



STATUTORY INSTRUMENTS.

S.I. No. 656 of 2024

HEALTH (PROVISION OF FOOD ALLERGEN INFORMATION TO
CONSUMERS IN RESPECT OF NON-PREPARED FOOD)
(AMENDMENT) REGULATIONS 2024

HEALTH (PROVISION OF FOOD ALLERGEN INFORMATION TO CONSUMERS IN RESPECT OF NON-PREPACKED FOOD) (AMENDMENT) REGULATIONS 2024

I, COLM BURKE, Minister of State at the Department of Health, in exercise of the powers conferred on me by section 54 (substituted by section 25 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006)) of the Health Act 1947 (No. 28 of 1947) and Article 2 of the Health (Delegation of Ministerial Functions) (No. 2) Order 2024 (S.I. No. 210 of 2024), after consultation with the Minister for Enterprise, Trade and Employment (as adapted by Business, Enterprise and Innovation (Alteration of Name of Department and Title of Minister) Order 2020 (S.I. No. 519 of 2020)) and the Minister for Agriculture, Food and the Marine (as adapted by Agriculture, Food and the Marine (Alteration of Name and Title of Minister) Order 2011 (S.I. No. 455 of 2011)) hereby make the following regulations:

1. (1) These Regulations may be cited as the Health (Provision of Food Allergen Information to Consumers in respect of Non-Prepacked Food) (Amendment) Regulations 2024.

(2) The Principal Regulations and these Regulations may be cited together as the Health (Provision of Food Allergen Information to Consumers in respect of Non-Prepacked Food) Regulations 2014 and 2024.

2. In these Regulations “Principal Regulations” means the Health (Provision of Food Allergen Information to Consumers in respect of Non-Prepacked Food) Regulations (S.I. No. 489 of 2014).

3. Regulation 2(1) of the Principal Regulations is hereby amended by inserting the following definition:

“Official Controls Regulation” means Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017¹.

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

“Taking of Samples

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

¹ OJ No. L 95, 7.4.2017, p.1.

(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, 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 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 8A.

(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, 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.”.

5. The Principal Regulations are hereby amended by inserting after Regulation 8 the following Regulation:

“Second expert opinion

8A. (1) Where a sample of food or any relevant thing is purchased or taken pursuant to Regulation 8, 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, 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 sample of food or any relevant thing is purchased or taken pursuant to Regulation 8, 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.”.

6. The Principal Regulations are hereby amended by substituting for Regulation 9 the following:

“Division of food samples

9. (1) An authorised officer who purchases or takes a sample of food pursuant to Regulation 8 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,

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 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 8(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 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 8A.

(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 8A.”.

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

“Samples of relevant things

10. (1) An authorised officer who purchases or takes a sample of a relevant thing pursuant to Regulation 8 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 food legislation, 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 8A, 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 8A.”.

8. Regulation 12 of the Principal Regulations is hereby amended by substituting for paragraph (1) the following:

“(1) Where a sample is taken by an authorised officer in pursuance of these Regulations for analysis, test or inspection, the Authority, or an official agency as the case may be, shall draw up a report in accordance with Article 13 of the Official Controls Regulation.”.

9. The Principal Regulations are amended by substituting for Regulation 15 the following:

“Compliance notice

15. (1) Where an authorised officer is of the opinion that there is non-compliance with a requirement of these Regulations, he or she may, following consultation with the chief executive or such other officer of the Authority or an official agency designated in that behalf by the Board, serve, or arrange to have served, on the food business operator concerned or the person in charge a notice (‘compliance notice’) in accordance with paragraph (2).

(2) A compliance notice shall—

- (a) be signed by the authorised officer issuing it, or the officer consulted in accordance with paragraph (1),
- (b) identify the requirement(s) of these Regulations with which there has not been compliance,
- (c) where appropriate, direct the person on whom the compliance notice is served to ensure that the food is not placed or made available on the market until such time as all appropriate measures, including corrective measures, have been taken to bring the food into conformity with these Regulations,
- (d) where appropriate, direct the person on whom the compliance notice is served to recall and withdraw from the market any food which fails to comply with these Regulations,
- (e) specify a date, commensurate with the nature of the non-compliance, within which the food business operator must take such corrective action as is required to bring the non-compliance to an end, and
- (f) contain information regarding the bringing of an appeal under paragraph (5) against the notice, including the manner in which an appeal shall be brought.

(3) A compliance notice shall not specify a date in accordance with paragraph (2)(e) that falls on or before the date by which an appeal under paragraph (5) must be brought.

(4) The chief executive of the Authority or an official agency or another officer of the Authority or an official agency designated by the Board for that purpose may, for stated reasons, revoke or vary a compliance notice issued by an authorised officer appointed by the Authority or an official agency.

(5) A person may appeal a compliance notice served on him or her to the District Court not later than 7 days after the service of the compliance notice concerned.

(6) A person who appeals against a compliance notice shall at the same time notify the Authority or official agency of the appeal and the grounds for the appeal and the Authority or official agency shall be entitled to appear, be heard and adduce evidence on the hearing of the appeal.

(7) In the event of non-compliance or delay by the person on whom a compliance notice has been served, an authorised officer may, with the approval of the chief executive of the Authority or official agency, or another officer thereof designated by the Board for that purpose, take whatever measures are considered necessary to ensure compliance with the compliance notice, including the seizure and destruction of the food in question or the making of any arrangements for such seizure or destruction or both.

(8) The District Court shall, upon an appeal under this Regulation, do one of the following:

- (a) affirm the compliance notice concerned;
- (b) direct the authorised officer to withdraw the compliance notice concerned; or
- (c) direct the authorised officer to modify the compliance notice concerned.

(9) An authorised officer shall comply with a direction under paragraph (8)(b) or (c).

(10) A person who fails to comply with a compliance notice by the specified date shall be guilty of an offence and shall be liable on summary conviction to a class A fine or to imprisonment for a term not exceeding 6 months, or to both.

(11) This Regulation shall not operate to prevent or restrict—

- (a) the entitlement of the Authority or an official agency to bring proceedings for the purpose of securing compliance with these Regulations by a person, or
- (b) the bringing or prosecuting of any proceedings for an offence under these Regulations.

(12) In this Regulation, ‘specified date’ means, in relation to a compliance notice—

- (a) the date specified in the notice in accordance with paragraph (2)(e), where no appeal against the notice is brought under this Regulation, or
- (b) the day falling immediately after the expiration of the period of 7 days from the date on which the District Court so affirms the notice, where an appeal against the notice is brought under paragraph (5) and the District Court affirms the notice in accordance with paragraph (8)(a).

(13) Nothing in this Regulation shall prevent the Authority or an official agency from serving a prohibition order or closure order at any time in respect of any business which is subject to a compliance notice if, in the opinion of an authorised officer, the circumstances require the service of such order.”.

10. The Principal Regulations are hereby amended by inserting after Regulation 15 the following Regulation:

“Service of notices

15A. (1) A notice served or given by or under these Regulations shall be addressed to the person concerned and served or given in one of the following:

- (a) by addressing it to the person by name and delivering it to him or her;
- (b) by leaving it at the address at which the person ordinarily resides or carries on business;
- (c) by sending it by post in a prepaid registered letter addressed to the person at the address at which he or she ordinarily resides or carries on business;
- (d) if an address for the service of notices has been furnished by the person, by leaving it at, or sending it by prepaid registered post addressed to him or her to, that address;
- (e) where the address at which the person ordinarily resides or carries on business cannot be ascertained by reasonable inquiry and notice is required to be served on, or given to, him or her in respect of any premises by delivering it to a person over the age of 16 years resident in or employed on the premises, or by affixing it in a conspicuous position on or near the premises; or
- (f) by sending it by means of electronic mail to a device or facility for the reception of electronic mail where such an electronic mail address has been furnished by the person, but only if the sender's facility for the reception of electronic mail generates a message confirming a receipt of the electronic mail confirming successful transmission of the notice.

(2) Where the name of the person concerned cannot be ascertained by reasonable inquiry, a notice under these Regulations may be addressed to ‘the occupier’, ‘the owner’ or ‘the person in charge’, as the case may be.

(3) For the purposes of this Regulation, a company within the meaning of the Companies Act 2014 (No. 38 of 2014) shall be deemed to be ordinarily resident at its registered office, and every other body corporate and every unincorporated body shall be deemed to be ordinarily resident at its principal office or place of business.

(4) A person shall not at any time during the period of 3 months after a notice is affixed under paragraph (1)(e) remove, damage or deface the notice without lawful authority.”.

GIVEN under my hand,
25 November 2024

COLM BURKE
Minister of State at the Department of Health

EXPLANATORY NOTE

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

These Regulations amend the Health (Provision of Food Allergen Information to Consumers in Respect of Non-Prepacked Food) Regulations 2014 (S.I. No. 489 of 2014) by aligning the provisions regarding compliance notices and sampling with the provisions contained in, *inter alia*, European Union (Food Intended for Infants and Young Children, Food for Special Medical Purposes, and Total Diet Replacement for Weight Control) (Amendment) Regulations 2024.

These Regulations may be cited as Health (Provision of Food Allergen Information to Consumers in Respect of Non-Prepacked Food) (Amendment) Regulations 2024.

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