STATUTORY INSTRUMENTS.

S.I. No. 226 of 2026

EUROPEAN COMMUNITIES (FOOD SUPPLEMENTS) (AMENDMENT) REGULATIONS 2026

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I, JENNIFER CARROLL MACNEILL, 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 Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002[1], and full effect to Commission Regulation (EU) 2024/248 of 16 January 2024[2], Commission Regulation (EU) 2024/1821 of 25 June 2024[3], Commission Regulation (EU) 2025/352 of 21 February 2025[4], Commission Regulation (EU) 2025/2224 of 5 November 2025[5], and Commission Regulation (EU) 2025/2225 of 5 November 2025[6], hereby make the following regulations:

1. These Regulations may be cited as the European Communities (Food Supplements) (Amendment) Regulations 2026.

2. In these Regulations "Principal Regulations" means European Communities (Food Supplements) Regulations 2007 (S.I. No. 506 of 2007).

3. Regulation 2(1) of the Principal Regulations is amended -

(a) after the definition of "Act of 1998", by inserting the following:

'"'Annex I' means Annex I to Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002[1], as amended by Commission Regulation (EC) No. 1170/2009 of 30 November 2009[7] and Commission Regulation (EC) 2021/418 of 9 March 2021[8];

'Annex II' means Annex II to Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002[1], as amended by Commission Regulation (EC) No. 1170/2009 of 30 November 2009[7], Commission Regulation (EC) No. 1161/2011 of 14 November 2011[9], Commission Regulation (EC) No. 119/2014 of 7 February 2014[10], Commission Regulation (EC) 2015/414 of 12 March 2015[11], Commission Regulation (EC)

[1] OJ No. L 183 12.7.2002, p. 51.
[2] OJ L, 2024/248, 17.1.2024.
[3] OJ L, 2024/1821, 27.6.2024.
[4] OJ L, 2025/352, 24.2.2025.
[5] OJ L, 2025/2224, 6.11.2025.
[6] OJ L, 2025/2225, 6.11.2025.
[7] OJ No. L 314, 1.12.2009, p. 36.
[8] OJ No. L 83, 10.3.2021, p. 1.
[9] OJ No. L 296, 15.11.2011, p. 29.
[10] OJ No. L 39, 8.2.2014, p. 44.
[11] OJ No. L 68, 13.3.2015, p. 26.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 29*th May,* 2026.

2017/1203 of 5 July 2017[12], Commission Regulation (EC) 2021/418 of 9 March 2021[8], Commission Regulation (EC) 2024/248 of 16 January 2024[2], Commission Regulation (EU) 2024/1821 of 25 June 2024[3], Commission Regulation (EU) 2025/352 of 21 February 2025[4], Commission Regulation (EU) 2025/2224 of 5 November 2025[5] and Commission Regulation (EU) 2025/2225 of 5 November 2025[6];",

(b) by substituting for the definition of "Directive" (inserted by Regulation 3 of (S.I. No. 540 of 2021)) the following:

"'Directive' means Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002[1], as amended by Commission Directive 2006/37/EC of 30 March 2006[13], Commission Regulation (EC) No. 1170/2009 of 30 November 2009[7], Commission Regulation (EU) No. 1161/2011 of 14 November 2011[9], Commission Regulation (EU) No. 119/2014 of 7 February 2014[10], Commission Regulation (EU) 2015/414 of 12 March 2015[11], Commission Regulation (EU) 2017/1203 of 5 July 2017[12], Commission Regulation (EU) 2021/418 of 9 March 2021[8], Commission Regulation (EU) 2024/248 of 16 January 2024[2], Commission Regulation (EU) 2024/1821 of 25 June 2024[3], Commission Regulation (EU) 2025/352 of 21 February 2025[4], Commission Regulation (EU) 2025/2224 of 5 November 2025[5] and Commission Regulation (EU) 2025/2225 of 5 November 2025[6];",

(c) by substituting for the definition of "the Minister" the following:

"'Minister' means Minister for Health;",

(d) by substituting for the definition of "Official Controls Regulation" the following:

"'Official Controls Regulation' means Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017[14] as amended by Commission Delegated Regulation (EU) 2019/478 of 14 January 2019[15];",

and

(e) by inserting after the definition of "official laboratory" the following:

"'relevant thing' means –

(a) a label, labelling, packaging or container related to food, or

(b) materials used in the presentation or advertising of food or other accompanying material;".

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[12] OJ No. L 173, 6.7.2017, p. 9.
[13] OJ No. L 94, 1.4.2006, p. 32.
[14] OJ No. L 95, 7.4.2017, p. 1.
[15] OJ No. L 82, 25.3.2019, p. 4.

4. In Regulation 2 of the Principal Regulations, paragraph (3) is deleted.

5. The Principal Regulations are amended—

(a) in paragraphs (1) and (4) of Regulation 4, and in paragraph (6) of Regulation 5, by substituting "Annex I" for "Schedule 1", and

(b) in paragraphs (1), (2), (3) and (4) of Regulation 4, by substituting "Annex II" for "Schedule 2".

6. The Principal Regulations are amended by substituting for Regulations 9, 10, 11, and 12 the following:

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

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

(3) An authorised officer may, for the purposes of these Regulations, inspect, take or make copies, whether in writing, by photography, electronically or otherwise, of a relevant thing.

(4) Subject to paragraphs (5) and (6), an authorised officer who purchases or takes without payment a sample of food or any relevant thing, with the intention of having it analysed, tested or inspected in the context of official controls, shall, at the time of such purchasing or taking, notify the food business operator or the person in apparent charge or control of the food or relevant thing of his or her intention of having the sample analysed, tested or inspected.

(5) In the case of food or a relevant thing offered for sale by means of distance communication, an authorised officer may order samples without identifying himself or herself.

(6) Where a sample is obtained under paragraph (5), the authorised officer shall take all reasonable steps to ensure that the person from whom the sample is ordered—

(a) is informed that such sample has been taken in the context of an official control and, where appropriate, is analysed, tested or inspected for the purposes of such official control, and

(b) where the sample is analysed or tested, is able to exercise his or her right to a second expert opinion under Article 35(1) of the Official Controls Regulation and Regulation 10.

(7) An authorised officer who suspects that food or a relevant thing fails to comply with these Regulations, and who purchases or takes a sample of that food or relevant thing without payment, with the intention

of having it analysed, tested or inspected in the context of official controls, may, by notice in writing to the food business operator, or the person in apparent charge or control of such food or relevant thing, prohibit its 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.

(8) An authorised officer who serves a notice under paragraph (7) may, by further notice in writing to the recipient of the first notice, extend the period during which the removal of the food or relevant thing is prohibited for a further period specified in the second notice not exceeding 10 working days, provided that such extension is necessary for the purposes of completing analysis, testing or inspection of the food or relevant thing.

10. (1) Where a sample of food or any relevant thing is purchased or taken pursuant to Regulation 9, the authorised officer shall ensure that the food business operator whose food or relevant thing is being analysed, tested or inspected has the right to a second expert opinion ("second expert opinion"), at the expense of the food business operator, in accordance with Article 35 of the Official Controls Regulation, provided that the second expert opinion is requested by notice in writing to the authorised officer within a period of 7 working days after the food business operator is notified of the results of the analysis, testing or inspection.

(2) Following receipt of a request pursuant to paragraph (1), the authorised officer shall issue a written acknowledgement of the request.

(3) A food business operator who makes a request pursuant to paragraph (1) shall provide to the authorised officer, in writing within 7 working days of the date of the acknowledgement issued pursuant to paragraph (2), written details of the recognised and appropriately qualified expert who shall be giving the second expert opinion and a written list of documents and records relating to the sampling, analysis, or test required for the purpose of the documentary review under Article 35 of the Official Controls Regulation.

(4) The documentary review under Article 35 of the Official Controls Regulation shall be completed within 15 working days of the date on which the documents and records required for the purpose of the review are issued to the food business operator.

(5) Where a sample of food or any relevant thing is purchased or taken pursuant to Regulation 9, and where relevant, appropriate and technically feasible having regard in particular to—

(a) the prevalence and distribution of the hazard in the food or relevant thing,

(b) the perishability of the sample of food or relevant thing, and

(c) the amount of available substrate,

the authorised officer shall—

(i) when purchasing or taking the sample, and if so requested by the food business operator or the person in apparent charge or control of the food or relevant thing, ensure that a sufficient quantity is taken to allow for a second expert opinion referred to in Article 35(3) of the Official Controls Regulation, or

(ii) where it is not possible to take a sufficient quantity as referred to in subparagraph (i), inform the food business operator or person in charge or control thereof.

(6) The Authority shall publish guidelines in relation to the recognition of appropriately qualified experts for the purposes of a documentary review.

(7) Where there is a dispute between the Authority or the official agency and the food business operator that is based on a second expert opinion, the food business operator may, by notice in writing delivered to the authorised officer no more than 10 working days after the issuance of the opinion, request pursuant to Article 35(3) of the Official Controls Regulation and at his or her own expense, a documentary review of the initial analysis or test or another analysis, test or inspection by another official laboratory.

(8) The official laboratory, official agency or the Authority, as the case may be, shall grant reasonable access, in such manner as it prescribes, for a recognised and appropriately qualified expert appointed by a food business operator to the records required for a documentary review.

11. (1) An authorised officer who purchases or takes a sample of food pursuant to Regulation 9 for the purpose of proceedings for an offence under these Regulations may, where the division of the sample is reasonably practicable, 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.

(2) An authorised officer who divides a sample pursuant to paragraph (1) shall—

(a) in the presence of the food business operator, or the person in apparent charge or control of the food mark, close and seal 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 an approved examiner in an official laboratory for analysis, test or inspection,

(c) give or send one part to such food business operator or person, or where necessary retain such part in his or her possession on behalf of the food business operator or person, and

(d) retain the third part.

(3) Notwithstanding paragraph (2)(a), an authorised officer may mark, close and seal a part of a sample, as appropriate, in the absence of the food business operator, or the person in apparent charge or control of the food, where no such person agrees to be present or it is not technically feasible for such person to be present during such marking, closing and sealing.

(4) Where an authorised officer purchases or takes a sample of food contained in unopened containers and its division into parts—

(a) is not reasonably practicable, or

(b) might affect the composition, integrity or impede the proper analysis of the sample,

paragraphs (1) and (2) 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 paragraphs (1) and (2).

(5) Where a sample is obtained pursuant to Regulation 9(5), the requirement in paragraph (2) to carry out the actions referred to therein in the presence of the food business operator or the person in apparent charge or control of the food shall not apply.

(6) In proceedings for an offence under these Regulations the result of any analysis, test or inspection of, or report on, a sample of food purchased or taken pursuant to these Regulations and the Official Controls Regulation shall not be adduced unless before the proceedings were instituted the sample was divided as specified in this Regulation, or the food business operator concerned availed of its right to a second expert opinion under Article 35 of the Official Controls Regulation and Regulation 10.

(7) Notwithstanding paragraph (6), in proceedings for an offence under these Regulations arising out of a consumer complaint in relation to a single sample of food which was not—

(a) divided into parts in accordance with paragraph (1), or

(b) divided into lots in accordance with paragraph (3),

the result of any analysis, test or inspection of the sample may be adduced where the sample has, before trial of the proceedings been made reasonably available to the accused person, or his or her agent, for inspection and second expert opinion and, where requested, the person who carried out the documentary review pursuant to Article 35 of the Official Controls Regulation.

(8) The Authority or the official agency, as the case may be, may, where it considers that it is necessary to eliminate or contain the risks to human, animal or plant health, animal welfare, or, as regards GMOs and plant protection products, also to the environment, take immediate action notwithstanding that the sampling procedures set out in this Regulation have not been carried out and notwithstanding any application by the food

business operator for a second expert opinion under Article 35 of the Official Controls Regulation and Regulation 10.

12. (1) An authorised officer who purchases or takes a sample of a relevant thing pursuant to Regulation 9 shall, where possible, obtain three identical such relevant things, or take 3 copies or photographs thereof.

(2) An authorised officer who purchases or takes three relevant things, copies or photographs pursuant to paragraph (1) shall—

(a) in the presence of the food business operator, or the person in apparent charge or control of the relevant thing, mark, close and seal each relevant thing, copy or photograph, 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 of the relevant things, copies or photographs, to an approved examiner in an official laboratory for analysis or test, or retain it for the purpose of inspection, as appropriate,

(c) give or send one of the relevant things, copies or photographs, to the food business operator or the person in apparent charge or control of the relevant thing, or where necessary retain such relevant thing, copy or photograph in his or her possession on behalf of the food business operator or person, and

(d) retain the third relevant thing, copy or photograph.

(3) Notwithstanding paragraph (2)(a), an authorised officer may mark, close and seal a part of a sample, as appropriate, in the absence of the food business operator, or the person in apparent charge or control of the relevant thing, where no such person agrees to be present or it is not technically feasible for such person to be present during such marking, closing and sealing.

(4) In proceedings for an offence under these Regulations, where three relevant things, copies or photographs were purchased or taken pursuant to paragraph (1), or the food business operator concerned availed of its right to a second expert opinion under Article 35 of the Official Controls Regulation and Regulation 10, the result of any analysis, test or inspection of, or report on, the relevant thing, copy or photograph shall not be adduced unless the relevant thing, copy or photograph retained by the authorised officer is produced at the hearing.

(5) Where it is not possible to purchase or take three identical relevant things, copies or photographs pursuant to paragraph (1), the result of any analysis, test or inspection of the sample of the relevant thing may be adduced where the sample has, before trial of the proceedings, been made reasonably available to the accused person, or his or her agent, for inspection and, where requested, the person who carried out the documentary review pursuant to Article 35 of the Official Controls Regulation.

(6) The Authority or the official agency, as the case may be, may, where it considers that it is necessary to eliminate or contain the risks to human, animal or plant health, animal welfare, or, as regards GMOs and plant protection products, also to the environment, take immediate action notwithstanding that the sampling procedures set out in this Regulation have not been carried out and notwithstanding any application by the food business operator for a second expert opinion under Article 35 of the Official Controls Regulation and Regulation 10.

12A. Where the results of an analysis, test or inspection carried out on a sample of food or a relevant thing during official controls or other official activities indicate a risk to human health or point to the likelihood of non-compliance with these Regulations, the official laboratory concerned shall immediately inform the Authority and the official agency.

12B. (1) The approved examiner or a person under his or her direction shall analyse as soon as possible any sample of food or any relevant thing, or a copy or photograph thereof, submitted to him or her in pursuance of these Regulations and, in accordance with the criteria set out in Annex III to the Official Controls Regulation, the approved examiner shall certify to the person who submitted the sample to him or her the result of such analysis.

(2) For the purposes of paragraph (1), the form of certificate set out in Schedule 3, or a certificate in like form, shall be used.

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

7. Regulation 16 of the Principal Regulations is amended by—

(a) substituting for paragraph (1) (inserted by Regulation 6 of S. I. No. 540 of 2021) the following:

"16 (1) A person who fails to comply with Regulation 4(1), 5 or 6 is guilty of an offence and is liable—

(a) on summary conviction, to a class A fine or 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 to imprisonment for a term not exceeding 2 years, or both.",

(b) in paragraph (3), by substituting "is guilty of an offence and is liable on summary conviction to a class A fine" for "is guilty of an offence", and

(c) by inserting after paragraph (3) the following:

"(4) Where a person is convicted of an offence under paragraph (1), 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.

(5) An order for costs and expenses under paragraph (4) is in addition to, and not instead of, any fine or penalty the court may impose under paragraph (1).".

8. Regulation 18 of the Principal Regulations is amended by inserting after paragraph (5) the following:

"(6) A person who is guilty of an offence under this Regulation is liable—

(a) on summary conviction, to a class A fine or 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 to imprisonment for a term not exceeding 2 years, or both.".

9. Regulation 19 of the Principal Regulations is deleted.

10. The Principal Regulations are amended by substituting for Regulation 20 the following:

"20. An offence under these Regulations may be brought and prosecuted summarily by the Authority or an official agency.".

11. Schedules 1 and 2 to the Principal Regulations are deleted.

12. The following are revoked:

(a) the European Communities (Food Supplements) (Amendment) Regulations 2021 (S. I. No. 540 of 2021);

(b) the European Communities (Food Supplements) (Amendment) Regulations 2018 (S. I. No. 225 of 2018);

(c) the European Communities (Food Supplements) (Amendment) Regulations 2015 (S. I. No. 282 of 2015);

(d) the European Communities (Food Supplements) (Amendment) Regulations 2010 (S. I. No. 355 of 2010).

L.S.

GIVEN under my Official Seal,
27 May, 2026.

JENNIFER CARROLL MACNEILL,
Minister for Health.

EXPLANATORY NOTE

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

These Regulations which relate to food supplements —

- give further effect to Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 and full effect to to the Commission Regulations that amend an Annex to that Directive; and
- amend the European Communities (Food Supplements) Regulations 2007 (S.I. No. 506 of 2007).

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ó
FOILSEACHÁIN RIALTAIS,
BÓTHAR BHAILE UÍ BHEOLÁIN,
CILL MHAIGHNEANN,
BAILE ÁTHA CLIATH 8,
D08 XAO6

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r-phost: publications@opw.ie

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