STATUTORY INSTRUMENTS.

S.I. No. 138 of 2015

EUROPEAN UNION (EMERGENCY MEASURES REGARDING UNAUTHORISED GENETICALLY MODIFIED RICE IN RICE PRODUCTS FOR FOOD USE ORIGINATING IN OR CONSIGNED FROM CHINA) REGULATIONS 2015

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EUROPEAN UNION (EMERGENCY MEASURES REGARDING UNAUTHORISED GENETICALLY MODIFIED RICE IN RICE PRODUCTS FOR FOOD USE ORIGINATING IN OR CONSIGNED FROM CHINA) REGULATIONS 2015

I, LEO VARADKAR, 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 Commission Implementing Decision 2011/884/EU of 22 December 2011[1], as amended by Commission Implementing Decision 2013/287/EU of 13 June 2013[2], insofar as it relates to food, hereby make the following regulations:

Part 1

Preliminary

Citation

1. These Regulations may be cited as the European Union (Emergency Measures Regarding Unauthorised Genetically Modified Rice in Rice Products for Food Use Originating in or Consigned from China) Regulations 2015.

Interpretation

2. (1) In these Regulations—

"Act of 1998" means the Food Safety Authority of Ireland Act 1998 (No. 29 of 1998);

"analytical report" means the analytical report required by Article 4 of EU Decision 2011/884/EU, a model for which is set out in Annex IV to that Decision, completed in English;

"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, or

(*d*) a person, or member of a class of persons, designated by the Minister pursuant to Regulation 8;

[1]OJ No. L 343, 23.12.2011, p. 140.
[2]OJ No. L 162, 14.6.2013, p. 10.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 24*th April*, 2015.

"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;

"China" means the People's Republic of China;

"consignment" means a quantity of rice products for food use originating in or consigned from China covered by Article 1(1) of, and Annex I to, EU Decision 2011/884/EU of the same class or description, covered by the same document(s), conveyed by the same means of transport and coming from China;

"designated point of entry (DPE)" means a particular point of entry designated by the State pursuant to Article 17 of EC Regulation 882/2004, and listed on the website www.fsai.ie for the purposes of importation of a product listed in Annex I to EU Decision 2011/884/EU; in cases of consignments arriving by sea, which are unloaded at a port in the State for the purposes of being loaded on another vessel for onwards transportation to a port in another Member State of the European Union, the designated point of entry shall be the latter port;

"EU Decision 2011/884/EU" means Commission Implementing Decision 2011/884/EU of 22 December 2011[1], as amended by Commission Implementing Decision 2013/287/EU of 13 June 2013[2];

"EC Regulation 669/2009" has the meaning assigned to it by Regulation 2(1) of the European Communities (Official Controls on the Import of Food of Non-Animal Origin) Regulations 2010 (S.I. No. 391 of 2010);

"food business operator" means a food business operator engaged in the import of rice products for food use covered by Article 1(1) of, and Annex I to, EU Decision 2011/884/EU;

"General Food Law Regulation" means Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002[3];

"health certificate" means the health certificate required by Article 4 of EU Decision 2011/884/EU, a model for which is set out in Annex III to that Decision, completed in English;

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

"lot" means a distinct and specified quantity of material;

"official agency" means the Health Service Executive, carrying out functions under these Regulations and EU Decision 2011/884/EU, pursuant to section 48 of the Act of 1998;

[3]OJ No. L 31, 1.2.2002, p. 1.

"Official Controls Regulation" means Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 29 April 2004[4], as affected by the Corrigendum to Regulation (EC) No. 882/2004 of 28 May 2004[5], as amended by Council Regulation (EC) No. 301/2008 of 17 March 2008[6], Commission Regulation (EC) No. 1029/2008 of 20 October 2008[7], Commission Regulation (EC) No. 596/2009 of 18 June 2009[8] and Commission Regulation (EU) No. 208/2011 of 2 March 2011[9];

"official detention" has the meaning assigned to it by Article 2(13) of the Official Controls Regulation;

"official laboratory" means—

(*a*) the Public Analyst's Laboratory, Cork, or

(*b*) a laboratory designated by the Minister pursuant to Regulation 8.

(2) A word or expression which is used in these Regulations and which is also used in EU Decision 2011/884/EU, the General Food Law Regulation, the Official Controls Regulation or EC Regulation 669/2009 has, unless the context otherwise requires, the same meaning in these Regulations as it has in EU Decision 2011/884/EU, the General Food Law Regulation, the Official Controls Regulation or EC Regulation 669/2009.

Food legislation

3. These Regulations shall be deemed to be food legislation for the purposes of the Act of 1998.

Part 2

General Provisions

Competent authority

4. The competent authority for the purposes of EU Decision 2011/884/EU and of these Regulations shall be the Authority, or the official agency, as appropriate.

Carrying out of official controls

5. The Authority or the official agency, as the case may be, shall carry out official controls on consignments of rice products for food use covered by EU Decision 2011/884/EU in accordance with that Decision and these Regulations.

Detention of consignments

6. The Authority or the official agency, as the case may be, may order the official detention of consignments of rice products for food use where that is required to fulfil its obligations under EU Decision 2011/884/EU and the place

[4]OJ No. L 165, 30.4.2004, p. 1.
[5]OJ No. L 191, 28.5.2004, p. 1.
[6]OJ No. L 97, 9.4.2008, p. 85.
[7]OJ No. L 278, 21.10.2008, p. 6.
[8]OJ No. L 188, 18.7.2009, p. 14.
[9]OJ No. L 58, 3.3.2011, p. 29.

and duration of such detention shall be determined by the Authority or the official agency, as appropriate.

Import conditions

7. (1) Subject to paragraphs (2), (3) and (5) in the case of consignments of rice products for food use originating in or consigned from China and covered by Article 1(1) of, and Annex I to, EU Decision 2011/884/EU—

(*a*) food business operators may only import consignments of such products into the State through the designated point of entry for the particular product;

(*b*) food business operators or their representatives shall, at least one working day prior to the physical arrival of a consignment of such products, notify the official agency at the designated point of entry of—

(i) the estimated date and time of the arrival,

(ii) the nature of the consignment, and

(iii) the designation of the product as food,

by completing and transmitting Part I of the common entry document, referred to in Annex II to EC Regulation 669/2009;

(*c*) consignments of such products shall be subject to official controls at designated points of entry, in accordance with Article 5 of EU Decision 2011/884/EU;

(*d*) food business operators shall, at the time of presentation for import into the State, present an analytical report for each lot, completed, signed and verified in accordance with Article 4(1) of EU Decision 2011/884/EU;

(*e*) food business operators shall, at the time of presentation for import into the State, present a health certificate, completed, signed and verified in accordance with Article 4(1) of EU Decision 2011/884/EU;

(*f*) food business operators shall ensure that sampling and analysis for the purposes of the analytical report referred to in sub-paragraph (*d*) is performed in accordance with Annex II to EU Decision 2011/884/EU;

(*g*) food business operators shall ensure that each consignment is identified with a code which corresponds to that appearing on the health certificate and each individual bag or other form of packaging of the consignment must be identified with that code;

(*h*) where such products are not accompanied by an analytical report and health certificate in accordance with any specific requirements in Article 4, the official agency shall order that the consignment be

recalled and placed under official detention without delay and that it then be either destroyed or re-dispatched to the country of origin in accordance with Article 5(2) of EU Decision 2011/884/EU;

(*i*) the release for free circulation of consignments of such products shall be subject to the confirmation that sampling and analysis has been performed in accordance with Annex II to EU Decision 2011/884/EU and all lots of that consignment are compliant with European Union law;

(*j*) food business operators shall not split consignments until all official controls have been completed by the official agency in accordance with Article 7 of EU Decision 2011/884/EU; and

(*k*) food business operators shall ensure that, where a consignment is subsequently split, an authenticated copy of the analytical report and the health certificate accompany each part of the consignment.

(2) Paragraph (1)(*d*), (*e*), (*f*) and (*h*) shall not apply to consignments of products for food use originating in or consigned from China and covered by Article 1(1) of, and Annex I to, EU Decision 2011/884/EU, but not containing, consisting of, or produced from rice, provided that a statement to that effect, completed in English, is provided by the food business operator in accordance with Article 4(2) of EU Decision 2011/884/EU.

(3) Paragraph (1) shall not apply to consignments of food which are destined to a private person for personal consumption and use only.

(4) It is the responsibility of the recipient of the consignment to prove that paragraph (3) applies.

(5) Paragraph (1)(*a*) and (*b*) shall not apply to consignments of products for food use originating in or consigned from China and covered by Article 1(1) of, and Annex I to, EU Decision 2011/884/EU, but not containing, consisting of, or produced from rice.

(6) The release for free circulation of consignments of products covered by, and tested in accordance with, Article 1(2) of EU Decision 2011/884/EU shall be subject to the confirmation that all lots of that consignment are compliant with Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003[10].

Part 3

Sampling and Analysis

Designation of laboratories and examiners

8. The Minister may, for the purposes of these Regulations, designate, by notice in writing published in *Iris Oifigiúil*:

[10]OJ No. L 268, 18.10.2003, p. 1.

(*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.

Carrying out of sampling and analysis

9. (1) Sampling and analysis for the official controls regarding unauthorised genetically modified organisms in rice products for food use originating in or consigned from China shall be carried out in accordance with the methods set out in Annex II to EU Decision 2011/884/EU.

(2) 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.

Taking of food samples

10. (1) An authorised officer may, for the purposes of these Regulations, purchase or take without payment a sample of food.

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

(3) Where an authorised officer purchases or takes without payment a sample of any food with the intention of having it analysed, he or she shall notify the food business operator or person in apparent charge or control of such food forthwith 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 food 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, 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.

(5) Samples of food taken for the purpose of these Regulations shall be taken in accordance with Annex II to EU Decision 2011/884/EU.

(6) Subject to paragraph (5), where an authorised officer purchases or takes without payment a sample of food, with the intention of having it analysed, he or she shall, in the presence of the food business operator or person in apparent charge or control of such food, 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 is not compromised and forward it to an approved examiner in an official laboratory for analysis.

(7) In proceedings for an offence under these Regulations, the result of analysis of a sample of food taken pursuant to these Regulations shall not be adduced unless the sample was taken in accordance with Annex II to EU Decision 2011/884/EU.

Analysis of food samples

11. (1) Where a sample of food is analysed for the purpose of these Regulations, the approved examiner, or a person under his or her direction, shall—

(*a*) issue to the food business operator, or the person in apparent charge or control of such food, a certificate in the form set out in Schedule 1, or a certificate in like form, confirming that the integrity of the sample has been preserved,

(*b*) prepare and sub-divide the sample in accordance with Annex II to EU Decision 2011/884/EU, and

(*c*) mark the enforcement sample, the trade (defence) sample and the referee sample in such a way as to identify them as a part of the sample taken by the authorised officer and forward the trade (defence) sample to the food business operator, or to the person in apparent charge or control of such food, in such a way that the integrity of the sample cannot be compromised.

(2) In proceedings for an offence under these Regulations, the result of analysis of food taken pursuant to these Regulations, shall not be adduced in evidence, unless the analysis was carried out in accordance with Annex II to EU Decision 2011/884/EU.

Analysis of sub-samples

12. (1) The approved examiner, or a person 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 2, or a certificate in like form, shall be completed.

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

Storage and transportation of food samples

13. Authorised officers and the approved examiners shall take all reasonable steps to ensure that samples taken under these Regulations are stored and transported in conditions that offer adequate protection from contamination and avoid any change in composition of the sample, which might arise during transportation or storage.

Part 4

Fees, Enforcement and Sanctions

Fees

14. (1) The Authority and the official agency shall, pursuant to Article 8 of EU Decision 2011/884/EU, set and charge fees to cover the costs occasioned by the official controls carried out pursuant to that Decision and these Regulations, including sampling, analysis, storage and any measures taken following non-compliance.

(2) The food business operator responsible for the particular consignment, or representatives thereof, shall pay the fees set pursuant to paragraph (1).

(3) A fee payable pursuant to this Regulation may be recovered by the Authority or the official agency from the person by whom it is payable as a simple contract debt in a court of competent jurisdiction.

(4) Moneys received under this Regulation shall be paid into or disposed of for the benefit of the Exchequer in accordance with the directions of the Minister for Finance.

(5) The Public Offices Fees Act 1879 (42 & 43 Vict. Cap 58) does not apply to a fee charged pursuant to this Regulation.

(6) The Authority or the official agency, as the case may be, may order that a consignment be destroyed, or otherwise disposed of, where a food business operator has failed to pay a fee charged pursuant to this Regulation in relation to said consignment and the Authority or official agency forms the view that the consignment has been abandoned.

Additional powers of authorised officers

15. In the course of his or her duties in enforcing these Regulations, 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.

Offences

16. (1) The offences provided for in these Regulations shall not apply to an authorised officer or 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.

(2) A person is guilty of an offence if he or she, by act or omission—

(*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;

(*e*) gives, in purported compliance with a request under these Regulations, a name, an address or corroborative evidence which is false or misleading;

(*f*) falsely represents himself or herself to be an authorised officer;

(*g*) imports a consignment into the State other than through the designated point of entry for the particular product, contrary to Regulation 7(1)(*a*);

(*h*) fails to notify the official agency at the designated point of entry of the physical arrival of the consignment in accordance with Regulation 7(1)(*b*);

(*i*) imports a consignment but fails to submit an analytical report in accordance with Regulation 7(1)(*d*);

(*j*) imports a consignment but fails to submit a health certificate in accordance with Regulation 7(1)(*e*);

(*k*) imports a consignment but fails to perform sampling and analysis for the purposes of the analytical report in accordance with Regulation 7(1)(*f*);

(*l*) fails to fully and properly identify a consignment with a code, in accordance with Regulation 7(1)(*g*);

(*m*) provides misleading information in relation to a proposed re-dispatch of a consignment under Regulation 7(1)(*h*);

(*n*) releases for free circulation in the State, a consignment not having presented to the customs authorities, confirmation by the official agency in relation to the consignment under Regulation 7(1)(*i*);

(*o*) releases for free circulation in the State, a consignment not having presented to the customs authorities, confirmation by the official agency in relation to the consignment under Regulation 7(6);

(*p*) splits a consignment, contrary to Regulation 7(1)(*j*);

(*q*) fails to ensure that an authenticated copy of the analytical report and the health certificate accompany each part of the consignment in accordance with Regulation 7(1)(*k*);

(*r*) imports into the State a consignment of products to which Regulation 7(2) applies without providing the statement required by that Regulation;

(*s*) forges, or utters knowing it to be forged, any document purporting to be issued, granted or given under these Regulations, or required for the purposes of these Regulations ("a forged document");

(*t*) alters with intent to defraud or deceive, or utters knowing it to be so altered, any document issued, granted or given under these Regulations, or required for the purposes of these Regulations ("an altered document");

(*u*) has in his or her possession, without lawful authority, a forged document or an altered document, knowing it to be a forged or altered document as the case may be;

(*v*) tampers with any substance or thing with intent to defraud or deceive and with the result that a sample taken pursuant to these Regulations does not correctly represent the substance sampled;

(*w*) tampers or interferes with any sample taken under these Regulations, with intent to defraud or deceive,

(*x*) fails to pay a fee payable pursuant to Regulation 14.

(3) 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.

(4) For the purposes of these Regulations, every contravention of a provision of these Regulations shall be deemed a separate contravention and every contravention of a paragraph or a subparagraph of such provision shall also be deemed to be a separate contravention and shall carry the same penalty as for a single contravention of any such provision.

(5) 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 6 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.

(6) 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.

(7) An order for costs and expenses under paragraph (6) is in addition to, and not instead of, any fine or penalty the court may impose under paragraph (5).

Prosecution of offences

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

(*a*) the Authority, or

(*b*) the official agency.

Schedule 1

Regulation 11(1)(a)

Form of certificate of integrity of sample

European Union (Emergency Measures Regarding Unauthorised Genetically Modified Rice in Rice Products for Food Use Originating in or Consigned from China) Regulations 2015

Certificate of Integrity of Sample

To(1) .....

I, the undersigned(2).....

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

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

a sample marked(3).....

Date.....

Number.....

Weight or Measure(4).....

was submitted to me by an authorised officer(5)..... and I certify that the seal 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(6).....

Name in BLOCK LETTERS.....

Status.....

Signature.....

Official Stamp

NOTES

(1) Insert the name and address of the food business operator.

(2) Insert description (e.g. Public Analyst 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.

(5) Insert the name of the authorised officer who submitted the sample.

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

Schedule 2

Regulation 12(2)

Form of certificate of analysis

European Union (Emergency Measures Regarding Unauthorised Genetically Modified Rice in Rice Products for Food Use Originating in or Consigned from China) Regulations 2015

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[4].....

was submitted to me by you and I certify that the sample was prepared and analysed/examined by me or under my direction[5]

and as a result I am of the opinion that[6]

Observations:[7]

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[8].....

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. Public Analyst 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) 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.

(6) Here the approved examiner should specify the result of the analysis having regard to the provisions of the relevant legislation.

(7) 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 such other observations as he or she may consider relevant.

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

L.S.

GIVEN under my Official Seal,
16 April 2015.

LEO VARADKAR,
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 partial effect to Commission Implementing Decision 2011/884/EU of 22 December 2011 on emergency measures regarding unauthorised genetically modified rice in rice products originating in or consigned from China and repealing Decision 2008/798/EC, as amended by Commission Implementing Decision 2013/287/EU of 13 June 2013.

These Regulations may be cited as the European Union (Emergency Measures Regarding Unauthorised Genetically Modified Rice in Rice Products for Food Use Originating in or Consigned from China) Regulations 2015.

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