STATUTORY INSTRUMENTS.

S.I. No. 474 of 2012

EUROPEAN UNION (MICROBIOLOGICAL CRITERIA FOR FOODSTUFFS) REGULATIONS 2012

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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 further effect to Commission Regulation (EC) No. 2073/2005 of 15 November 2005[1] on microbiological criteria for foodstuffs as amended by Commission Regulation (EC) No. 1441/2007 of 5 December 2007[2], Commission Regulation (EU) No. 365/2010 of 28 April 2010[3] and Commission Regulation (EU) No. 1086/2011 of 27 October 2011[4], hereby make the following regulations—

PART I

Preliminary

1. (1) These Regulations may be cited as the European Union (Microbiological Criteria for Foodstuffs) Regulations 2012.

(2) These Regulations apply to all food business operators involved in the processing, manufacturing, handling and distribution of food, including retailers and caterers with the exception of those food businesses engaged in activities which are subject to the European Communities (Food and Feed Hygiene) Regulations 2009 (S.I. No. 432 of 2009), only to the extent that the food business engages in those activities.

2. (1) In these Regulations—

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

"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;

"compliance with microbiological criteria" means obtaining satisfactory or acceptable results set in Annex I to the EU Regulation when testing against the values set for the criteria through the taking of samples, the conduct of analyses

[1]OJ L No. 338, 22.12.2005, p.1.
[2]OJ L No. 322, 7.12.2007, p.12.
[3]OJ L No. 107, 29.4.2010, p.9.
[4]OJ L No. 281, 28.10.2011, p.7.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 4*th December*, 2012.

and the implementation of corrective action, in accordance with food law and the instructions given by the official agency;

"EU Regulation" means Commission Regulation (EC) No. 2073/2005 of 15 November 2005[1] on microbiological criteria for foodstuffs as amended by Commission Regulation (EC) No. 1441/2007 of 5 December 2007[2], Commission Regulation (EU) No. 365/2010 of 28 April 2010[3] and Commission Regulation (EU) No. 1086/2011 of 27 October 2011[4];

"food business operator" means a food business operator as defined in the General Food Law Regulation, insofar as such operator has responsibility for—

(*a*) any stage of production, processing or distribution of—

(i) food of non-animal origin,

(ii) food of animal origin sold directly to the final consumer except if the sale or supply is from an establishment registered or approved under the European Communities (Food and Feed Hygiene) Regulations 2009 (S.I. No. 432 of 2009),

(iii) food of animal origin insofar as the food business supplies such food from a retail establishment to other retail establishments where such supply is a marginal, localised and restricted activity as defined in national law, or

(iv) food containing both products of plant origin and processed products of animal origin, or

(*b*) the import or export of foods of non-animal origin or food containing both products of plant origin and processed products of animal origin,

or any related activities;

"food safety criterion" means a criterion defining the acceptability of a product or a batch of foodstuff applicable to products placed on the market;

"General Food Law Regulation" means Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002[5];

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

"manufacture" includes the production and processing of food, other than primary production for private domestic use and domestic preparation, handling and storage of food for private domestic consumption, and cognate words shall be construed accordingly;

"microbiological criterion" means a criterion defining the acceptability of a product, a batch of foodstuffs or a process, based on the absence, presence or

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

number of micro-organisms, and/or on the quantity of their toxins/metabolites, per unit(*s*) of mass, volume, area or batch;

"official agency" means the Health Service Executive, 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[6], as affected by the Corrigendum to Regulation (EC) No. 882/2004 of 28 May 2004[7], as amended by Council Regulation (EC) No. 301/2008 of 17 March 2008[8], Commission Regulation (EC) No. 1029/2008 of 20 October 2008[9], Regulation (EC) No. 596/2009 of 18 June 2009[10] and Commission Regulation (EU) No. 208/2011 of 2 March 2011[11];

"process hygiene criterion" means a criterion indicating the acceptable functioning of the production process. Such a criterion is not applicable to products placed on the market. It sets an indicative contamination value above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law;

"service contract" means a contract entered into between the Authority and the official agency pursuant to section 48 of the Act of 1998.

(2) A word or expression which is used in these Regulations and which is also used in the EU Regulation or in the General Food Law Regulation has, unless the context otherwise requires, the same meaning in these Regulations as it has in the EU Regulation or in the General Food Law Regulation.

(3) (*a*) A reference in these Regulations to a Regulation is to a Regulation of these Regulations, unless it is indicated that reference to some other Regulations is intended.

(*b*) A reference in these Regulations to a paragraph or subparagraph is to the paragraph or subparagraph of the provision in which the reference occurs, unless it is indicated that reference to some other provision is intended.

(*c*) A reference in these Regulations to an Article is to an Article of the EU Regulation, unless it is indicated that reference to some other instrument is intended.

[6]OJ L 165, 30.4.2004, p.1.
[7]OJ L 191, 28.5.2004, p.1.
[8]OJ L 97, 9.4.2008, p.85.
[9]OJ L 278, 21.10.2008, p.6.
[10]OJ L 188, 18.7.2009, p.14.
[11]OJ L 58, 3.3.2011, p.29.

PART 2

GENERAL PROVISIONS

3. The competent authority for the purposes of the EU Regulation and of these Regulations shall be—

(*a*) the Authority, or

(*b*) the official agency where these Regulations provide for the execution of a competent authority function under the EU Regulation by such an agency.

4. The official agency shall verify compliance with the rules and criteria laid down in the EU Regulation, in accordance with the Official Controls Regulation, without prejudice to its right to undertake further sampling and analyses for the purpose of detecting and measuring other micro-organisms, their toxins or metabolites, either as a verification of processes, for food suspected of being unsafe, or in the context of a risk analysis. This Regulation applies without prejudice to other specific rules for the control of micro-organisms set out in other European Union legislation and any corresponding national regulations.

5. (1) Food business operators shall take measures, at each stage of production, processing, and distribution, including retail, to ensure that foodstuffs comply with the relevant microbiological criteria set out in Annex I to the EU Regulation as part of their procedures based on HACCP (Hazard Analysis and Critical Control Point) principles and good hygiene practice, to ensure that:

(*a*) the supply, handling and processing of raw materials and foodstuffs under their control are carried out in such a way that the process hygiene criteria are met, and

(*b*) the food safety criteria applicable throughout the shelf-life of the products can be met under reasonably foreseeable conditions of distribution, storage and use.

(2) A food business operator is guilty of an offence if—

(*a*) he or she fails to ensure (in accordance with Article 3) that foodstuffs comply with the relevant microbiological criteria set out in Annex I to the EU Regulation, or

(*b*) he or she fails to meet (in the context set out in Article 3) the process hygiene criteria and food safety criteria laid down in Annex I to the EU Regulation.

6. (1) Where necessary, food business operators responsible for the manufacture of the product shall conduct studies in accordance with Annex II to the EU Regulation in order to investigate compliance with the criteria throughout the shelf-life. In particular, this is applicable to ready-to-eat foods that are able

to support the growth of *Listeria monocytogenes* and that may pose a *Listeria monocytogenes* risk for public health.

(2) A food business operator responsible for the manufacture of the product is guilty of an offence if he or she fails to conduct the studies in the manner required in paragraph (1).

7. (1) Food business operators shall perform testing, as appropriate, against the microbiological criteria set out in Annex I to the EU Regulation, as part of validation and verification of the correct functioning of their procedures based on HACCP principles and good hygiene practice.

(2) Food business operators shall decide the appropriate sampling frequencies, save in relation to certain food business operators where Annex I to the EU Regulation so specifies the sampling frequencies. In such cases the sampling frequency shall be as a minimum that provided for in Annex I to the EU Regulation. Food business operators shall make this decision in the context of their procedures based on HACCP principles and good hygiene practice, taking into account the instructions for use of the foodstuff.

(3) The frequency of sampling may be adapted to the nature and size of the food businesses, provided that the safety of foodstuffs will not be endangered.

(4) Food business operators producing minced meat, meat preparations and mechanically separated meat in small establishments, when justified on the basis of risk analysis and consequently authorised by the official agency, may be exempted from the sampling frequencies required by this Regulation.

(5) Subject to paragraph 4, a food business operator is guilty of an offence if he or she fails—

(*a*) to perform testing, as appropriate, against the microbiological criteria set out in Annex I to the EU Regulation, as part of validation and verification of the correct functioning of their procedures based on HACCP principles and good hygiene practice,

(*b*) to adhere to the sampling frequency requirements and obligations set out in paragraph (2),

(*c*) to ensure that the safety of foodstuffs will not be endangered when adapting the frequency of sampling as envisaged by paragraph (3),

(*d*) in any other way to comply with Article 4.

8. (1) Subject to paragraphs (3), (5), (7) and (8) the analytical methods and the sampling plans and methods in Annex I to the EU Regulation shall be applied as reference methods.

(2) (*a*) Samples shall be taken from processing areas and equipment used in food production, when such sampling is necessary for ensuring that

the criteria are met. In that sampling, the ISO standard 18593 shall be used as a reference method.

(*b*) Food business operators manufacturing ready-to-eat foods, which may pose a *Listeria monocytogenes* risk for public health, shall sample the processing areas and equipment for *Listeria monocytogenes* as part of their sampling scheme.

(*c*) Food business operators manufacturing dried foods for special medical purposes intended for infants below six months which pose an *Enterobacter sakazakii* (also known as *Cronobacter* spp) risk shall monitor the processing areas and equipment for Enterobacteriaceae as part of their sampling scheme.

(3) A food business operator may reduce the number of sample units of the sampling plans set out in Annex I to the EU Regulation if that food business operator can show by historical documentation, to the satisfaction of the official agency that it has effective HACCP-based procedures.

(4) Where the purpose of testing is to specifically assess the acceptability of a certain batch of foodstuffs or a process, the sampling plans set out in Annex I to the EU Regulation shall be followed as a minimum.

(5) Food business operators may use other sampling and testing procedures, where he or she can demonstrate to the satisfaction of the official agency that the alternative procedures provide at least equivalent guarantees. This may include alternative sampling sites and use of trend analyses.

(6) Testing against alternative micro-organisms and related microbiological limits as well as testing of analytes other than microbiological ones, shall be permitted for process hygiene criteria only.

(7) The use of alternative analytical methods is acceptable when the methods are validated against the reference method in Annex I to the EU Regulation and if a proprietary method, certified by a third party in accordance with EN/ISO standard 16140 or similar internationally accepted protocol, is used.

(8) If a food business operator wishes to use analytical methods other than those validated and certified as set out in paragraph (7), the methods shall be validated in accordance with internationally accepted protocols, and their use shall be authorised by the official agency.

(9) Without prejudice to paragraphs (3), (5), (7) and (8), a food business operator is guilty of an offence if the food business operator fails–

(*a*) to adhere to the reference methods set out in Annex I to the EU Regulation or the ISO standard 18593 where required by Article 5,

(*b*) to sample the processing areas and equipment for *Listeria monocytogenes* as part of their sampling scheme in the case of a food business

operator manufacturing ready-to-eat foods which may pose a *Listeria monocytogenes* risk for public health,

(*c*) to monitor the processing areas and equipment for Enterobacteriaceae as part of its sampling scheme in the case of a food business operator manufacturing dried foods for special medical purposes intended for infants below six months which pose an *Enterobacter sakazakii* (also known as *Cronobacter* spp) risk,

(*d*) to respect the sampling plans set out in Annex I to the EU Regulation as a minimum where the aim of the testing is to specifically assess the acceptability of a certain batch of foodstuffs or a process,

(*e*) in any other way to comply with Article 5.

9. (1) When the requirements for *Salmonella* in minced meat, meat preparations and meat products of all species other than poultrymeat intended to be eaten cooked, set down in Annex I to the EU Regulation are fulfilled, the batches of those products placed on the market must be clearly labelled by the manufacturer in order to inform the consumer of the need for thorough cooking prior to consumption.

(2) A manufacturer shall be guilty of an offence if the manufacturer fails to comply with the labelling obligations set out in paragraph (1).

10. (1) (*a*) Food business operators shall, when results of testing against the criteria set out in Annex I to the EU Regulation are unsatisfactory, take the measures set out in paragraphs (2) and (3) of this Regulation together with other corrective actions defined in their HACCP-based procedures and other actions necessary to protect the health of consumers.

(*b*) Food business operators shall also take measures to find the cause of the unsatisfactory results in order to prevent the recurrence of the unacceptable microbiological contamination. Those measures may include modifications to the HACCP-based procedures or other food hygiene control measures in place.

(2) (*a*) Subject to sub-paragraphs (*b*) and (*c*), when testing against food safety criteria set out in Chapter 1 of Annex I to the EU Regulation provides unsatisfactory results, the product or batch of foodstuffs shall be withdrawn or recalled in accordance with Article 19 of the General Food Law Regulation.

(*b*) Products placed on the market, which are not yet at retail level and which do not fulfil the food safety criteria, may be submitted to further processing by a treatment eliminating the hazard in question. This treatment may only be carried out by food business operators other than those at retail level.

(*c*) The food business operator may use the batch for purposes other than those for which it was originally intended, provided that this use does not pose a risk for public or animal health and that this use has been decided within the procedures based on HACCP principles and good hygiene practise and authorised by the official agency.

(3) In the event of unsatisfactory results as regards process hygiene criteria, the actions laid down in Chapter 2 of Annex I to the EU Regulation shall be taken.

11. (1) Save in the circumstances provided for in Section 10 (2) (*b*) and (*c*), a food business operator is guilty of an offence when testing against the food safety criteria set out in Chapter 1 of Annex I to the EU Regulation provides unsatisfactory results and the food business operator fails to—

(*a*) initiate procedures to withdraw the product or batch of foodstuffs which is the subject of the unsatisfactory results,

(*b*) ensure that the product or batch of foodstuffs which is the subject of the unsatisfactory results is withdrawn,

(*c*) inform the Authority or the official agency of the initiation of procedures to withdraw the product or batch of foodstuffs which is the subject of the unsatisfactory results,

(*d*) where the product may have reached the consumer, effectively and accurately inform consumers of the reasons for withdrawal of the product or batch of foodstuffs which is the subject of the unsatisfactory results, or

(*e*) recall products or batch of foodstuffs which are the subject of the unsatisfactory results from consumers,

in accordance with Article 19(1) of the General Food Law Regulation.

(2) A food business operator is guilty of an offence when results of testing against the criteria set out in Annex I to the EU Regulation are unsatisfactory and he or she fails—

(*a*) to implement other corrective actions defined in their HACCP-based procedures and other actions necessary to protect the health of consumers in the event of unsatisfactory results,

(*b*) to take measures to find the cause of the unsatisfactory results in order to prevent the recurrence of the unacceptable microbiological contamination,

(*c*) to take the actions required in Chapter 2 of Annex I to the EU Regulation as regards process hygiene criteria, or

(*d*) in any other way to comply with Article 7.

(3) Where the Authority or the official agency forms the view that a food business operator should be taking measures pursuant to Article 19 of the General Food Law Regulation, but is failing to do so, the Authority, or the official agency, or both, may take action pursuant to Regulation 16.

12. (1) Food business operators shall analyse trends in the test results and take appropriate action if there is a trend towards unsatisfactory results. The appropriate actions shall be taken without undue delay to remedy the situation in order to prevent the occurrence of microbiological risks.

(2) A food business operator is guilty of an offence if the food business operator fails to comply with the obligations set out in paragraph (1).

PART 3

Enforcement

13. (1) The enforcement of these Regulations and of the EU Regulation shall be carried out in accordance with the provisions of these Regulations.

(2) These Regulations shall be deemed to be food legislation for the purposes of the Act of 1998.

(3) These Regulations shall be enforced by the Authority or by the official agency acting pursuant to a service contract with the Authority, or by both, and, without prejudice to paragraph (1), the enforcement provisions contained in the Act of 1998 shall apply for the purposes of ensuring compliance with the requirements of these Regulations.

14. 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.

15. Without prejudice to the provisions of the Official Controls Regulation and S.I. No. 117 of 2010, official sampling and analysis for the purpose of verifying compliance with the microbiological criteria for foodstuffs laid down in the EU Regulation shall be carried out in accordance with the specific rules for testing and sampling in Article 5.

16. An authorised officer may, for the purposes of these Regulations, seize, remove, detain or direct the withdrawal from the market of any food where he or she suspect that the food fails to comply with the relevant provisions of the EU Regulation, or where a food business operator has failed to take measures pursuant to Article 19 of the General Food Law Regulation, which in the view of the Authority or the official agency, or both, should have been taken.

17. (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 he or she 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.

18. 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.

19. (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.

20. (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 subsection (2).

21. 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.

L.S.

GIVEN under my Official Seal,
29 November 2012.

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 further effect to Commission Regulation (EC) No. 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs as amended by Commission Regulation (EC) No. 1441/2007 of 5 December 2007, Commission Regulation (EU) No. 365/2010 of 28 April 2010 and Commission Regulation (EU) No. 1086/2011 of 27 October 2011.

The principal effect of these Regulations is that it lays down microbiological food safety criteria and process hygiene criteria for certain important foodborne bacteria, their toxins and metabolites.

These Regulations may be cited as the European Union (Microbiological Criteria for Foodstuffs) Regulations 2012.

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