



STATUTORY INSTRUMENTS.

S.I. No. 159 of 2024

EUROPEAN UNION (NOVEL FOODS) (AMENDMENT)
REGULATIONS 2024

EUROPEAN UNION (NOVEL FOODS) (AMENDMENT)
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I, STEPHEN DONNELLY, Minister for Health, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving further effect to Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017¹, and all other associated European acts specified in Part A of Schedule 1 to these Regulations, hereby make the following Regulations:

1. (1) These Regulations may be cited as the European Union (Novel Foods) (Amendment) Regulations 2024.
(2) The Principal Regulations and these Regulations may be cited together as the European Union (Novel Foods) Regulations 2022 and 2024.
2. In these Regulations “Principal Regulations” means the European Union (Novel Foods) Regulations 2022 (S.I. No. 253 of 2022).
3. Regulation 11 of the Principal Regulations is amended—
 - (a) in paragraph (6)(b), by inserting “and Regulation 12” after “the Official Controls Regulation”, and
 - (b) by inserting after paragraph (7) the following paragraph:

“(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.”.
4. Regulation 12 of the Principal Regulations is amended —
 - (a) in paragraph (1), by inserting “, 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 operator is notified of the results of the analysis, testing or inspection” after “(‘a second expert opinion’)”,
 - (b) by inserting after paragraph (1) the following paragraphs:

¹ OJ No. L 351, 30.12.2017, p. 72.

- “(1A) Following receipt of a request pursuant to paragraph (1), the authorised officer shall issue a written acknowledgement of the request.
- (1B) An 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 (1A), 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.
- (1C) 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 operator.”,
- (c) in paragraph (2), by substituting for subparagraph (i) the following:
- “when purchasing or taking the sample, and if so requested by the 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”, and
- (d) by substituting for paragraph (4) the following:
- “(4) Where there is a dispute between the Authority or the official agency and the operator that is based on a second expert opinion, the 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.”.

5. Regulation 13 of the Principal Regulations is amended—
- (a) in paragraph (2)(a) by substituting “close and seal” for “seal and fasten”,
- (b) by inserting after paragraph (2) the following paragraph:
- “(2A) Notwithstanding paragraph (2)(a), an authorised officer may mark, close and seal a part of a sample, as appropriate, in the absence of the 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.”,

- (c) in paragraph (5), by inserting “, or the operator concerned availed of its right to a second expert opinion under Article 35 of the Official Controls Regulation and Regulation 12” after “as specified in this Regulation”, and
- (d) by substituting for paragraph (7) the following:

“(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 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 operator for a second expert opinion under Article 35 of the Official Controls Regulation and Regulation 12.”.

6. Regulation 14 of the Principal Regulations is amended—

- (a) by substituting for subparagraph (2)(a) the following:

“(a) in the presence of the 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) by inserting after paragraph (2) the following paragraph:

“(2A) Notwithstanding paragraph (2)(a), an authorised officer may mark, close and seal a part of a sample, as appropriate, in the absence of the 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,”,
- (c) in paragraph (3), by inserting “, or the operator concerned availed of its right to a second expert opinion under Article 35 of the Official Controls Regulation and Regulation 12,” after “taken pursuant to paragraph (1)”, and
- (d) by substituting for paragraph (5) the following:

“(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 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 operator for a second expert opinion under Article 35 of the Official Controls Regulation and Regulation 12.”.

7. Regulation 23 of the Principal Regulations is amended by inserting after paragraph (3) the following paragraphs:

- “(4) *Calanus finmarchicus* oil food supplements which were lawfully placed on the market before 12 July 2022 may be marketed until their date of minimum durability or use by date.
- (5) *Calanus finmarchicus* oil food supplements which were dispatched from a third country and were on their way to the Union before 12 July 2022 and complying with the rules in force before 12 July 2022, may be marketed until their date of minimum durability or use by date.”.

8. The Principal Regulations are amended by substituting for Part A of Schedule 1 the following:

“Schedule 1

Part A

1. Commission Implementing Regulation (EU) 2018/460 of 20 March 2018²
2. Commission Implementing Regulation (EU) 2018/461 of 20 March 2018³
3. Commission Implementing Regulation (EU) 2018/462 of 20 March 2018⁴
4. Commission Implementing Regulation (EU) 2018/469 of 21 March 2018⁵
5. Commission Implementing Regulation (EU) 2018/991 of 12 July 2018⁶
6. Commission Implementing Regulation (EU) 2018/1011 of 17 July 2018⁷
7. Commission Implementing Regulation (EU) 2018/1018 of 18 July 2018⁸
8. Commission Implementing Regulation (EU) 2018/1032 of 20 July 2018⁹
9. Commission Implementing Regulation (EU) 2018/1023 of 23 July 2018¹⁰
10. Commission Implementing Regulation (EU) 2018/1122 of 10 August 2018¹¹
11. Commission Implementing Regulation (EU) 2018/1123 of 10 August 2018¹²
12. Commission Implementing Regulation (EU) 2018/1132 of 13 August 2018¹³
13. Commission Implementing Regulation (EU) 2018/1133 of 13 August 2018¹⁴
14. Commission Implementing Regulation (EU) 2018/1293 of 26 September 2018¹⁵

² OJ No. L 78, 21.3.2018, p. 2.

³ OJ No. L 78, 21.3.2018, p. 7.

⁴ OJ No. L 78, 21.3.2018, p. 11.

⁵ OJ No. L 79, 22.3.2018, p. 11.

⁶ OJ No. L 177, 13.7.2018, p. 9.

⁷ OJ No. L 181, 18.7.2018, p. 4.

⁸ OJ No. L 183, 19.7.2018, p. 9.

⁹ OJ No. L 185, 23.7.2018, p. 9.

¹⁰ OJ No. L 187, 24.7.2018, p. 1.

¹¹ OJ No. L 204, 13.8.2018, p. 36.

¹² OJ No. L 204, 13.8.2018, p. 41.

¹³ OJ No. L 205, 14.8.2018, p. 15.

¹⁴ OJ No. L 205, 14.8.2018, p. 18.

¹⁵ OJ No. L 243, 27.9.2018, p. 2.

15. Commission Implementing Regulation (EU) 2018/1631 of 30 October 2018¹⁶
16. Commission Implementing Regulation (EU) 2018/1632 of 30 October 2018¹⁷
17. Commission Implementing Regulation (EU) 2018/1633 of 30 October 2018¹⁸
18. Commission Implementing Regulation (EU) 2018/1647 of 31 October 2018¹⁹
19. Commission Implementing Regulation (EU) 2018/1648 of 29 October 2018²⁰
20. Commission Implementing Regulation (EU) 2018/1991 of 13 December 2018²¹
21. Commission Implementing Regulation (EU) 2018/2016 of 18 December 2018²²
22. Commission Implementing Regulation (EU) 2018/2017 of 18 December 2018²³
23. Commission Implementing Regulation (EU) 2019/108 of 24 January 2019²⁴
24. Commission Implementing Regulation (EU) 2019/109 of 24 January 2019²⁵
25. Commission Implementing Regulation (EU) 2019/110 of 24 January 2019²⁶
26. Commission Implementing Regulation (EU) 2019/387 of 11 March 2019²⁷
27. Commission Implementing Regulation (EU) 2019/388 of 11 March 2019²⁸
28. Commission Implementing Regulation (EU) 2019/456 of 20 March 2019²⁹
29. Commission Implementing Regulation (EU) 2019/506 of 26 March 2019³⁰

¹⁶ OJ No. L 272, 31.10.2018, p. 17.

¹⁷ OJ No. L 272, 31.10.2018, p. 23.

¹⁸ OJ No. L 272, 31.10.2018, p. 29.

¹⁹ OJ No. L 274, 5.11.2018, p. 51.

²⁰ OJ No. L 275, 6.11.2018, p. 1.

²¹ OJ No. L 320, 17.12.2018, p. 22.

²² OJ No. L 323, 19.12.2018, p. 1.

²³ OJ No. L 323, 19.12.2018, p. 4.

²⁴ OJ No. L 23, 25.1.2019, p. 4.

²⁵ OJ No. L 23, 25.1.2019, p. 7.

²⁶ OJ No. L 23, 25.1.2019, p. 11.

²⁷ OJ No. L 70, 12.3.2019, p. 17.

²⁸ OJ No. L 70, 12.3.2019, p. 21.

²⁹ OJ No. L 79, 21.3.2019, p. 13.

³⁰ OJ No. L 85, 27.3.2019, p. 11.

30. Commission Implementing Regulation (EU) 2019/760 of 13 May 2019³¹
31. Commission Implementing Regulation (EU) 2019/1272 of 29 July 2019³²
32. Commission Implementing Regulation (EU) 2019/1294 of 1 August 2019³³
33. Commission Implementing Regulation (EU) 2019/1314 of 2 August 2019³⁴
34. Commission Implementing Regulation (EU) 2019/1686 of 8 October 2019³⁵
35. Commission Implementing Regulation (EU) 2019/1976 of 25 November 2019³⁶
36. Commission Implementing Regulation (EU) 2019/1979 of 26 November 2019³⁷
37. Commission Implementing Regulation (EU) 2019/2165 of 17 December 2019³⁸
38. Commission Implementing Regulation (EU) 2020/16 of 10 January 2020³⁹
39. Commission Implementing Regulation (EU) 2020/24 of 13 January 2020⁴⁰
40. Commission Implementing Regulation (EU) 2020/206 of 14 February 2020⁴¹
41. Commission Implementing Regulation (EU) 2020/443 of 25 March 2020⁴²
42. Commission Implementing Regulation (EU) 2020/478 of 1 April 2020⁴³
43. Commission Implementing Regulation (EU) 2020/484 of 2 April 2020⁴⁴
44. Commission Implementing Regulation (EU) 2020/500 of 6 April 2020⁴⁵

³¹ OJ No. L 125, 14.5.2019, p. 13.

³² OJ No. L 201, 30.7.2019, p. 3.

³³ OJ No. L 204, 2.8.2019, p. 16.

³⁴ OJ No. L 205, 5.8.2019, p. 4.

³⁵ OJ No. L 258, 9.10.2019, p. 13.

³⁶ OJ No. L 308, 29.11.2019, p. 40.

³⁷ OJ No. L 308, 29.11.2019, p. 62.

³⁸ OJ No. L 328, 18.12.2019, p. 81.

³⁹ OJ No. L 7, 13.1.2020, p. 6.

⁴⁰ OJ No. L 8, 14.1.2020, p. 12.

⁴¹ OJ No. L 43, 17.2.2020, p. 66.

⁴² OJ No. L 92, 26.3.2020, p. 7.

⁴³ OJ No. L 102, 2.4.2020, p. 1.

⁴⁴ OJ No. L 103, 3.4.2020, p. 3.

⁴⁵ OJ No. L 109, 7.4.2020, p. 2.

45. Commission Implementing Regulation (EU) 2020/916 of 1 July 2020⁴⁶
46. Commission Implementing Regulation (EU) 2020/917 of 1 July 2020⁴⁷
47. Commission Implementing Regulation (EU) 2020/973 of 6 July 2020⁴⁸
48. Commission Implementing Regulation (EU) 2020/1163 of 6 August 2020⁴⁹
49. Commission Implementing Regulation (EU) 2020/1559 of 26 October 2020⁵⁰
50. Commission Implementing Regulation (EU) 2020/1634 of 4 November 2020⁵¹
51. Commission Implementing Regulation (EU) 2020/1820 of 2 December 2020⁵²
52. Commission Implementing Regulation (EU) 2020/1821 of 2 December 2020⁵³
53. Commission Implementing Regulation (EU) 2020/1822 of 2 December 2020⁵⁴
54. Commission Implementing Regulation (EU) 2020/1993 of 4 December 2020⁵⁵
55. Commission Implementing Regulation (EU) 2021/50 of 22 January 2021⁵⁶
56. Commission Implementing Regulation (EU) 2021/51 of 22 January 2021⁵⁷
57. Commission Implementing Regulation (EU) 2021/82 of 27 January 2021⁵⁸
58. Commission Implementing Regulation (EU) 2021/96 of 28 January 2021⁵⁹
59. Commission Implementing Regulation (EU) 2021/120 of 2 February 2021⁶⁰
60. Commission Implementing Regulation (EU) 2021/668 of 23 April 2021⁶¹

⁴⁶ OJ No. L 209, 2.7.2020, p. 6.

⁴⁷ OJ No. L 209, 2.7.2020, p. 10.

⁴⁸ OJ No. L 215, 7.7.2020, p. 7.

⁴⁹ OJ No. L 258, 7.8.2020, p. 1.

⁵⁰ OJ No. L 357, 27.10.2020, p. 7.

⁵¹ OJ No. L 367, 5.11.2020, p. 39.

⁵² OJ No. L 406, 3.12.2020, p. 29.

⁵³ OJ No. L 406, 3.12.2020, p. 34.

⁵⁴ OJ No. L 406, 3.12.2020, p. 39.

⁵⁵ OJ No. L 410, 7.12.2020, p. 62.

⁵⁶ OJ No. L 23, 25.1.2021, p. 7.

⁵⁷ OJ No. L 23, 25.1.2021, p. 10.

⁵⁸ OJ No. L 29, 28.1.2021, p. 16.

⁵⁹ OJ No. L 31, 29.1.2021, p. 201.

⁶⁰ OJ No. L 37, 3.2.2021, p. 1.

⁶¹ OJ No. L 141, 26.4.2021, p. 3.

61. Commission Implementing Regulation (EU) 2021/670 of 23 April 2021⁶²
62. Commission Implementing Regulation (EU) 2021/882 of 1 June 2021⁶³
63. Commission Implementing Regulation (EU) 2021/900 of 3 June 2021⁶⁴
64. Commission Implementing Regulation (EU) 2021/912 of 4 June 2021⁶⁵
65. Commission Implementing Regulation (EU) 2021/1318 of 9 August 2021⁶⁶
66. Commission Implementing Regulation (EU) 2021/1319 of 9 August 2021⁶⁷
67. Commission Implementing Regulation (EU) 2021/1326 of 10 August 2021⁶⁸
68. Commission Implementing Regulation (EU) 2021/1377 of 19 August 2021⁶⁹
69. Commission Implementing Regulation (EU) 2021/1974 of 12 November 2021⁷⁰
70. Commission Implementing Regulation (EU) 2021/1975 of 12 November 2021⁷¹
71. Commission Implementing Regulation (EU) 2021/2029 of 19 November 2021⁷²
72. Commission Implementing Regulation (EU) 2021/2079 of 26 November 2021⁷³
73. Commission Implementing Regulation (EU) 2021/2129 of 2 December 2021⁷⁴
74. Commission Implementing Regulation (EU) 2021/2191 of 10 December 2021⁷⁵
75. Commission Implementing Regulation (EU) 2022/47 of 13 January 2022⁷⁶
76. Commission Implementing Regulation (EU) 2022/168 of 8 February 2022⁷⁷

⁶² OJ No. L 141, 26.4.2021, p. 14.

⁶³ OJ No. L 194, 2.6.2021, p. 16.

⁶⁴ OJ No. L 197, 4.6.2021, p. 71.

⁶⁵ OJ No. L 199, 7.6.2021, p. 10.

⁶⁶ OJ No. L 286, 10.8.2021, p. 5.

⁶⁷ OJ No. L 286, 10.8.2021, p. 12.

⁶⁸ OJ No. L 288, 11.8.2021, p. 24.

⁶⁹ OJ No. L 297, 20.8.2021, p. 20.

⁷⁰ OJ No. L 402, 15.11.2021, p. 5.

⁷¹ OJ No. L 402, 15.11.2021, p. 10.

⁷² OJ No. L 415, 22.11.2021, p. 9.

⁷³ OJ No. L 426, 29.11.2021, p. 16.

⁷⁴ OJ No. L 432, 3.12.2021, p. 13.

⁷⁵ OJ No. L 445, 13.12.2021, p. 1.

⁷⁶ OJ No. L 9, 14.1.2022, p. 29.

⁷⁷ OJ No. L 28, 9.2.2022, p. 5.

77. Commission Implementing Regulation (EU) 2022/169 of 8 February 2022⁷⁸
78. Commission Implementing Regulation (EU) 2022/187 of 10 February 2022⁷⁹
79. Commission Implementing Regulation (EU) 2022/188 of 10 February 2022⁸⁰
80. Commission Implementing Regulation (EU) 2022/196 of 11 February 2022⁸¹
81. Commission Implementing Regulation (EU) 2022/202 of 14 February 2022⁸²
82. Commission Implementing Regulation (EU) 2022/672 of 22 April 2022⁸³
83. Commission Implementing Regulation (EU) 2022/673 of 22 April 2022⁸⁴
84. Commission Implementing Regulation (EU) 2022/684 of 28 April 2022⁸⁵
85. Commission Implementing Regulation (EU) 2022/961 of 20 June 2022⁸⁶
86. Commission Implementing Regulation (EU) 2022/965 of 21 June 2022⁸⁷
87. Commission Implementing Regulation (EU) 2022/966 of 21 June 2022⁸⁸
88. Commission Implementing Regulation (EU) 2022/1160 of 5 July 2022⁸⁹
89. Commission Implementing Regulation (EU) 2022/1365 of 4 August 2022⁹⁰
90. Commission Implementing Regulation (EU) 2022/1373 of 5 August 2022⁹¹
91. Commission Implementing Regulation (EU) 2022/1381 of 8 August 2022⁹²

⁷⁸ OJ No. L 28, 9.2.2022, p. 10.

⁷⁹ OJ No. L 30, 11.2.2022, p. 102.

⁸⁰ OJ No. L 30, 11.2.2022, p. 108.

⁸¹ OJ No. L 31, 14.2.2022, p. 46.

⁸² OJ No. L 33, 15.2.2022, p. 41.

⁸³ OJ No. L 122, 25.4.2022, p. 24.

⁸⁴ OJ No. L 122, 25.4.2022, p. 27.

⁸⁵ OJ No. L 126, 29.4.2022, p. 10.

⁸⁶ OJ No. L 165, 21.6.2022, p. 41.

⁸⁷ OJ No. L 166, 22.6.2022, p. 118.

⁸⁸ OJ No. L 166, 22.6.2022, p. 125.

⁸⁹ OJ No. L 179, 6.7.2022, p. 25.

⁹⁰ OJ No. L 205, 5.8.2022, p. 230.

⁹¹ OJ No. L 206, 8.8.2022, p. 28.

⁹² OJ No. L 207, 9.8.2022, p. 12.

92. Commission Implementing Regulation (EU) 2022/2534 of 21 December 2022⁹³
93. Commission Implementing Regulation (EU) 2022/2535 of 21 December 2022⁹⁴
94. Commission Implementing Regulation (EU) 2023/4 of 3 January 2023⁹⁵
95. Commission Implementing Regulation (EU) 2023/5 of 3 January 2023⁹⁶
96. Commission Implementing Regulation (EU) 2023/6 of 3 January 2023⁹⁷
97. Commission Implementing Regulation (EU) 2023/7 of 3 January 2023⁹⁸
98. Commission Implementing Regulation (EU) 2023/65 of 6 January 2023⁹⁹
99. Commission Implementing Regulation (EU) 2023/463 of 3 March 2023¹⁰⁰.



GIVEN under my Official Seal,
17 April, 2024.

STEPHEN DONNELLY,
Minister for Health.

⁹³ OJ No. L 328, 22.12.2022, p. 85.

⁹⁴ OJ No. L 328, 22.12.2022, p. 91.

⁹⁵ OJ No. L 2, 4.1.2023, p. 3.

⁹⁶ OJ No. L 2, 4.1.2023, p. 9.

⁹⁷ OJ No. L 2, 4.1.2023, p. 16.

⁹⁸ OJ No. L 2, 4.1.2023, p. 21.

⁹⁹ OJ No. L 6, 9.1.2023, p. 1.

¹⁰⁰ OJ No. L 68, 6.3.2023, p. 32.

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 Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 which establishes the Union List of Novel Foods as amended by the Commission Implementing Regulations specified in the Schedule to these Regulations.

These Regulations amend the European Union (Novel Foods) Regulations 2022 (S.I. No. 253 of 2022) in the manner specified in these Regulations.

These Regulations may be cited as the European Union (Novel Foods) (Amendment) Regulations 2024.

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