

STATUTORY INSTRUMENTS.

S.I. No. 204 of 2025

EUROPEAN UNION (NATURAL MINERAL WATERS, SPRING WATERS AND OTHER WATERS IN BOTTLES OR CONTAINERS) (AMENDMENT) REGULATIONS 2025

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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 (EU) 2020/2184 of the European Parliament and the Council of 16 December 2020¹, hereby make the following regulations:

1. (1) These Regulations may be cited as the European Union (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) (Amendment) Regulations 2025.

(2) The Principal Regulations, the European Union (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) (Amendment) Regulations 2020 (S.I. No. 55 of 2020), the Regulations of 2022 and these Regulations may be cited together as the European Union (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) Regulations 2016 to 2025.

2. In these Regulations -

"Principal Regulations" means the European Union (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) Regulations 2016 (S.I. No. 282 of 2016);

"Regulations of 2022" means the European Union (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) (Amendment) Regulations 2022 (S.I. No. 691 of 2022).

3. Regulation 2(1) of the Principal Regulations (as amended by Regulation 4(a) of the Regulations of 2022) is amended by inserting the following definition:

"water sample' means a sample of bottled waters, or a sample from the spring or source from which the bottled waters are derived.".

4. Regulation 16 of the Principal Regulations (as amended by Regulation 6(a) of the Regulations of 2022) is amended by substituting for paragraph (1) the following:

"16. (1) A person shall not place on the market other waters unless-

(a) they are wholesome and clean,

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 27th May, 2025.

¹ OJ No. L 435, 23.12.2020, p. 1.

- (b) the parametric values set down in Parts A and B of Annex I to Directive 2020/2184 are complied with at the point at which the waters are put into bottles or containers,
- (c) the parametric value for radon of 500Bq/l is complied with at the point at which the waters are put into bottles or containers,
- (d) the parametric values set down in Annex I to Council Directive 2013/51/EURATOM for tritium and indicative dose are complied with at the point at which the waters are put into bottles or containers,
- (e) the parametric value for *Pseudomonas aeruginosa* of 0/250ml is complied with at the point at which the waters are put into bottles or containers,
- (f) the parametric value for colony count at 22°C of 100/ml is complied with at the point at which the waters are put into bottles or containers, and
- (g) the parametric value for colony count at 37°C of 20/ml is complied with at the point at which the waters are put into bottles or containers.".

5. The Principal Regulations are hereby amended by substituting for Regulation 22 the following:

"Taking of Samples

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

(2) An authorised officer may, for the purpose of taking a water sample 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 referred to in paragraph (1), with the intention of having it analysed, tested or inspected, shall, at the time of such purchasing or taking, notify the food business operator or the person in apparent charge or control of the bottled waters, spring or source or relevant thing of his or her intention of having the sample analysed, tested or inspected.

(5) In the case of bottled waters 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 and where appropriate, is analysed, tested or inspected for the purposes of these Regulations, 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 22A.

(7) Where an authorised officer purchases or takes without payment, with the intention of having it analysed, a sample referred to in paragraph (1) 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 person in apparent charge or control of the bottled waters, spring or source from which the bottled waters are derived, or relevant thing, prohibit the removal of the bottled waters, or relevant thing, 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 bottled waters, or the waters from the spring or source from which the bottled waters are derived 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 water sample or sample of a relevant thing.".

6. The Principal Regulations are hereby amended by inserting after Regulation 22 the following Regulation:

"Second expert opinion

22A. (1) Where a water sample or a sample of any relevant thing is purchased or taken pursuant to Regulation 22, the authorised officer shall ensure that the food business operator whose water sample or sample of a relevant thing is being analysed, tested or inspected has the right to a second expert opinion, at the expense of the food business operator, in accordance with Article 35 of the Official Controls Regulation ('a second expert opinion'), 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 water sample or a sample of any relevant thing is purchased or taken pursuant to Regulation 22, and where relevant, appropriate and technically feasible having regard in particular to—

(a) the prevalence and distribution of the hazard in the bottled waters, or the waters from the spring or source from which the bottled waters are derived or relevant thing,

(b) the perishability of the water sample or the sample of the 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 bottled waters, or the waters from the spring or source from which the bottled waters are derived 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.".

7. The Principal Regulations are hereby amended by substituting for Regulation 23 the following:

"Division of samples

23. (1) An authorised officer who purchases or takes a water sample pursuant to Regulation 22 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 such bottled waters, or the waters from the spring or source from which the bottled waters are derived, 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 in apparent charge or control of such bottled waters, or the waters from the spring or source from which the bottled waters are derived, 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 such bottled waters, or the waters from the spring or source from which the bottled waters are derived, 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 bottled waters contained in unopened bottles or 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,

the provisions of 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 bottles or containers into three lots and deals with each lot as if it were a sample as specified under paragraph (1) and (2).

(5) Where a sample is obtained pursuant to Regulation 22(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 such bottled waters 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 water sample, purchased or taken pursuant to these Regulations 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 22A.

(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 bottled waters 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 22A.".

8. The Principal Regulations are hereby amended by substituting for Regulation 24 the following:

"Samples of relevant things

24. (1) An authorised officer who purchases or takes a sample of a relevant thing pursuant to Regulation 22 shall, where possible, obtain three identical such relevant things, or take three 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 22A, 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 22A.".



GIVEN under my Official Seal, 16 May, 2025.

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 give further effect to Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption.

These Regulations amend the European Union (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) Regulations 2016 by prescribing additional parameters for Other Waters and updating the sampling provisions.

These Regulations may be cited as the European Union (Natural Mineral Waters, Spring Waters and Other Waters in Bottles or Containers) (Amendment) Regulations 2025. 10 [204]

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