



STATUTORY INSTRUMENTS.

**S.I. No. 268 of 2013**



EUROPEAN UNION (GENETICALLY MODIFIED FOODSTUFFS)  
REGULATIONS 2013

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I, JAMES REILLY, Minister for Health, 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 effect to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003<sup>1</sup> and Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003<sup>2</sup> in so far as such Regulations relate to foodstuffs, hereby make the following regulations:

**PART I****PRELIMINARY**

1. These Regulations may be cited as the European Union (Genetically Modified Foodstuffs) Regulations 2013.

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,
- (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 23;

“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;

“Directive” means Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001<sup>3</sup> on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC;

<sup>1</sup>OJ No. L 268, 18.10.2003, p. 1.

<sup>2</sup>OJ No. L 268, 18.10.2003, p. 24.

<sup>3</sup>OJ No. L 106, 17.4.2001, p. 1.

*Notice of the making of this Statutory Instrument was published in  
“Iris Oifigiúil” of 23rd July, 2013.*

“EC Regulation 1829/2003” means Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003<sup>1</sup> on genetically modified food and feed;

“EC Regulation 1830/2003” means Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003<sup>2</sup> concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms;

“EC Regulation 65/2004” means Commission Regulation (EC) No. 65/2004 of 14 January 2004<sup>4</sup> establishing a system for the development and assignment of unique identifiers for genetically modified organisms;

“EC Regulations” means EC Regulation 1829/2003, EC Regulation 1830/2003 and EC Regulation 65/2004;

“first stage of the placing on the market of a product” means the initial transaction in the production and distribution chains, where a product is made available to a third party;

“General Food Law Regulation” means Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002<sup>5</sup>;

“genetically modified organism” or “GMO” means genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex IB to that Directive;

“Minister” means the Minister for Health;

“official agency” means an official agency carrying out functions under a service contract and acting on behalf of the Authority pursuant to section 48 of the Act of 1998;

“Official Controls Regulation” means Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 29 April 2004<sup>6</sup>, as affected by the Corrigendum to Regulation (EC) No. 882/2004 of 28 May 2004<sup>7</sup>, as amended by Council Regulation (EC) No. 301/2008 of 17 March 2008<sup>8</sup>, Commission Regulation (EC) No. 1029/2008 of 20 October 2008<sup>9</sup>, Council Regulation (EC) No. 596/2009 of 18 July 2009<sup>10</sup> and Commission Regulation (EU) No. 208/2011 of 2 March 2011<sup>11</sup>;

“official laboratory” means—

<sup>4</sup>OJ No. L 10, 16.1.2004, p. 5.

<sup>5</sup>OJ No. L 31, 1.2.2002, p. 1.

<sup>6</sup>OJ No. L 165, 30.4.2004, p. 1.

<sup>7</sup>OJ No. L 191, 28.5.2004, p. 1.

<sup>8</sup>OJ No. L 97, 9.4.2008, p. 85.

<sup>9</sup>OJ No. L 278, 21.10.2008, p. 6.

<sup>10</sup>OJ No. L 188, 18.7.2009, p. 14.

<sup>11</sup>OJ No. L 58, 3.3.2011, p. 29.

(a) Public Analyst's Laboratory, Cork,

(b) A laboratory designated by the Minister pursuant to Regulation 23;

“produced from GMOs” means derived, in whole or in part, from GMOs, but not containing or consisting of GMOs;

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

“traceability” means the ability to trace GMOs and products produced from GMOs at all stages of their placing on the market through the production and distribution chains;

“unique identifier” means a simple numeric or alphanumeric code which serves to identify a GMO on the basis of the authorised transformation event from which it was developed and providing the means to retrieve specific information pertinent to that GMO.

(2) A word or expression which is used in these Regulations and which is also used in EC Regulation 1829/2003 or EC Regulation 1830/2003 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 Regulations 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 the Schedule is to the Schedule to these Regulations, unless it is indicated that reference to some other Regulations is intended.

(d) A reference in these Regulations to an Article is to the Article of the instrument indicated in the context of the reference.

3. The national competent authority for the purposes of the EC Regulations and for the purposes of these Regulations shall be the Authority.

## **PART 2**

### **GENERAL PROVISIONS FOR GENETICALLY MODIFIED FOOD (EC Regulation 1829/2003)**

4. In this Part—

“conventional counterpart” means a similar food produced without the help of genetic modification and for which there is a well-established history of safe use;

“genetically modified food” means food containing, consisting of or produced from GMOs;

“genetically modified organism for food use” means a GMO that may be used as food or as a source material for the production of food;

“operator” means the natural or legal person responsible for ensuring that the requirements of this Part and of EC Regulation 1829/2003 are met within the food businesses under its control;

“placing on the market” means the holding of food for the purpose of sale, including offering for sale, or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer themselves;

“pre-packaged food” means any single item for presentation as such consisting of a food and the packaging into which it was put before being offered for sale, whether such packaging encloses the food completely or only partially, provided that the contents cannot be altered without opening or changing the packaging.

5. This Part shall apply to—

- (a) GMOs for food use,
- (b) food containing or consisting of GMOs,
- (c) food produced from or containing ingredients produced from GMOs.

6. (1) A person is guilty of an offence if he or she places a GMO for food use or food referred to in Regulation 5 on the market, save where—

- (a) it is covered by an authorisation granted in accordance with EC Regulation 1829/2003,
- (b) the conditions of the authorisation are complied with.

(2) Where an authorisation has been issued in accordance with EC Regulation 1829/2003, the authorisation-holder is guilty of an offence if he or she fails to—

- (a) comply with any conditions or restrictions which have been imposed in the authorisation,
- (b) ensure that products not covered by the authorisation are not placed on the market as food.

(3) Where monitoring has been imposed, the authorisation-holder is guilty of an offence if he or she fails to—

- (a) ensure that the monitoring is carried out,

(b) submit reports to the Commission in accordance with the terms of the authorisation.

(4) An authorisation-holder is guilty of an offence if he or she fails to inform the Commission forthwith of—

(a) any new scientific or technical information which might influence the evaluation of the safety in use of the food,

(b) any prohibition or restriction imposed by the competent authority of any third country in which the food is placed on the market.

7. (1) Subject to paragraph (2), this Regulation shall apply where foods are to be delivered as such to the final consumer or mass caterers in the European Economic Area which—

(a) contain or consist of GMOs,

(b) are produced from or contain ingredients produced from GMOs.

(2) This Regulation shall not apply to foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0.9 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.

(3) In cases where paragraph (2) applies, for food containing or consisting of GMOs, or produced from or containing ingredients produced from GMOs as referred to in paragraph (1), it shall be an offence if an operator fails to supply evidence to satisfy the official agency that he or she has taken appropriate steps to avoid the presence of the genetically modified material.

(4) Subject to paragraph (5), and without prejudice to the other requirements of European Union law concerning the labelling of foodstuffs, where foods fall within the scope of this Regulation, an operator is guilty of an offence if he or she fails to ensure that—

(a) where the food consists of more than one ingredient, the words ‘genetically modified’ or ‘produced from genetically modified (name of the ingredient)’ appear in the list of ingredients provided for in Article 6 of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000<sup>12</sup> on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs in parentheses immediately following the ingredient concerned,

(b) where the ingredient is designated by the name of a category, the words ‘contains genetically modified (name of organism)’ or ‘contains (name of ingredient) produced from genetically modified (name of organism)’ appear in the list of ingredients,

<sup>12</sup>OJ No. L 109, 6.5.2000, p. 29.

- (c) where there is no list of ingredients, the words ‘genetically modified’ or ‘produced from genetically modified (name of organism)’ appear clearly on the labelling.

(5) The indications referred to in paragraphs (4)(a) and (b) may appear in a footnote to the list of ingredients and where they so appear, an operator is guilty of an offence if he or she fails to ensure that—

- (a) they are printed in a font of a least the same size as the list of ingredients, or,
- (b) where there is no list of ingredients, they appear clearly on the labelling.

(6) Where the food is offered for sale to the final consumer as—

- (a) non-pre-packaged food, or
- (b) pre-packaged food in small containers of which the largest surface has an area of less than 10cm<sup>2</sup>,

an operator is guilty of an offence if he or she fails to ensure that the information required in paragraphs (4) and (5), is permanently and visibly displayed either on the food display or immediately next to it, or on the packaging material, in a font sufficiently large for it to be easily identified and read.

(7) In addition to the labelling requirements referred to in paragraphs (4), (5) and (6), an operator is guilty of an offence if he or she fails to ensure that the labelling also mentions any characteristic or property, as specified in the authorisation, in the following cases:

- (a) where a food is different from its conventional counterpart as regards the following characteristics or properties—
  - (i) composition,
  - (ii) nutritional value or nutritional effects,
  - (iii) intended use of the food,
  - (iv) implications for the health of certain sections of the population,
- (b) where a food may give rise to ethical or religious concerns.

(8) In addition to the labelling requirements referred to in paragraphs (4), (5) and (6), and as specified in the authorisation, an operator is guilty of an offence if he or she fails to ensure that the labelling of foods referred to in paragraph (1), which do not have a conventional counterpart, contains appropriate information about the nature and the characteristics of the foods concerned.

(9) An operator is guilty of an offence if the information transmitted by him or her pursuant to this Regulation is partial, incomplete, false or misleading.

**PART 3****GENERAL PROVISIONS FOR TRACEABILITY AND LABELLING OF  
GENETICALLY MODIFIED ORGANISMS AND TRACEABILITY OF  
FOOD PRODUCED FROM GENETICALLY MODIFIED ORGANISMS  
(EC Regulation 1830/2003)**

8. In this Part—

“operator” means a natural or legal person who places a product on the market or who receives a product that has been placed on the market in the European Union, either from a Member State or from a third country, at any stage of the production and distribution chain, but does not include the final consumer;

“placing on the market” means placing on the market as defined in the specific European Union legislation under which the relevant product has been authorised; in other cases, it is defined as in Article 2(4) of Directive 2001/18/EC;

“pre-packaged product” means any single item offered for sale consisting of a product and the packaging into which it was put before being offered for sale, whether such packaging encloses the product completely or only partially, provided that the contents cannot be altered without opening or changing the packaging.

9. (1) Subject to paragraph (2), this Part shall apply, at all stages of the placing on the market, to—

- (a) products consisting of, or containing, GMOs, placed on the market in accordance with European Union legislation,
- (b) food produced from GMOs, placed on the market in accordance with European Union legislation.

(2) This Part does not apply to those medicinal products authorised under Regulation (EEC) No. 2309/93 of 22 July 1993<sup>13</sup>.

10. (1) Subject to paragraph (2) and to Regulation 14, an operator is guilty of an offence if he or she fails—

- (a) at the first stage of placing on the market of a product consisting of or containing GMOs, including bulk quantities, to transmit to the operator receiving the product information in writing—
  - (i) that the product contains or consists of GMOs,
  - (ii) the unique identifier(s) assigned to those GMOs in accordance with EC Regulation 65/2004.
- (b) at any subsequent stage of placing on the market of a product consisting of or containing GMOs, including bulk quantities, to transmit

<sup>13</sup>OJ No. L.214, 24.08.1993, p.1.



to the operator receiving the product, the information in writing required under paragraph (1)(a).

(2) Subject to Regulation 14 in the case of products consisting of or containing mixtures of GMOs to be used only and directly as food or for processing, the information referred to in paragraph (1), subparagraph (a)(ii) may be replaced by—

- (a) a declaration of use by the operator, accompanied by,
- (b) a list of the unique identifiers for all those GMOs that have been used to constitute the mixture.

(3) An operator is guilty of an offence if the information transmitted by him or her pursuant to this Regulation is partial, incomplete, false or misleading.

(4) Subject to Regulation 14 an operator is guilty of an offence if he or she fails to—

- (a) have systems and standardised procedures in place which allow for the holding of the information required under paragraphs (1) and (2),
- (b) maintain for a period of five years from each transaction, records of the identification of the operator from whom the products referred to in paragraph (1)(a) were received by the operator,
- (c) maintain for a period of five years from each transaction, records of the identification of the operator to whom the products referred to in paragraph (1)(a) were supplied by the operator.

(5) This Regulation shall be without prejudice to any other specific requirements in European Union legislation.

11. (1) An operator is guilty of an offence if he or she fails to ensure that—

- (a) for pre-packaged products consisting of, or containing GMOs, the words ‘This product contains genetically modified organisms’ or ‘This product contains genetically modified [name of organism(s)]’ appear on a label, or
- (b) for non-pre-packaged products consisting of, or containing GMOs, offered to the final consumer the words ‘This product contains genetically modified organisms’ or ‘This product contains genetically modified [name of organism(s)]’ appear on, or in connection with, the display of the product.

(2) This Regulation shall be without prejudice to any other specific requirements in European Union legislation.

12. (1) Regulations 10 and 11 shall not apply to traces of GMOs in products intended for direct use as food or for processing, in a proportion no higher than

0.9 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.

(2) In cases where paragraph (1) applies, for products intended for direct use as food or for processing as referred to in Regulation 9(1), it shall be an offence if an operator fails to supply evidence to satisfy the official agency that he or she has taken appropriate steps to avoid the presence of the genetically modified material.

13. (1) Subject to paragraph (4) and (5) and to Regulation 14, an operator is guilty of an offence if he or she fails, when placing products produced from GMOs on the market, to transmit in writing to the operator receiving the product—

- (a) an indication of each of the food ingredients which is produced from GMOs, or
- (b) in the case of products for which no list of ingredients exists, an indication that the product is produced from GMOs.

(2) Subject to paragraph (4) and (5) and to Regulation 14, an operator is guilty of an offence if he or she fails to—

- (a) have systems and standardised procedures in place which allow for the holding of the information required under paragraph (1),
- (b) maintain for a period of 5 years for each transaction, records of the identification of the operator from whom the products referred to in paragraph (1) were received by the operator,
- (c) maintain for a period of 5 years for each transaction, records of the identification of the operator to whom the products referred to in paragraph (1) were supplied by the operator.

(3) It is an offence for an operator to transmit or maintain information or records required by this Regulation which he or she knows to be false, incomplete or misleading.

(4) Paragraphs (1) and (2) of this Regulation shall be without prejudice to any other specific requirements in European Union legislation.

(5) This Regulation shall not apply to traces of GMOs in products for food produced from GMOs, in a proportion no higher than 0.9 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.

(6) In cases where paragraph (5) applies, for products intended for direct use as food or for processing as referred to in Regulation 9(1), it shall be an offence if an operator fails to supply evidence to satisfy the official agency that he or

she has taken appropriate steps to avoid the presence of the genetically modified material.

14. (1) Subject to paragraph (2), and in cases where European Union legislation provides for specific identification systems, such as lot numbering for pre-packaged products, operators shall not be obliged to hold the information specified in Regulation 10, paragraphs (1) and (2) and Regulation 13, paragraph (1), provided that this information and the lot number are clearly marked on the package and that information about lot numbers is held for 5 years from each transaction.

(2) This Regulation shall not apply to the first stage of placing on the market of a product or to primary manufacture or re-packaging of a product.

(3) Subject to paragraph (2) and in cases where paragraph (1) applies, an operator is guilty of an offence if he or she fails to—

(a) provide the information referred to in paragraph (1) clearly marked on the package,

(b) hold information on lot numbers for a period of five years from each transaction.

(4) It is an offence for an operator to provide or hold information or records required by this Regulation which he or she knows to be false, incomplete or misleading.

#### **PART 4**

#### **ENFORCEMENT**

15. (1) The enforcement of these Regulations and of the EC Regulations 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.

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

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

(3) Where an authorised officer purchases or takes without payment a sample of foodstuffs or a sample of any 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 foodstuffs or any 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 foodstuffs or a sample of any 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 foods or other substances, prohibit their removal except to any place which may be specified in the notice, during such period as may be specified in the notice, but not exceeding 15 working days from the date of the taking of the sample.

17. (1) Where a sample of foodstuffs or a sample of any 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 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 foodstuffs or a sample of any 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 foodstuffs or a sample of any 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.

18. (1) The approved examiner or a person under his or her direction shall analyse as soon as possible any sample of foodstuffs or a sample of any 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 the Schedule to these Regulations or a certificate in like form shall be used.

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

19. (1) Where a sample of foodstuffs or a sample of any 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.

(2) Where the certificate given in accordance with Regulation 18 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 or person in apparent control of such food, with a copy of the report referred to in paragraph (1).

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

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

21. (1) An authorised officer may, for the purposes of these Regulations, seize, remove or detain foodstuffs or other products, which are suspected by him or her of failing 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 foodstuffs 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 the food being used for human consumption.

(3) An authorised officer who has seized, removed or detained foodstuffs or other products in pursuance of the provisions of this Regulation may, on giving notice in writing to the food business operator, or the person in apparent charge,

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 such foods or 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 the food accordingly.

22. In the course of his or her duties, an authorised officer may require a person to state his or her name and address and, if the authorised officer thinks it necessary, to produce corroborative evidence of same.

23. 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.

24. (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 or to a person acting under such an officer's or examiner's express direction, acting in the course of his or her duties pursuant to these Regulations.

(3) A person is guilty of an offence if he or she:

- (a) obstructs or interferes with an authorised officer in the exercise of the officer's powers under these Regulations,
- (b) fails or refuses to state his or her name or address in compliance with a request under these Regulations,
- (c) fails to comply with a request or notice from an authorised officer under these Regulations,
- (d) makes a statement 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, an address or corroborative evidence which is false or misleading.

25. Where a body corporate, or a person acting on behalf of a body corporate, commits an offence under these Regulations and the offence is committed with

the consent, connivance or approval of, or is attributable to any neglect or default on the part of, any director, manager, secretary or any other officer of such body, or a person purporting to act in any such capacity, such person is also guilty of an offence and is liable to be proceeded against and punished as if he or she were guilty of the first-mentioned offence.

26. (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 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 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.

27. (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 who is guilty of an offence under these Regulations is liable:

(a) on summary conviction, to a class A fine 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) Where a person is convicted of an offence under these Regulations, the court shall, unless it is satisfied that there are special and substantial reasons for not so doing, order the person to pay to the Authority or the official agency, as the case may be, the costs and expenses, measured by the court, incurred by the Authority or official agency in relation to the investigation, detection and

prosecution of the offence, including costs and expenses incurred in the taking of samples, the carrying out of tests, examinations and analyses and in respect of the remuneration and other expenses of employees, consultants and advisors engaged by the Authority or official agency.

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

28. 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.



**SCHEDULE**

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

**European Union  
(Genetically Modified Foodstuffs) Regulations 2013**

***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.....

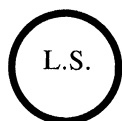
Status.....

Signature.....

..... Official Stamp

## NOTES

- (1) Insert the name and address of the person submitting the sample for analysis.
- (2) Insert description (e.g. Executive Analytical Chemist located at a Public Analyst's Laboratory).
- (3) Insert particulars of marking (e.g. name, date etc.).
- (4) This may be left unanswered if the sample cannot be conveniently weighed or measured or the weight or measurement is not material to the result of analysis.
- (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,  
19 July 2013.

JAMES REILLY,  
Minister for Health.

## EXPLANATORY NOTE

*(This note is not part of the Instrument and does not purport to be a legal interpretation.)*

These Regulations give effect to Regulation 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed and to Regulation 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organism. Part 2 of these Regulations gives effect to the provisions contained in the former Regulation, while Part 3 gives effect to the provisions contained in the latter.

These Regulations may be cited as the European Union (Genetically Modified Foodstuffs) Regulations 2013 and they come into effect on the date they were signed.

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