STATUTORY INSTRUMENTS.

S.I. No. 425 of 2020

EUROPEAN UNION (MICROBIOLOGICAL CRITERIA FOR FOODSTUFFS) (AMENDMENT) REGULATIONS 2020

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I, STEPHEN DONNELLY, 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 (EU) No. 1086/2011 of 27 October 2011[1] as affected by Corrigendum of 13 March 2015[2], Commission Regulation (EU) 2015/2285 of 8 December 2015[3], Commission Regulation (EC) No. 1441/2007 of 5 December 2007[4] as affected by Corrigendum of 20 July 2016[5], Commission Regulation (EU) No. 1019/2013 of 23 October 2013[6] as affected by Corrigendum of 20 July 2016[7], Commission Regulation (EU) 2019/229 of 7 February 2019[8] and Commission Regulation (EU) 2020/205 of 14 February 2020[9], hereby make the following regulations:

1. (1) These Regulations may be cited as the European Union (Microbiological Criteria for Foodstuffs) (Amendment) Regulations 2020.

(2) The Principal Regulations, the European Union (Microbiological Criteria for Foodstuffs) (Amendment) Regulations 2013 (S.I. No. 301 of 2013), the Regulations of 2014 and these Regulations may be cited together as the European Union (Microbiological Criteria for Foodstuffs) Regulations 2012 to 2020.

2. In these Regulations—

"Principal Regulations" means the European Union (Microbiological Criteria for Foodstuffs) Regulations 2012 (S.I. No. 474 of 2012);

"Regulations of 2014" means the European Union (Microbiological Criteria for Foodstuffs) (Amendment) Regulations 2014 (S.I. No. 15 of 2014).

3. Regulation 2(1) (as amended by Regulation 3 of the Regulations of 2014) of the Principal Regulation is amended by substituting for the definition of "EU Regulation" the following:

> "'EU Regulation' means Commission Regulation (EC) No. 2073/2005 of 15 November 2005[10], as amended by Commission Regulation (EC)

[1] OJ No. L 281, 28.10.2011, p. 7.
[2] OJ No. L 68, 13.3.2015, p. 90.
[3] OJ No. L 323, 9.12.2015, p. 2.
[4] OJ No. L 322, 7.12.2007, p. 12.
[5] OJ No. L 195, 20.7.2016, p. 82.
[6] OJ No. L 282, 24.10.2013, p. 46.
[7] OJ No. L 195, 20.7.2016, p. 83.
[8] OJ No. L 37, 8.2.2019, p. 106.
[9] OJ No. L 43, 17.2.2020, p. 63.
[10] OJ No. L 338, 22.12.2005, p. 1.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 30*th October,* 2020.

No. 1441/2007 of 5 December 2007[4] (as affected by Corrigendum of 20 July 2016[5]), Commission Regulation (EU) No. 365/2010 of 28 April 2010[11], Commission Regulation (EU) No. 1086/2011 of 27 October 2011[1] (as affected by Corrigendum of 13 March 2015[2]), Commission Regulation (EU) No. 209/2013 of 11 March 2013[12], Commission Regulation (EU) No. 1019/2013 of 23 October 2013[6] (as affected by Corrigendum of 20 July 2016[7]), Commission Regulation (EU) 2015/2285 of 8 December 2015[3], Commission Regulation (EU) 2019/229 of 7 February 2019[8] and Commission Regulation (EU) 2020/205 of 14 February 2020[9];".

4. Regulation 8 of the Principal Regulations is amended—

(*a*) in paragraph (1), by substituting "paragraphs (3), (5), (7), (7A), (7B) and (8)" for "paragraphs (3), (5), (7) and (8)",

(*b*) by substituting for paragraph (2)(c) the following:

"(*c*) Food business operators manufacturing dried infant formulae or dried foods for special medical purposes intended for infants below six months, which pose a *Cronobacter* spp. risk shall monitor the processing areas and equipment for Enterobacteriaceae as part of their sampling scheme.",

(*c*) by substituting for paragraph (7) the following paragraphs:

"(7) The use of alternative analytical methods is acceptable provided they are—

(*a*) validated against the specific reference method provided for in Annex I to the EU Regulation in accordance with the protocol set out in standard EN ISO 16140-2, and

(*b*) validated for the food category specified in the relevant microbiological criterion set in Annex I to the EU Regulation the compliance with which is verified by the food business operator, or validated for a broad range of food as referred to in EN ISO 16140-2.

(7A) Proprietary methods may be used as alternative analytical methods, provided they are—

(*a*) validated, in accordance with the protocol set out in standard EN ISO 16140-2, against the specific

[11] OJ No. L 107, 29.4.2010, p. 9.
[12] OJ No. L 68, 12.3.2013, p. 19.

reference method provided for verifying compliance with the microbiological criteria laid down in Annex I to the EU Regulation, as provided for in paragraph (7), and

(*b*) certified by an independent certification body.

(7B) The certification of the proprietary method referred to in paragraph (7A)(b) shall—

(*a*) be subject, at least every 5 years, to reassessment through renewal procedures,

(*b*) show that the production process assurance of the manufacturer was evaluated, and

(*c*) include a summary of or a reference to the validation results of the proprietary method and a statement on the quality management of the production process of the method.",

(*d*) in paragraph (8), by substituting "paragraphs (7), (7A) and (7B)" for "paragraph (7)", and

(*e*) in paragraph (9) —

(i) by substituting "paragraphs (3), (5), (7), (7A), (7B) and (8)" for "paragraphs (3), (5), (7) and (8)", and

(ii) by substituting for subparagraph (c) the following:

"(*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 infant formulae or dried foods for special medical purposes intended for infants below six months which pose a *Cronobacter* spp. risk,".

5. The Principal Regulations are amended by inserting after Regulation 21 the following Regulation:

"22. Notwithstanding Regulations 8 and 17(1), a food business operator is not guilty of an offence if, on or before 31 December 2021, he or she uses the alternative analytical methods referred to in Regulation 8(7) prior to its amendment by Regulation 4(c) of the European Union (Microbiological Criteria for Foodstuffs) (Amendment) Regulations 2020 (S.I. No. 425 of 2020).".

GIVEN under my Official Seal,
27 October, 2020.

STEPHEN DONNELLY,
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 (1) Commission Regulation (EU) 2015/2285 of 8 December 2015 amending Annex I to Commission Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs insofar as it relates to food safety criteria for live bivalve molluscs, echinoderms, tunicates and marine gastropods, (2) Commission Regulation (EU) 2019/229 of 7 February 2019 amending Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs as regards certain methods, the food safety criterion for Listeria monocytogenes in sprouted seeds, and the process hygiene criterion and food safety criterion for unpasteurised fruit and vegetable juices (ready-to-eat) and (3) Commission Regulation (EU) 2020/205 of 14 February 2020 amending Regulation (EC) No. 2073/2005 as regards Salmonella in reptile meat. They also give effect to three corrigenda correcting previous amending Commission Regulations.

These Regulations amend the European Union (Microbiological Criteria for Foodstuffs) Regulations 2012 (S.I. No. 474 of 2012) in the manner specified in these Regulations.

These Regulations may be cited as the European Union (Microbiological Criteria for Foodstuffs) (Amendment) Regulations 2020.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ó
FOILSEACHÁIN RIALTAIS,
52 FAICHE STIABHNA, BAILE ÁTHA CLIATH 2,
D02 DR67.

Teil: 076 110 6834
r-post: publications@opw.ie

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