STATUTORY INSTRUMENTS.

S.I. No. 253 of 2022

EUROPEAN UNION (NOVEL FOODS) REGULATIONS 2022

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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 full effect to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015[1] as amended by Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019[2] and associated Implementing Regulations of Commission Implementing Regulation (EU) 2017/2468 of 20 December 2017[3] as amended by Commission Implementing Regulation (EU) 2020/1824 of 2 December 2020[4], Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017[5], and Commission Implementing Regulation (EU) 2018/456 of 19 March 2018[6], and all other associated European acts specified in Schedule 1 to these Regulations, hereby make the following Regulations:

PART I

PRELIMINARY

Citation

1. These Regulations may be cited as the European Union (Novel Foods) Regulations 2022.

Interpretation

2. (1) In these Regulations—

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

"approved examiner" means—

(*a*) a Chief Medical Scientist located at an official laboratory,

(*b*) a Consultant Microbiologist located at an official laboratory,

(*c*) a Deputy Public Analyst located at a Public Analyst's Laboratory,

(*d*) an Executive Analytical Chemist located at a Public Analyst's Laboratory,

(*e*) a Public Analyst located at a Public Analyst's Laboratory, or

1 OJ No. L 327, 11.12.2015, p. 1.
2 OJ No. L 231, 6.9.2019, p. 1.
3 OJ No. L 351, 30.12.2017, p. 55.
4 OJ No. L 406, 3.12.2020, p. 51.
5 OJ No. L 351, 30.12.2017, p. 72.
6 OJ No. L 77, 20.3.2018, p. 6.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 27*th May,* 2022.

(*f*) a person, or member of a class of persons, designated by the Minister pursuant to Regulation 19;

"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;

"Commission" means EU Commission;

"EU Regulation on Novel Foods" means Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015[1] as amended by Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019[2];

"EU Regulation 2017/2468" means Commission Implementing Regulation (EU) 2017/2468 of 20 December 2017[3] as amended by Commission Implementing Regulation (EU) 2020/1824 of 2 December 2020[4];

"EU Regulation 2018/456" means Commission Implementing Regulation (EU) 2018/456 of 19 March 2018[6];

"food business operator" has the same meaning as assigned to it by Article 3(2) of the General Food Law Regulation;

"General Food Law Regulation" means Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002[7], as amended by Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019[2] as well as the European acts specified in Part B of Schedule 1 to these Regulations;

"Minister" means the Minister for Health;

"novel food" has the same meaning as assigned to it in Article 3(2)(a) of the EU Regulation on Novel Foods;

"official agency" means the Health Service Executive carrying out functions under food legislation pursuant to section 48 of the Act of 1998;

"Official Controls Regulation" means Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017[8];

"Official laboratory" means—

(*a*) Public Analyst's Laboratory, Cork,

(*b*) Public Analyst's Laboratory, Dublin,

(*c*) Public Analyst's Laboratory, Galway,

(*d*) Public Health Laboratory, Health Service Executive, Dublin Mid-Leinster,

(*e*) Public Health Laboratory, Sligo,

(*f*) Public Health Laboratory, Waterford,

(*g*) Public Health Microbiology Laboratory, Cork,

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[7] OJ No. L 31, 1.2.2002, p. 1.
[8] OJ No. L 95, 7.4.2017, p. 1.

(*h*) Public Health Microbiology Laboratory, Galway,

(*i*) Public Health Microbiology Laboratory, Limerick, or

(*j*) a laboratory designated by the Minister pursuant to Regulation 19;

"record" includes, in addition to a record in writing—

(*a*) a disc, tape, sound-track or other device in which information, sounds or signals are embodied so as to be capable, with or without the aid or some other instrument, of being reproduced in legible or audible form,

(*b*) a film, tape or other device in which visual images are embodied so as to be capable, with or without the aid or some other instrument, of being reproduced in visual form, and

(*c*) a photograph;

and any reference to a copy of a record includes—

(i) in the case of a record to which subparagraph (a) of this definition applies, a transcript of the sounds or signals embodied therein,

(ii) in the case of a record to which paragraph (b) of this definition applies, a still reproduction of the images embodied therein, and

(iii) in the case of a record to which paragraphs (a) and (b) of this definition apply, such a transcript together with such a still reproduction;

"relevant thing" means—

(*a*) label, labelling, packaging or container related to food,
(*b*) materials used in the presentation or advertising of food or other accompanying material, or
(*c*) a notice to consumers to be displayed at the place of sale informing them about the food;

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

"Union list" has the same meaning as assigned to it by Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017[5], as amended by Commission Implementing Regulations specified in Part A of Schedule 1 to these Regulations and established in accordance with Article 6 (1) of the EU Regulation on Novel Foods.

(2) A word or expression which is used in these Regulations, and which is also used in the EU Regulation on Novel Foods, the General Food Law Regulation and all other associated European acts specified in Schedule 1 to these Regulations has, unless the context otherwise requires, the same meaning in these Regulations as it has in those Regulations.

Scope

3. (1) These Regulations apply to the placing on the market of novel foods.

(2) These Regulations do not apply to:

(*a*) genetically modified foods falling within the scope of Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003[9];

(*b*) foods when and in so far as they are used as:

(i) food enzymes falling within the scope of Regulation (EC) No. 1332/2008 of the European Parliament and of the Council of 16 December 2008[10];

(ii) food additives falling within the scope of Regulation (EC) No. 1333/2008 of the European Parliament and of the Council of 16 December 2008[11];

(iii) food flavourings falling within the scope of Regulation (EC) No. 1334/2008 of the European Parliament and of the Council of 16 December 2008[12];

(iv) extraction solvents used or intended to be used in the production of foodstuffs or food ingredients and falling within the scope of Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009[13].

Responsibility for functions under EU Regulation on Novel Foods, EU Regulation 2017/2468, and EU Regulation 2018/456

4. The functions of the State referred to in Articles 4(2), 4(3), 10(6) second paragraph and 15(2) of EU Regulation on Novel Foods, Article 7(2) of EU Regulation 2017/2468 and Articles 3, 4, 5, 6, and 9 of EU Regulation 2018/456 shall be performed by the Authority.

PART 2

REQUIREMENTS FOR PLACING NOVEL FOODS ON THE MARKET

Determination of novel food status

5. (1) A food business operator shall verify whether or not the food which it intends to place on the market falls within the scope of EU Regulation on Novel Foods in accordance with Article 4 of the EU Regulation on Novel Foods and the rules for its implementation as provided for in EU Regulation 2018/456.

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[9] OJ No. L 268, 18.10.2003, p. 1.
[10] OJ No. L 354, 31.12.2008, p. 7.
[11] OJ No. L 354, 31.12.2008, p. 16.
[12] OJ No. L 354, 31.12.2008, p. 34.
[13] OJ No. L 141, 6.6.2009, p. 3.

(2) A consultation request, as provided for in EU Regulation 2018/456, shall be submitted to the Authority in the manner and form prescribed in that regulation.

Union list of authorised novel foods

6. A food business operator shall only place on the market a novel food which is included in the Union list, and in accordance with the corresponding:

(*a*) conditions under which the novel food may be used;

(*b*) additional specific labelling requirements;

(*c*) other requirements as specified;

(*d*) data protection requirements;

(*e*) description/definition and specifications; and

as detailed in Table 1 and Table 2 of the Union list for that novel food.

Additional information requirements

7. A food business operator which has placed a novel food on the market shall immediately inform the Commission of any information of which it has become aware concerning-

(*a*) any new scientific or technical information which might influence the evaluation of the safety of use of the novel food, or

(*b*) any prohibition or restriction imposed by a third country in which the novel food is placed on the market.

Display of Notice

8. A food business operator marketing food supplements containing 8,0 mg astaxanthin or less intended for the general population and that were lawfully placed on the market before the 9 September 2021, shall provide a notice to be displayed at the place of sale, advising that those supplements should not be consumed by infants, children and adolescents below the age of 14 years.

PART 3

OFFENCES, ENFORCEMENT, AND PENALTIES

Offences

9. Subject to Regulations 3 and 23 of these Regulations, a person who contravenes or fails to comply with any of the Regulations set out in Part 2 of these Regulations is guilty of an offence.

Enforcement generally

10. (1) The enforcement of these Regulations, the EU Regulation on Novel Foods, EU Regulation 2017/2468, EU Regulation 2018/456, the Union list and

all other associated European acts specified in Schedule 1 to these Regulations, shall be carried out in accordance with this Part.

(2) These Regulations, the EU Regulation on Novel Foods, EU Regulation 2017/2468, EU Regulation 2018/456, the Union list and all other associated European acts specified in Schedule 1 to 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 and the European Union (Official Controls in relation to Food Legislation) Regulations 2020 (S.I. No. 79 of 2020) shall apply for the purposes of ensuring compliance with the requirements of these Regulations.

Taking of samples

11. (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.

(7) An authorised officer who suspects that a food or relevant thing fails to comply with these Regulations, and who purchases or takes a sample of that food 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.

Second expert opinion

12. (1) Where a sample of food or any relevant thing is purchased or taken pursuant to Regulation 11, 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").

(2) Where a sample of food or any relevant thing is purchased or taken pursuant to Regulation 11, 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 and for the documentary review referred to in Article 35(1) and (3) of the Official Controls Regulation ("a documentary review"), should that prove necessary, 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.

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

(4) 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 request, pursuant to Article 35(3) of the Official Controls Regulation and at his or her own expense, a documentary review and, where appropriate, another analysis, test or inspection by another official laboratory.

(5) 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 an operator to the records required for a documentary review.

Division of food samples

13. (1) An authorised officer who purchases or takes a sample of food pursuant to these Regulations, for the purposes of official controls 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, seal and fasten 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) 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).

(4) Where a sample is obtained pursuant to Regulation 11(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.

(5) 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.

(6) Notwithstanding paragraph (5), 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.

(7) The Authority or the official agency, as the case may be, may, where it considers that it is necessary to eliminate or contain the risk to human health, 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.

Samples of relevant things

14. (1) An authorised officer who purchases or takes a sample of a relevant thing pursuant to Regulation 11 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*) mark, seal and fasten 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) In proceedings for an offence under these Regulations, where three relevant things, copies or photographs were purchased or taken pursuant to paragraph (1), 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.

(4) 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.

(5) The Authority or the official agency, as the case may be, may, where it considers that it is necessary to eliminate or contain the risk to human health,

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.

Analysis by approved examiners

15. (1) The approved examiner or a person under his or her direction shall analyse as soon as possible any sample of food, relevant thing or copy or photograph of a relevant thing submitted to him or her in pursuance of these Regulations and the approved examiner shall certify to the person who submitted same to him or her the result of such analysis.

(2) For the purposes of paragraph (1), the form of certificate set out in Schedule 2 to these Regulations, 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.

Written records of official controls

16. Where an official control is carried out pursuance to the Official Controls Regulation, the Authority, or the official agency as the case may be, shall draw up a written record in accordance with Article 13 of the Official Controls Regulation and provide same to the food business operator concerned as required by that Article.

Powers of authorised officers

17. An authorised officer may, for the purposes of these Regulations—

(*a*) examine any procedure connected with the production, processing and placing on the market of food, and

(*b*) 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.

Seizure, removal, detention and destruction

18. (1) An authorised officer may seize, remove or detain, any food or relevant thing which is suspected by him or her of failing to comply with these Regulations.

(2) An authorised officer may, with the consent in writing of the food business operator concerned or the person in apparent charge or control of such food, or in accordance with an order of a judge of the District Court under paragraph (5), destroy or otherwise dispose of food so as to prevent it being used for human consumption.

(3) An authorised officer may, with the consent in writing of the food business operator concerned or the person in apparent charge or control of such relevant thing, or in accordance with an order of a judge of the District Court

under paragraph (5), destroy or otherwise dispose of a relevant thing so as to prevent consumers from being misled or a risk to human health.

(4) An authorised officer who has seized, removed or detained food or a relevant thing in pursuance of the provisions of this Regulation may, on giving notice in writing to the food business operator, or the person in apparent charge or control of such food or relevant thing, of his or her intention to do so, apply to a judge of the District Court for an order directing that such food or relevant thing be destroyed or otherwise disposed of.

(5) A judge of the District Court, to whom an application is made for an order under paragraph (4), may, if satisfied that the food or relevant thing fails to comply with these Regulations, order that it be destroyed or otherwise disposed of, after such period, not exceeding 14 days, as may be specified in such order, and an authorised officer shall destroy or dispose of it accordingly.

Designation of official laboratories and approved examiners

19. The Minister may, for the purposes of these Regulations designate, by notice in writing published in *Iris Oifigiúil*—

(*a*) a laboratory as a laboratory at which samples taken under these Regulations may be analysed, tested or inspected and verification may be carried out, and

(*b*) a person as being a person who, or a class of persons the members of which, may, at a designated laboratory engage in analysis, testing or inspection and verification for the purposes of these Regulations.

Ancillary Offences

20. (1) The ancillary offences provided for in paragraphs (2) – (8), inclusive, of these Regulations shall not apply to an authorised officer, 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.

(2) 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*) in purported compliance with a request or requirement under these Regulations, makes a statement or provides information to an authorised officer which the person knows is false or misleading in any material respect,

(*e*) provides records or documents, or copies thereof, which the person knows to be false or misleading in content,

(*f*) gives, in purported compliance with a request under these Regulations, a name, an address or corroborative evidence which is false or misleading,

(*g*) aids or abets a contravention of these Regulations,

(*h*) fails to give access to an authorised officer, in accordance with Article 15(1) of the Official Controls Regulation,

(*i*) fails to assist or cooperate with an authorised officer, in accordance with Article 15(2) of the Official Controls Regulation, or

(*j*) removes, damages or defaces a notice pursuant to Regulation 8.

(3) A person who 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"), is guilty of an offence.

(4) A person who 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"), is guilty of an offence.

(5) A person who, without lawful authority, has in his or her possession a forged document or an altered document, knowing it to be a false or altered document, as the case may be, is guilty of an offence.

(6) A person who, with the intent to defraud or deceive:

(*a*) tampers with any food or relevant thing, or

(*b*) tampers or interferes with any sample taken under these Regulations,

is guilty of an offence.

(7) A person who falsely represents himself or herself to be an authorised officer, is guilty of an offence.

(8) 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.

Bodies corporate

21. 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.

Prosecution of offences

22. (1) Subject to paragraph (2) of this Regulation, 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 6 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.

(2) A person who is guilty of an offence through contravening or failing to comply with Regulation 8 is liable only on summary conviction, to a class A fine.

(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 the 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 the official agency.

(4) An order for costs and expenses under paragraph (2) is in addition to, and not instead of, any fine or penalty the court may impose under paragraph (1).

(5) Notwithstanding section 57 of the Act of 1998, an offence under these Regulations may be prosecuted summarily by the Authority, or the official agency.

PART 4

TRANSITIONAL MEASURES

Transitional measures

23. (1) Food supplements containing synthetic zeaxanthin and complying with Regulation (EU) 2015/2283 of the European Parliament and the Council of 25 November 2015[1] as applicable before 3 September 2018 may be placed on the market until 3 September 2019 and may remain on the market until exhaustion of stocks.

(2) Food supplements containing 8.0 mg or less of astaxanthin intended for the general population which were lawfully placed on the market before 9 September 2021 may be marketed until their date of minimum durability or use-by-date.

(3) Food supplements containing 8.0 mg or less of astaxanthin intended for the general population imported into the European Union may be marketed until their date of minimum durability or use by date where the importer of such food can demonstrate that they were dispatched from the third country concerned and were on their way to the European Union before the 9 September 2021.

Schedule 1

Part A

1. Commission Implementing Regulation (EU) 2018/460 of 20 March 2018[14]
2. Commission Implementing Regulation (EU) 2018/461 of 20 March 2018[15]
3. Commission Implementing Regulation (EU) 2018/462 of 20 March 2018[16]
4. Commission Implementing Regulation (EU) 2018/469 of 21 March 2018[17]
5. Commission Implementing Regulation (EU) 2018/991 of 12 July 2018[18]
6. Commission Implementing Regulation (EU) 2018/1011 of 17 July 2018[19]
7. Commission Implementing Regulation (EU) 2018/1018 of 18 July 2018[20]
8. Commission Implementing Regulation (EU) 2018/1023 of 23 July 2018[21]
9. Commission Implementing Regulation (EU) 2018/1032 of 20 July 2018[22]
10. Commission Implementing Regulation (EU) 2018/1122 of 10 August 2018[23]
11. Commission Implementing Regulation (EU) 2018/1123 of 10 August 2018[24]
12. Commission Implementing Regulation (EU) 2018/1132 of 13 August 2018[25]
13. Commission Implementing Regulation (EU) 2018/1133 of 13 August 2018[26]

[14] OJ No. L 78, 21.3.2018, p. 2.
[15] OJ No. L 78, 21.3.2018, p. 7.
[16] OJ No. L 78, 21.3.2018, p. 11.
[17] OJ No. L 79, 22.3.2018, p. 11.
[18] OJ No. L 177, 13.7.2018, p. 9.
[19] OJ No. L 181, 18.7.2018, p. 4.
[20] OJ No. L 183, 19.7.2018, p. 9.
[21] OJ No. L 187, 24.7.2018, p. 1.
[22] OJ No. L 185, 23.7.2018, p. 9.
[23] OJ No. L 204, 13.8.2018, p. 36.
[24] OJ No. L 204, 13.8.2018, p. 41.
[25] OJ No. L 205, 14.8.2018, p. 15.
[26] OJ No. L 205, 14.8.2018, p. 18.

14. Commission Implementing Regulation (EU) 2018/1293 of 26 September 2018[27]

15. Commission Implementing Regulation (EU) 2018/1631 of 30 October 2018[28]

16. Commission Implementing Regulation (EU) 2018/1632 of 30 October 2018[29]

17. Commission Implementing Regulation (EU) 2018/1633 of 30 October 2018[30]

18. Commission Implementing Regulation (EU) 2018/1647 of 31 October 2018[31]

19. Commission Implementing Regulation (EU) 2018/1648 of 29 October 2018[32]

20. Commission Implementing Regulation (EU) 2018/1991 of 13 December 2018[33]

21. Commission Implementing Regulation (EU) 2018/2016 of 18 December 2018[34]

22. Commission Implementing Regulation (EU) 2018/2017 of 18 December 2018[35]

23. Commission Implementing Regulation (EU) 2019/108 of 24 January 2019[36]

24. Commission Implementing Regulation (EU) 2019/109 of 24 January 2019[37]

25. Commission Implementing Regulation (EU) 2019/110 of 24 January 2019[38]

26. Commission Implementing Regulation (EU) 2019/387 of 11 March 2019[39]

27. Commission Implementing Regulation (EU) 2019/388 of 11 March 2019[40]

28. Commission Implementing Regulation (EU) 2019/456 of 20 March 2019[41]

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[27] OJ No. L 243, 27.9.2018, p. 2.
[28] OJ No. L 272, 31.10.2018, p. 17.
[29] OJ No. L 272, 31.10.2018, p. 23.
[30] OJ No. L 272, 31.10.2018, p. 29.
[31] OJ No. L 274, 5.11.2018, p. 51.
[32] OJ No. L 275, 6.11.2018, p. 1.
[33] OJ No. L 320, 17.12.2018, p. 22.
[34] OJ No. L 323, 19.12.2018, p. 1.
[35] OJ No. L 323, 19.12.2018, p. 4.
[36] OJ No. L 23, 25.1.2019, p. 4.
[37] OJ No. L 23, 25.1.2019, p. 7.
[38] OJ No. L 23, 25.1.2019, p. 11.
[39] OJ No. L 70, 12.3.2019, p. 17.
[40] OJ No. L 70, 12.3.2019, p. 21.
[41] OJ No. L 79, 21.3.2019, p. 13.

29. Commission Implementing Regulation (EU) 2019/506 of 26 March 2019[42]
30. Commission Implementing Regulation (EU) 2019/760 of 13 May 2019[43]
31. Commission Implementing Regulation (EU) 2019/1272 of 29 July 2019[44]
32. Commission Implementing Regulation (EU) 2019/1294 of 1 August 2019[45]
33. Commission Implementing Regulation (EU) 2019/1314 of 2 August 2019[46]
34. Commission Implementing Regulation (EU) 2019/1686 of 8 October 2019[47]
35. Commission Implementing Regulation (EU) 2019/1976 of 25 November 2019[48]
36. Commission Implementing Regulation (EU) 2019/1979 of 26 November 2019[49]
37. Commission Implementing Regulation (EU) 2019/2165 of 17 December 2019[50]
38. Commission Implementing Regulation (EU) 2020/16 of 10 January 2020[51]
39. Commission Implementing Regulation (EU) 2020/24 of 13 January 2020[52]
40. Commission Implementing Regulation (EU) 2020/206 of 14 February 2020[53]
41. Commission Implementing Regulation (EU) 2020/443 of 25 March 2020[54]
42. Commission Implementing Regulation (EU) 2020/478 of 1 April 2020[55]
43. Commission Implementing Regulation (EU) 2020/484 of 2 April 2020[56]
44. Commission Implementing Regulation (EU) 2020/500 of 6 April 2020[57]
45. Commission Implementing Regulation (EU) 2020/916 of 1 July 2020[58]

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[42] OJ No. L 85, 27.3.2019, p. 11.
[43] OJ No. L 125, 14.5.2019, p. 13.
[44] OJ No. L 201, 30.7.2019, p. 3.
[45] OJ No. L 204, 2.8.2019, p. 16.
[46] OJ No. L 205, 5.8.2019, p. 4.
[47] OJ No. L 258, 9.10.2019, p. 13.
[48] OJ No. L 308, 29.11.2019, p. 40.
[49] OJ No. L 308, 29.11.2019, p. 62.
[50] OJ No. L 328, 18.12.2019, p. 81.
[51] OJ No. L 7, 13.1.2020, p. 6.
[52] OJ No. L 8, 14.1.2020, p. 12.
[53] OJ No. L 43, 17.2.2020, p. 66.
[54] OJ No. L 92, 26.3.2020, p. 7.
[55] OJ No. L 102, 2.4.2020, p. 1.
[56] OJ No. L 103, 3.4.2020, p. 3.
[57] OJ No. L 109, 7.4.2020, p. 2.
[58] OJ No. L 209, 2.7.2020, p. 6.

46. Commission Implementing Regulation (EU) 2020/917 of 1 July 2021[59]
47. Commission Implementing Regulation (EU) 2020/973 of 6 July 2020[60]
48. Commission Implementing Regulation (EU) 2020/1163 of 6 August 2020[61]
49. Commission Implementing Regulation (EU) 2020/1559 of 26 October 2020[62]
50. Commission Implementing Regulation (EU) 2020/1634 of 4 November 2020[63]
51. Commission Implementing Regulation (EU) 2020/1820 of 2 December 2020[64]
52. Commission Implementing Regulation (EU) 2020/1821 of 2 December 2020[65]
53. Commission Implementing Regulation (EU) 2020/1822 of 2 December 2020[66]
54. Commission Implementing Regulation (EU) 2020/1993 of 4 December 2020[67]
55. Commission Implementing Regulation (EU) 2021/50 of 22 January 2021[68]
56. Commission Implementing Regulation (EU) 2021/51 of 22 January 2021[69]
57. Commission Implementing Regulation (EU) 2021/82 of 27 January 2021[70]
58. Commission Implementing Regulation (EU) 2021/96 of 28 January 2021[71]
59. Commission Implementing Regulation (EU) 2021/120 of 2 February 2021[72]
60. Commission Implementing Regulation (EU) 2021/668 of 23 April 2021[73]
61. Commission Implementing Regulation (EU) 2021/670 of 23 April 2021[74]

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[59] OJ No. L 209, 2.7.2020, p. 10.
[60] OJ No. L 215, 7.7.2020, p. 7.
[61] OJ No. L 258, 7.8.2020, p. 1.
[62] OJ No. L 357, 27.10.2020, p. 7.
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[65] OJ No. L 406, 3.12.2020, p. 34.
[66] OJ No. L 406, 3.12.2020, p. 39.
[67] OJ No. L 410, 7.12.2020, p. 62.
[68] OJ No. L 23, 25.1.2021, p. 7.
[69] OJ No. L 23, 25.1.2021, p. 10.
[70] OJ No. L 29, 28.1.2021, p. 16.
[71] OJ No. L 31, 29.1.2021, p. 201.
[72] OJ No. L 37, 3.2.2021, p. 1.
[73] OJ No. L 141, 26.4.2021, p. 3.
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62. Commission Implementing Regulation (EU) 2021/882 of 1 June 2021[75]
63. Commission Implementing Regulation (EU) 2021/900 of 3 June 2021[76]
64. Commission Implementing Regulation (EU) 2021/912 of 4 June 2021[77]
65. Commission Implementing Regulation (EU) 2021/1318 of 9 August 2021[78]
66. Commission Implementing Regulation (EU) 2021/1319 of 9 August 2021[79]
67. Commission Implementing Regulation (EU) 2021/1326 of 10 August 2021[80]
68. Commission Implementing Regulation (EU) 2021/1377 of 19 August 2021[81]
69. Commission Implementing Regulation (EU) 2021/1974 of 12 November 2021[82]
70. Commission Implementing Regulation (EU) 2021/1975 of 12 November 2021[83]
71. Commission Implementing Regulation (EU) 2021/2029 of 19 November 2021[84]
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73. Commission Implementing Regulation (EU) 2022/47 of 13 January 2022[86]
74. Commission Implementing Regulation (EU) 2022/168 of 8 February 2022[87]
75. Commission Implementing Regulation (EU) 2022/169 of 8 February 2022[88]
76. Commission Implementing Regulation (EU) 2022/187 of 10 February 2022[89]
77. Commission Implementing Regulation (EU) 2022/188 of 10 February 2022[90]

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[75] OJ No. L 194, 2.6.2021, p. 16.
[76] OJ No. L 197, 4.6.2021, p. 71.
[77] OJ No. L 199, 7.6.2021, p. 10.
[78] OJ No. L 286, 10.8.2021, p. 5.
[79] OJ No. L 286, 10.8.2021, p. 12.
[80] OJ No. L 288, 11.8.2021, p. 24.
[81] OJ No. L 297, 20.8.2021, p. 20.
[82] OJ No. L 402, 15.11.2021, p. 5.
[83] OJ No. L 402, 15.11.2021, p.10.
[84] OJ No. L 415, 22.11.2021, p. 9.
[85] OJ No. L 432, 3.12.2021, p. 13.
[86] OJ No. L 9, 14.1.2022, p. 29.
[87] OJ No. L 28, 9.2.2022, p. 5.
[88] OJ No. L 28, 9.2.2022, p. 10.
[89] OJ No. L 30, 11.2.2022, p. 102.
[90] OJ No. L 30, 11.2.2022, p. 108.

Part B

1. Regulation (EC) No. 1642/2003 of the European Parliament and of the Council of 22 July 2003[91]
2. Commission Regulation (EC) No. 575/2006 of 7 April 2006[92]
3. Commission Regulation (EC) No. 202/2008 of 4 March 2008[93]
4. Regulation (EU) No. 652/2014 of the European Parliament and of the Council of 15 May 2014[94]
5. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017[95]
6. Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019[96]

Schedule 2

Form of official certificate to be given by an approved examiner to an authorised officer.

European Union (Novel Foods) Regulations 2022

Certificate of Analysis

To (1) .....

I, the undersigned (2) .....

being an approved examiner for the purpose of the above Regulations certify that on

the .....day of ..... 20.....

a sample marked (3) .....

Date .....

Number .....

[91] OJ No. L 245, 29.9.2003, p. 4.
[92] OJ No. L 100, 8.4.2006, p. 3.
[93] OJ No. L 60, 5.3.2008, p. 17.
[94] OJ No. L 189, 27.6.2014, p. 1.
[95] OJ No. L 117, 5.5.2017, p. 1.
[96] OJ No. L 198, 25.7.2019, p. 241.

Weight or Measure [4] .....

was submitted to me by you and I certify that the sample/relevant thing/copy/photograph of relevant thing was prepared and analysed/examined by me or under my direction [5]

and as a result I am of the opinion that [6]

Observations: [7]

I further certify that the sample has undergone no change which would affect my opinion/observations expressed above.

Certified by me this ..... day of ..... 20.....

At [8] .....

Name in BLOCK LETTERS .....

Status .....

Signature .....

_____

Official Stamp

NOTES

(1) Insert the name and address of the person submitting the sample for analysis.

(2) Insert description (e.g. Executive Analytical Chemist located at a Public Analyst's Laboratory).

(3) Insert particulars of marking (e.g. name, date, etc.).

(4) This may be left unanswered if the sample cannot be conveniently weighed or measured or the weight or measurement is not material to the result of analysis.

(5) Indicate whether the approved examiner carried out the analysis himself or herself or whether it was carried out by another under the direction of the approved examiner.

(6) Here the approved examiner should specify the result of the analysis having regard to the provisions of the relevant legislation. He or she may also add, if

required, a statement, or statements of conformity as per ISO/IEC 17025:2017 on the "General Requirements for the Competence of Testing and Calibration Laboratories".

(7) Here the approved examiner may insert, at his or her discretion, his or her opinion whether the analysis indicates any addition, abstraction, deficiency or the presence of foreign matter or other defect and whether the composition or quality is thereby affected; any physical, chemical or other properties bearing on the composition or quality of the article; whether the article is injurious to health or unfit for human consumption; whether and in what respect a label and description relating to the sample is incorrect or misleading; and he or she may add any other observations as he or she may consider relevant. In the case of analysis or examination of a relevant thing, or a copy or photograph thereof, the approved examiner may insert, at his or her discretion, any observations in relation to the relevant thing that he or she may consider relevant.

(8) Insert the name and address of the laboratory carrying out the analysis/examination.

L.S.

GIVEN under my Official Seal,
24 May, 2022.

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 full effect to Regulation (EU) No. 2015/2283 of the European Parliament and of the Council of 25 November 2015, on novel foods. They also give full effect to Commission Implementing Regulation (EU) 2017/2468 of 20 December 2017, Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 and Commission Implementing Regulation (EU) 2018/456 of 19 March 2018 setting out administrative, scientific and consultative requirements to be followed. They also give full effect to Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 which establishes the Union List of Novel Foods.

These Regulations introduce offences and penalties for persons that fail to comply with specific provisions of the foregoing Regulations as provided for in these Regulations.

These Regulations may be cited as the European Union (Novel Foods) Regulations 2022.

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