

STATUTORY INSTRUMENTS.

S.I. No. 40 of 2025

EUROPEAN UNION (NOVEL FOODS) (AMENDMENT) REGULATIONS $2025\,$

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EUROPEAN UNION (NOVEL FOODS) (AMENDMENT) REGULATIONS 2025

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 Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017¹, as amended by the Commission implementing 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 2025.
- (2) The Principal Regulations, the Regulations of 2024 and these Regulations may be cited together as the European Union (Novel Food) Regulations 2022 to 2025.

2. In these Regulations –

"Principal Regulations" means the European Union (Novel Foods) Regulations 2022 (S.I. No. 253 of 2022);

"Regulations of 2024" means the European Union (Novel Foods) (Amendment) Regulations 2024 (S.I. No. 159 of 2024).

- 3. Regulation 13 (as amended by Regulation 5 of the Regulations of 2024) of the Principal Regulations is amended by substituting for paragraph (3) the following:
- "(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

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¹ OJ No. L 351, 30.12.2017, p. 72.

(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. Regulation 23 (as amended by Regulation 7 of the Regulations of 2024) of the Principal Regulations is amended by inserting after paragraph (5) the following paragraph:
- "(6) Food supplements containing 8.0 mg or less of astaxanthin intended for the general population older than 14 years of age, complying with the requirements of Commission Implementing Regulation (EU) 2021/1377 of 19 August 2021² may continue to be placed on the market until 1 February 2024 and may be marketed until their date of minimum durability or use by date."
- 5. Part A of Schedule 1 (as amended by Regulation 8 of the Regulations of 2024) of the Principal Regulations is substituted by the following:

"Schedule 1

Part A

- 1. Commission Implementing Regulation (EU) 2018/460 of 20 March 2018^3
- 2. Commission Implementing Regulation (EU) 2018/461 of 20 March 2018⁴
- 3. Commission Implementing Regulation (EU) 2018/462 of 20 March 2018⁵
- 4. Commission Implementing Regulation (EU) 2018/469 of 21 March 2018⁶

² OJ No. L 297, 20.8.2021, p. 20.

³ OJ No. L 78, 21.3.2018, p. 2.

⁴ OJ No. L 78, 21.3.2018, p. 7.

⁵ OJ No. L 78, 21.3.2018, p. 11.

⁶ OJ No. L 79, 22.3.2018, p. 11.

- 5. Commission Implementing Regulation (EU) 2018/991 of 12 July 2018⁷
- 6. Commission Implementing Regulation (EU) 2018/1011 of 17 July 2018⁸
- 7. Commission Implementing Regulation (EU) 2018/1018 of 18 July 2018⁹
- 8. Commission Implementing Regulation (EU) 2018/1023 of 23 July 2018^{10}
- 9. Commission Implementing Regulation (EU) 2018/1032 of 20 July 2018¹¹
- 10. Commission Implementing Regulation (EU) 2018/1122 of 10 August 2018¹²
- 11. Commission Implementing Regulation (EU) 2018/1123 of 10 August 2018¹³
- 12. Commission Implementing Regulation (EU) 2018/1132 of 13 August 2018^{14}
- 13. Commission Implementing Regulation (EU) 2018/1133 of 13 August 2018^{15}
- 14. Commission Implementing Regulation (EU) 2018/1293 of 26 September 2018^{16}
- 15. Commission Implementing Regulation (EU) 2018/1631 of 30 October 2018^{17}
- 16. Commission Implementing Regulation (EU) 2018/1632 of 30 October 2018¹⁸
- 17. Commission Implementing Regulation (EU) 2018/1633 of 30 October 2018¹⁹
- 18. Commission Implementing Regulation (EU) 2018/1647 of 31 October 2018^{20}
- 19. Commission Implementing Regulation (EU) 2018/1648 of 29 October 2018^{21}

⁷ OJ No. L 177, 13.7.2018, p. 9.

⁸ OJ No. L 181, 18.7.2018, p. 4.

⁹ OJ No. L 183, 19.7.2018, p. 9.

¹⁰ OJ No. L 187, 24.7.2018, p. 1.

¹¹ OJ No. L 185, 23.7.2018, p. 9.

¹² OJ No. L 204, 13.8.2018, p. 36.

¹³ OJ No. L 204, 13.8.2018, p. 41.

¹⁴ OJ No. L 205, 14.8.2018, p. 15.

¹⁵ OJ No. L 205, 14.8.2018, p. 18.

¹⁶ OJ No. L 243, 27.9.2018, p. 2.

¹⁷ OJ No. L 272, 31.10.2018, p. 17.

¹⁸ OJ No. L 272, 31.10.2018, p. 23.

¹⁹ OJ No. L 272, 31.10.2018, p. 29.

²⁰ OJ No. L 274, 5.11.2018, p. 51.

²¹ OJ No. L 275, 6.11.2018, p. 1.

- 20. Commission Implementing Regulation (EU) 2018/1991 of 13 December 2018²²
- 21. Commission Implementing Regulation (EU) 2018/2016 of December 2018²³
- Commission Implementing Regulation (EU) 2018/2017 of 22. December 2018²⁴
- 23. Commission Implementing Regulation (EU) 2019/108 of 24 January 2019^{25}
- Commission Implementing Regulation (EU) 2019/109 of 24 January 24. 2019^{26}
- 25. Commission Implementing Regulation (EU) 2019/110 of 24 January 2019^{27}
- Commission Implementing Regulation (EU) 2019/387 of 11 March 26. 2019^{28}
- 27. Commission Implementing Regulation (EU) 2019/388 of 11 March 2019^{29}
- Commission Implementing Regulation (EU) 2019/456 of 20 March 28. 2019^{30}
- Commission Implementing Regulation (EU) 2019/506 of 26 March 29. 2019^{31}
- 30. Commission Implementing Regulation (EU) 2019/760 of 13 May 2019^{32}
- 31. Commission Implementing Regulation (EU) 2019/1272 of 29 July
- 32. Commission Implementing Regulation (EU) 2019/1294 of 1 August 2019^{34}
- Commission Implementing Regulation (EU) 2019/1314 of 2 August 33.
- 34. Commission Implementing Regulation (EU) 2019/1686 of 8 October 2019^{36}

²² OJ No. L 320, 17.12.2018, p. 22.

²³ OJ No. L 323, 19.12.2018, p. 1.

²⁴ OJ No. L 323, 19.12.2018, p. 4.

²⁵ OJ No. L 23, 25.1.2019, p. 4.

²⁶ OJ No. L 23, 25.1.2019, p. 7.

²⁷ OJ No. L 23, 25.1.2019, p. 11.

²⁸ OJ No. L 70, 12.3.2019, p. 17.

²⁹ OJ No. L 70, 12.3.2019, p. 21.

³⁰ OJ No. L 79, 21.3.2019, p. 13.

³¹ OJ No. L 85, 27.3.2019, p. 11.

³² OJ No. L 125, 14.5.2019, p. 13.

³³ OJ No. L 201, 30.7.2019, p. 3.

³⁴ OJ No. L 204, 2.8.2019, p. 16. ³⁵ OJ No. L 205, 5.8.2019, p. 4.

³⁶ OJ No. L 258, 9.10.2019, p. 13.

- 35. Commission Implementing Regulation (EU) 2019/1976 of 25 November 2019³⁷
- 36. Commission Implementing Regulation (EU) 2019/1979 of 26 November 2019³⁸
- 37. Commission Implementing Regulation (EU) 2019/2165 of 17 December 2019³⁹
- 38. Commission Implementing Regulation (EU) 2020/16 of 10 January 2020^{40}
- 39. Commission Implementing Regulation (EU) 2020/24 of 13 January 2020^{41}
- 40. Commission Implementing Regulation (EU) 2020/206 of 14 February 2020⁴²
- 41. Commission Implementing Regulation (EU) 2020/443 of 25 March 2020^{43}
- 42. Commission Implementing Regulation (EU) 2020/478 of 1 April 2020^{44}
- 43. Commission Implementing Regulation (EU) 2020/484 of 2 April 2020^{45}
- 44. Commission Implementing Regulation (EU) 2020/500 of 6 April 2020⁴⁶
- 45. Commission Implementing Regulation (EU) 2020/916 of 1 July 2020⁴⁷
- 46. Commission Implementing Regulation (EU) 2020/917 of 1 July 2020⁴⁸
- 47. Commission Implementing Regulation (EU) 2020/973 of 6 July 2020⁴⁹
- 48. Commission Implementing Regulation (EU) 2020/1163 of 6 August 2020^{50}
- 49. Commission Implementing Regulation (EU) 2020/1559 of 26 October 2020⁵¹
- 50. Commission Implementing Regulation (EU) 2020/1634 of 4 November 2020⁵²

³⁷ OJ No. L 308, 29.11.2019, p. 40.

³⁸ OJ No. L 308, 29.11.2019, p. 62.

³⁹ OJ No. L 328, 18.12.2019, p. 81.

⁴⁰ OJ No. L 7, 13.1.2020, p. 6.

⁴¹ OJ No. L 8, 14.1.2020, p. 12.

⁴² OJ No. L 43, 17.2.2020, p. 66.

⁴³ OJ No. L 92, 26.3.2020, p. 7.

⁴⁴ OJ No. L 102, 2.4.2020, p. 1.

⁴⁵ OJ No. L 103, 3.4.2020, p. 3.

⁴⁶ OJ No. L 109, 7.4.2020, p. 2.

⁴⁷ OJ No. L 209, 2.7.2020, p. 6.

⁴⁸ OJ No. L 209, 2.7.2020, p. 10.

⁴⁹ OJ No. L 215, 7.7.2020, p. 7.

⁵⁰ OJ No. L 258, 7.8.2020, p. 1.

⁵¹ OJ No. L 357, 27.10.2020, p. 7.

⁵² OJ No. L 367, 5.11.2020, p. 39.

- 51. Commission Implementing Regulation (EU) 2020/1820 of 2 December 2020⁵³
- 52. Commission Implementing Regulation (EU) 2020/1821 of 2 December 2020⁵⁴
- 53. Commission Implementing Regulation (EU) 2020/1822 of 2 December 2020⁵⁵
- 54. Commission Implementing Regulation (EU) 2020/1993 of 4 December 2020⁵⁶
- 55. Commission Implementing Regulation (EU) 2021/50 of 22 January 2021⁵⁷
- 56. Commission Implementing Regulation (EU) 2021/51 of 22 January 2021⁵⁸
- 57. Commission Implementing Regulation (EU) 2021/82 of 27 January 2021^{59}
- 58. Commission Implementing Regulation (EU) 2021/96 of 28 January 2021^{60}
- 59. Commission Implementing Regulation (EU) 2021/120 of 2 February 2021⁶¹
- 60. Commission Implementing Regulation (EU) 2021/668 of 23 April 2021^{62}
- 61. Commission Implementing Regulation (EU) 2021/670 of 23 April 2021^{63}
- 62. Commission Implementing Regulation (EU) 2021/882 of 1 June 2021⁶⁴
- 63. Commission Implementing Regulation (EU) 2021/900 of 3 June 2021⁶⁵
- 64. Commission Implementing Regulation (EU) 2021/912 of 4 June 2021⁶⁶
- 65. Commission Implementing Regulation (EU) 2021/1318 of 9 August 2021⁶⁷
- 66. Commission Implementing Regulation (EU) 2021/1319 of 9 August 2021⁶⁸

⁵³ OJ No. L 406, 3.12.2020, p. 29.

⁵⁴ OJ No. L 406, 3.12.2020, p. 34.

⁵⁵ OJ No. L 406, 3.12.2020, p. 39.

⁵⁶ OJ No. L 410, 7.12.2020, p. 62.

⁵⁷ OJ No. L 23, 25.1.2021, p. 7.

⁵⁸ OJ No. L 23, 25.1.2021, p. 10.

⁵⁹ OJ No. L 29, 28.1.2021, p. 16.

⁶⁰ OJ No. L 31, 29.1.2021, p. 201.

⁶¹ OJ No. L 37, 3.2.2021, p. 1.

⁶² OJ No. L 141, 26.4.2021, p. 3.

⁶³ OJ No. L 141, 26.4.2021, p. 14.

⁶⁴ OJ No. L 194, 2.6,2021, p. 16.

⁶⁵ OJ No. L 197, 4.6.2021, p. 71.

⁶⁶ OJ No. L 199, 7.6.2021, p. 10.

⁶⁷ OJ No. L 286, 10.8.2021, p. 5.

⁶⁸ OJ No. L 286, 10.8.2021, p. 12.

- 67. Commission Implementing Regulation (EU) 2021/1326 of 10 August 2021⁶⁹
- 68. Commission Implementing Regulation (EU) 2021/1377 of 19 August 2021²
- 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 2021^{73}
- 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
- 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

⁶⁹ OJ No. L 288, 11.8.2021, p. 24.

² 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.

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.

- 82. Commission Implementing Regulation (EU) 2022/672 of 22 April 2022^{83}
- 83. Commission Implementing Regulation (EU) 2022/673 of 22 April 2022⁸⁴
- 84. Commission Implementing Regulation (EU) 2022/684 of 28 April 2022^{85}
- 85. Commission Implementing Regulation (EU) 2022/961 of 20 June 2022^{86}
- 86. Commission Implementing Regulation (EU) 2022/965 of 21 June 2022^{87}
- 87. Commission Implementing Regulation (EU) 2022/966 of 21 June 2022^{88}
- 88. Commission Implementing Regulation (EU) 2022/1160 of 5 July 2022⁸⁹
- 89. Commission Implementing Regulation (EU) 2022/1365 of 4 August 2022^{90}
- 90. Commission Implementing Regulation (EU) 2022/1373 of 5 August 2022⁹¹
- 91. Commission Implementing Regulation (EU) 2022/1381 of 8 August 2022⁹²
- 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

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.

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.

- 97. Commission Implementing Regulation (EU) 2023/7 of 3 January 2023⁹⁸
- 98. Commission Implementing Regulation (EU) 2023/52 of 4 January 2023⁹⁹
- 99. Commission Implementing Regulation (EU) 2023/58 of 5 January 2023¹⁰⁰
- 100. Commission Implementing Regulation (EU) 2023/65 of 6 January 2023^{101}
- 101. Commission Implementing Regulation (EU) 2023/113 of 16 January 2023^{102}
- 102. Commission Implementing Regulation (EU) 2023/267 of 8 February 2023¹⁰³
- 103. Commission Implementing Regulation (EU) 2023/463 of 3 March 2023^{104}
- 104. Commission Implementing Regulation (EU) 2023/652 of 20 March 2023^{105}
- 105. Commission Implementing Regulation (EU) 2023/667 of 22 March 2023¹⁰⁶
- 106. Commission Implementing Regulation (EU) 2023/859 of 25 April 2023^{107}
- 107. Commission Implementing Regulation (EU) 2023/931 of 8 May 2023¹⁰⁸
- 108. Commission Implementing Regulation (EU) 2023/937 of 10 May 2023^{109}
- 109. Commission Implementing Regulation (EU) 2023/938 of 10 May 2023^{110}
- 110. Commission Implementing Regulation (EU) 2023/943 of 11 May 2023¹¹¹
- 111. Commission Implementing Regulation (EU) 2023/948 of 12 May 2023¹¹²

⁹⁸ OJ No. L 2, 4.1.2023, p. 21.

⁹⁹ OJ No. L 3, 5.1.2023, p. 1.

¹⁰⁰ OJ No. L 5, 6.1.2023, p. 10.

¹⁰¹ OJ No. L 6, 9.1.2023, p. 1.

¹⁰² OJ No. L 15, 17.1.2023, p. 1.

¹⁰³ OJ No. L 39, 9.2.2023, p. 1.

¹⁰⁴ OJ No. L 68, 6.3.2023, p. 32.

¹⁰⁵ OJ No. L 81, 21.3.2023, p. 23.

¹⁰⁶ OJ No. L 84, 23.3.2023, p. 3.

¹⁰⁷ OJ No. L 111, 26.4.2023, p. 17.

¹⁰⁸ OJ No. L 124, 10.5.2023, p. 1.

¹⁰⁹ OJ No. L 125, 11.5.2023, p. 12.

OJ No. L 125, 11.5.2023, p. 16.OJ No. L 126, 12.5.2023, p. 41.

¹¹² OJ No. L 128, 15.5.2023, p. 52.

- 112. Commission Implementing Regulation (EU) 2023/949 of 12 May 2023^{113}
- 113. Commission Implementing Regulation (EU) 2023/950 of 12 May 2023¹¹⁴
- 114. Commission Implementing Regulation (EU) 2023/951 of 12 May 2023^{115}
- 115. Commission Implementing Regulation (EU) 2023/961 of 12 May 2023^{116}
- 116. Commission Implementing Regulation (EU) 2023/972 of 10 May 2023^{117}
- 117 Commission Implementing Regulation (EU) 2023/1581 of 1 August 2023¹¹⁸
- 118. Commission Implementing Regulation (EU) 2023/1582 of 1 August 2023¹¹⁹
- 119. Commission Implementing Regulation (EU) 2023/1583 of 1 August 2023^{120}
- 120. Commission Implementing Regulation (EU) 2023/2210 of 20 October 2023¹²¹
- 121. Commission Implementing Regulation (EU) 2023/2214 of 23 October 2023¹²²
- 122. Commission Implementing Regulation (EU) 2023/2215 of 23 October 2023¹²³
- 123. Commission Implementing Regulation (EU) 2023/2847 of 20 December 2023¹²⁴
- 124. Commission Implementing Regulation (EU) 2023/2851 of 20 December 2023¹²⁵
- 125. Commission Implementing Regulation (EU) 2023/2852 of 20 December 2023¹²⁶".

¹¹³ OJ No. L 128, 15.5.2023, p. 60.

¹¹⁴ OJ No. L 128, 15.5.2023, p. 68.

¹¹⁵ OJ No. L 128, 15.5.2023, p. 73.

¹¹⁶ OJ No. L 129, 16.5.2023, p. 3.

¹¹⁷ OJ No. L 132, 17.5.2023, p. 46.

¹¹⁸ OJ No. L 194, 2.8.2023, p. 4.

¹¹⁹ OJ No. L 194, 2.8.2023, p. 8.

¹²⁰ OJ No. L 194, 2.8.2023, p. 13.

¹²¹ OJ No. L 2210, 23.10.2023, p. 1.

¹²² OJ No. L 2214, 24.10.2023, p. 1.

¹²³ OJ No. L 2215, 24.10.2023, p. 1.

¹²⁴ OJ No. L 2847, 21.12.2023, p. 1.

¹²⁵ OJ No. L 2851, 21.12.2023, p. 1.

¹²⁶ OJ No. L 2852, 21.12.2023, p. 1.



GIVEN under my Official Seal, 20 February, 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 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 may be cited as the European Union (Novel Foods) (Amendment) Regulations 2025.

These Regulations amend the European Union (Novel Foods) Regulations 2022 (S.I. No. 253 of 2022) in the manner specified in these Regulations and can be cited together with all previous amending instruments as the European Union (Novel Foods) Regulations 2022 to 2025.

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