



STATUTORY INSTRUMENTS.

**S.I. No. 265 of 2023**



EUROPEAN UNION (ADDITION OF VITAMINS AND MINERALS AND  
OF CERTAIN OTHER SUBSTANCES TO FOODS) (AMENDMENT)  
REGULATIONS 2023

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EUROPEAN UNION (ADDITION OF VITAMINS AND MINERALS AND  
OF CERTAIN OTHER SUBSTANCES TO 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 effect to Commission Regulation (EU) 2022/860 of 1 June 2022<sup>1</sup> and Commission Regulation (EU) 2022/2340 of 30 November 2022<sup>2</sup>, hereby make the following regulations:

1. (1) These Regulations may be cited as the European Union (Addition of Vitamins and Minerals and of Certain Other Substances to Foods) (Amendment) Regulations 2023.

(2) The Principal Regulations, the European Union (Addition of Vitamins and Minerals and of Certain Other Substances to Foods) (Amendment) Regulations 2018 (S.I. No. 226 of 2018), the Regulations of 2021 and these Regulations may be cited together as the European Union (Addition of Vitamins and Minerals and of Certain Other Substances to Foods) Regulations 2017 to 2023.

2. In these Regulations—

“Principal Regulations” means European Union (Addition of Vitamins and Minerals and of Certain Other Substances to Foods) Regulations 2017 (S.I. No. 376 of 2017);

“Regulations of 2021” means European Union (Addition of Vitamins and Minerals and of Certain Other Substances to Foods) (Amendment) Regulations 2021 (S.I. No. 541 of 2021).

3. Regulation 2 of the Principal Regulations (as last amended by Regulation 3 of the Regulations of 2021) is amended—

(a) by substituting for the definition of “Annex III to EC Regulation 1925/2006” the following:

“‘Annex III to EC Regulation 1925/2006’ means Annex III to Regulation (EC) No. 1925/2006 of the European Parliament and of the Council of 20 December 2006<sup>3</sup>, as amended by Commission Regulation (EU) 2015/403 of 11 March 2015<sup>4</sup>, Commission Regulation (EU) 2019/649 of 24 April 2019<sup>5</sup>,

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<sup>1</sup> OJ No. L 151, 2.6.2022, p. 37.

<sup>2</sup> OJ No. L 310, 1.12.2022, p. 7.

<sup>3</sup> OJ No. L 404, 30.12.2006, p. 26.

<sup>4</sup> OJ No. L 67, 12.3.2015, p. 4.

<sup>5</sup> OJ No. L 110, 25.4.2019, p. 17.

Commission Regulation (EU) 2019/650 of 24 April 2019<sup>6</sup>, Commission Regulation (EU) 2021/468 of 18 March 2021<sup>7</sup>, Commission Regulation (EU) 2022/860 of 1 June 2022<sup>1</sup> and Commission Regulation (EU) 2022/2340 of 30 November 2022<sup>2</sup>,”

- (b) by substituting for the definition of “EC Regulation 1925/2006” the following:

“‘EC Regulation 1925/2006’ means Regulation (EC) No. 1925/2006 of the European Parliament and of the Council of 20 December 2006<sup>3</sup>, as amended by Regulation (EC) No. 108/2008 of the European Parliament and of the Council of 15 January 2008<sup>8</sup>, Commission Regulation (EC) No. 1170/2009 of 30 November 2009<sup>9</sup>, Commission Regulation (EU) No. 1161/2011 of 14 November 2011<sup>10</sup>, Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011<sup>11</sup>, Commission Implementing Regulation (EU) No. 307/2012 of 11 April 2012<sup>12</sup>, Commission Regulation (EU) No. 119/2014 of 7 February 2014<sup>13</sup>, Commission Regulation (EU) 2015/403 of 11 March 2015<sup>4</sup>, Commission Regulation (EU) 2019/649 of 24 April 2019<sup>5</sup>, Commission Regulation (EU) 2019/650 of 24 April 2019<sup>6</sup>, Commission Regulation (EU) 2021/468 of 18 March 2021<sup>7</sup>, Commission Regulation (EU) 2022/860 of 1 June 2022<sup>1</sup> and Commission Regulation (EU) 2022/2340 of 30 November 2022<sup>2</sup>.”

4. Regulation 8 of the Principal Regulations (as last amended by Regulation 4 of the Regulations of 2021) is amended by substituting for Regulation 8, the following:

“(1) Subject to paragraph (2), a food business operator who—

- (a) adds to food, uses in the manufacture of food, or places on the market a food containing—
  - (i) a prohibited substance listed in Part A of Annex III to EC Regulation 1925/2006, or
  - (ii) a restricted substance listed in Part B of Annex III to EC Regulation 1925/2006 in a manner contrary to the conditions of use specified therein,
- (b) supplies other food business operators with food not intended for the final consumer or not intended for supply

<sup>6</sup> OJ No. L 110, 25.4.2019, p. 21.

<sup>7</sup> OJ No. L 96, 19.3.2021, p. 6.

<sup>8</sup> OJ No. L 39, 13.2.2008, p. 11.

<sup>9</sup> OJ No. L 314, 1.12.2009, p. 36.

<sup>10</sup> OJ No. L 296, 15.11.2011, p. 29.

<sup>11</sup> OJ No. L 304, 22.11.2011, p. 18.

<sup>12</sup> OJ No. L 102, 12.4.2012, p. 2.

<sup>13</sup> OJ No. L 39, 8.2.2014, p. 44.

to retail, without providing information on the amount of trans fat, other than trans fat naturally occurring in fat of animal origin, where that amount exceeds 2 grams per 100 grams of fat, or

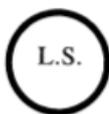
- (c) otherwise supplies a food in a manner contrary to the additional requirements contained in Part B of Annex III to EC Regulation 1925/2006, or places on the market a food which does not comply with those requirements,

is guilty of an offence.

(2) Notwithstanding paragraph (1) and subject to paragraph (3), a food business operator is not guilty of an offence under this Regulation where it placed on the market —

- (a) prior to 1 April 2021, a food containing trans fats other than trans fats naturally occurring in fat of animal origin which do not meet the conditions of use or the additional requirements in Part B of Annex III to EC Regulation 1925/2006, or
- (b) prior to 21 December 2022, a food containing green tea extracts containing (-)- epigallocatechin-3-gallate which do not meet the conditions of use or the additional requirements in Part B of Annex III to EC Regulation 1925/2006, which may remain on the market until 21 June 2023, provided that, such foods were placed on the market in conformity with the provisions applicable thereto at the date of their placing on the market.

(3) For the purposes of paragraph (2) (a) and (b), the food business operator shall bear the onus of proving that a food was placed on the market prior to 1 April 2021 or 21 December 2022, respectively.”



GIVEN under my Official Seal,  
24 May, 2023.

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 effect to Commission Regulation (EU) 2022/860 of 1 June 2022 and Commission Regulation (EU) 2022/2340 of 30 November 2022, both of which amend Annex III to Regulation (EC) No. 1925/2006 of the European Parliament and of the Council.

Commission Regulation (EU) 2022/860 amends Annex III of Regulation (EC) No. 1925/2006 in two ways, first by placing monacolins from red rice yeast on the list of “Restricted substances” in the table in Part B and, second, by placing the same entry on the list of “Substances under Community scrutiny” in the table in Part C of that Annex.

Commission Regulation (EU) 2022/2340 makes a similar amendment to Annex III of Regulation (EC) No. 1925/2006, placing green tea extracts containing (-)-epigallocatechin-3-gallate on the list of “Restricted substances” in the table in Part B and the same entry on the list of “Substances under Community scrutiny” in the table in Part C of that Annex.

These Regulations amend the European Union (Addition of Vitamins and Minerals and of Certain Other Substances to Foods) Regulations 2017 (S.I. No. 376 of 2017) in the manner specified in these Regulations.

These Regulations may be cited as the European Union (Addition of Vitamins and Minerals and of Certain Other Substances to Foods) (Amendment) Regulations 2023.

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