than colours and sweeteners, hereby make the following regulations—

PART 1

PRELIMINARY

1. These Regulations may be cited as the European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) Regulations 2009.

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

¹OJ L 253, 20.9.08, p. 1.

²OJ L 339, 30.12.1996, p. 1.

³OJ L 334, 9.12.98, p. 1.

⁴OJ L 277, 30.10.2000, p. 1.

⁵OJ L 146, 31.5.2001, p. 1.

⁶OJ L 292, 28.10.2002, p. 1.

⁷OJ L 283, 31.10.2003, p.71.

⁸OJ L 113, 20.4.2004, p. 19.

⁹OJ L 346, 9.12.2006, p. 15.

¹⁰OJ L 40, 11.2.89, p. 27.

¹¹OJ L 44, 14.2.09, p. 62.

*Notice of the making of this Statutory Instrument was published in
“Iris Oifigiúil” of 28th July, 2009.*

- (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 14;

“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;

“Commission Directive” means Commission Directive 2008/84/EC¹ of 27 August 2008, as amended by Commission Directive 2009/10/EC¹¹ of 13 February 2009, laying down specific purity criteria on food additives other than colours and sweeteners;

“Council Directive” means Council Directive 89/107/EEC¹⁰ of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption;

“Directive 95/2/EC” means European Parliament and Council Directive 95/2/EC¹² of 20 February 1995 on food additives other than colours and sweeteners, as amended by Directive 96/85/EC¹³ of the European Parliament and of the Council of 19 December 1996, by Directive 98/72/EC¹⁴ of the European Parliament and of the Council of 15 October 1998, by Directive 2001/5/EC¹⁵ of the European Council and the Parliament of 12 February 2001, by Directive 2003/114/EC¹⁶ of the European Council and the Parliament of 22 December 2003, and by Directive 2006/52/EC¹⁷ of the European Council and the Parliament of 5 July 2006, as corrected by Corrigendum to Directive 2006/52/EC¹⁸ of the European Council and the Parliament of 5 July 2006 amending Directive 95/2/EC on food additives other than colours and sweeteners and Directive 94/35/EC on sweeteners for use in foodstuffs;

“food additive” means any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods;

¹²OJ L 61, 18.3.1995, p. 1.

¹³OJ L 86, 28.3.1997, p. 4.

¹⁴OJ L 295, 4.11.1998, p. 18.

¹⁵OJ L 55, 24.2.2001, p. 59.

¹⁶OJ L 24, 29.1.2004, p. 58.

¹⁷OJ L 204, 26.7.2006, p. 10.

¹⁸OJ L 78, 17.3.2007, p. 32.

“General Food Law Regulation” means Regulation (EC) No. 178/2002¹⁹ 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;

“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 Controls Regulation” means Regulation (EC) No. 882/2004²⁰ 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) 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 14;

“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 Commission Directive, the Council Directive, Directive 95/2/EC¹² or in the General Food Law Regulation has, unless the context otherwise requires, the same meaning in these Regulations as it has in the said Directives 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 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 Schedule 1 to these Regulations, unless it is indicated that reference to some other Regulations is intended.

¹⁹OJ L 31, 1.2.2002, p. 1.

²⁰OJ L 165, 30.4.2004, p. 1.

PART 2

GENERAL PROVISIONS

3. (1) These Regulations concern and apply to the purity criteria as provided for in Article 3(3)(a) of the Council Directive that apply to food additives other than colours and sweeteners whose use in the manufacture or preparation of foodstuffs is permitted pursuant to the Annexes to Directive 95/2/EC¹².

(2) The said purity criteria are set out in Annex I to the Commission Directive.

4. (1) A person shall only use an additive listed in the Annexes to Directive 95/2/EC¹² in respect of a category of food additive listed in Annex I to the Council Directive which complies with the purity criteria as set out in Annex 1 to the Commission Directive in the production, processing and distribution of food.

(2) A person who fails to comply with this Regulation is guilty of an offence and is liable on conviction to the penalties set out in Regulation 18(2).

5. (1) A person shall only place a foodstuff on the market containing an additive listed in the Annexes to Directive 95/2/EC¹², in respect of a category of food additive listed in Annex I to the Council Directive which complies with the purity criteria as set out in Annex I to the Commission Directive.

(2) A person who fails to comply with this Regulation is guilty of an offence and is liable on conviction to the penalties set out in Regulation 18(2).

PART 3

ENFORCEMENT

6. (1) The enforcement of these Regulations, the Council Directive, the Commission Directive and Directive 95/2/EC¹² 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 shall be enforced by the Authority or by an 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.

7. (1) An authorised officer may, for the purposes of these Regulations, purchase or take without payment a sample of any food or other relevant substance.

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

(3) Where an authorised officer purchases or takes without payment a sample of any food or other relevant substance 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 any food or other relevant substance 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 any food or other relevant substance 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 or other relevant substance, prohibit the removal of the food or other relevant substance 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.

8. (1) Where a sample of any food or other relevant substance 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 may divide the sample into not more than 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. The authorised officer 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.

(2) Where an authorised officer takes a sample consisting of any food or other relevant 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 test, examination or analysis of, or report on a sample of any food or other relevant 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) of this Regulation. The part, package or container retained by the authorised officer shall be produced at the hearing.

9. (1) The approved examiner or a person under his or her direction shall analyse as soon as possible any sample of any food or other relevant 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 Schedule 1 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.

10. Where a sample of any food or other relevant substance 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 the Official Controls Regulation where the certificate given in accordance with Regulation 9 indicates that there has been non-compliance with these Regulations, the Authority, or the official agency, as the case may be, shall provide the food business operator with a copy of the report.

11. (1) An authorised officer may, for the purposes of these Regulations, inspect and take copies, or samples, of labels used on any food or other relevant substance.

(2) An authorised officer may examine any procedure connected with the manufacture of a food.

12. (1) An authorised officer may, for the purposes of these Regulations, seize, remove, detain or direct the withdrawal from the market of any food or other products, which are suspected by him or her to fail to comply with the provisions of these Regulations.

(2) An authorised officer may, with the consent in writing of the food business operator, or the person in apparent charge or control of such foods or other products or in accordance with an order of a judge of the District Court under paragraph (4) of this Regulation, destroy or otherwise dispose of same so as to prevent them being used for human consumption.

(3) An authorised officer who has seized, removed, detained or directed the withdrawal from the market of any food or other products 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 products be destroyed or otherwise disposed of.

(4) A judge of the District Court, to whom an application is made for an order under paragraph (3), may, if satisfied that such products fail to comply with these Regulations, order that they be destroyed or otherwise disposed of, after such period, not exceeding 14 days, as may be specified in such order and an authorised officer shall destroy or dispose of them accordingly.

13. Where an authorised officer has reasonable grounds for believing that a person has contravened any provision of these Regulations 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.

14. 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.

15. (1) 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 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.

16. (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 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 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 the 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.

17. 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.

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.

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

(a) 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, or,

(b) on conviction on indictment, to a fine not exceeding €500,000, or imprisonment for a term not exceeding 3 years, or both.

(3) No prosecution on indictment shall be taken on foot of these Regulations in respect of an offence that occurred before the entry into force of these Regulations.

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

- (a) the Authority, or
- (b) an official agency.

PART 4

REVOCATIONS

20. (1) The following are revoked:

- (a) European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) Regulations 1998 (S.I. No. 541 of 1998);
- (b) European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) (Amendment) Regulations 2000 (S.I. No. 438 of 2000);
- (c) European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) (Amendment) Regulations 2001 (S.I. No. 343 of 2001);
- (d) European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) (Amendment) Regulations 2002 (S.I. No. 260 of 2002);
- (e) European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) (Amendment) Regulations 2003 (S.I. No. 488 of 2003);
- (f) European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) (Amendment) Regulations 2004 (S.I. No. 892 of 2004);
- (g) European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) (Amendment) Regulations 2005 (S.I. No. 174 of 2005), and
- (h) European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) (Amendment) Regulations 2008 (S.I. No. 94 of 2008).

(2) Any reference in the Regulations revoked under paragraph (1), or in any other enactment or an instrument made under an enactment to Commission Directive 96/77/EC² of 2 December 1996, as amended, or to any provision of that Directive shall be construed as a reference to the Commission Directive or

to a corresponding provision thereof in accordance with the correlation table set out in Annex III to the Commission Directive.

Schedule 1

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

European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) Regulations 2009

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 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,
23 July 2009.

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 effect to Commission Directive 2008/84/EC of 27 August 2008 laying down specific purity criteria on food additives other than colours and sweeteners, as amended by Commission Directive 2009/10/EC of 13 February 2009. The purity criteria set out in Annex I to Commission Directive 2008/84/EC consolidates those set out in Commission Directive 96/77/EC as amended, which latter directive has been repealed by Commission Directive 2008/84/EC.

These Regulations revoke the Regulations giving effect to Commission Directive 96/77/EC as amended, which has been consolidated by Commission Directive 2008/84/EC, namely:

- (a) European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) Regulations 1998 (S.I. No. 541 of 1998);
- (b) European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) (Amendment) Regulations 2000 (S.I. No. 438 of 2000);
- (c) European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) (Amendment) Regulations 2001 (S.I. No. 343 of 2001);
- (d) European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) (Amendment) Regulations 2002 (S.I. No. 260 of 2002);
- (e) European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) (Amendment) Regulations 2003 (S.I. No. 488 of 2003);
- (f) European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) (Amendment) Regulations 2004 (S.I. No. 892 of 2004);
- (g) European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) (Amendment) Regulations 2005 (S.I. No. 174 of 2005),
and
- (h) European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) (Amendment) Regulations 2008 (S.I. No. 94 of 2008).

These Regulations may be cited as the European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) Regulations 2009 and they come into effect on the date they were signed.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ón
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