



STATUTORY INSTRUMENTS.

S.I. No. 541 of 2021

EUROPEAN UNION (ADDITION OF VITAMINS AND MINERALS AND
OF CERTAIN OTHER SUBSTANCES TO FOODS) (AMENDMENT)
REGULATIONS 2021

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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) 2019/649 of 24 April 2019¹, Commission Regulation (EU) 2019/650 of 24 April 2019² and Commission Regulation (EU) 2021/468 of 18 March 2021³, 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 2021.

(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) 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 2021.

2. In these Regulations—

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

(2) “trans fat” means the substance restricted in accordance with the conditions specified in Part B of Annex III to EC Regulation 1925/2006.

3. Regulation 2 of the Principal Regulations 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 2006⁴, as amended by Commission Regulation (EU) 2015/403 of 11 March 2015⁵, Commission Regulation (EU) 2019/649 of 24 April 2019¹, Commission Regulation (EU) 2019/650 of 24 April 2019² and Commission Regulation (EU) 2021/468 of 18 March 2021³;”,

¹ OJ No. L 110, 25.4.2019, p. 17.

² OJ No. L 110, 25.4.2019, p. 21.

³ OJ No. L 96, 19.3.2021, p. 6.

⁴ OJ No. L 404, 30.12.2006, p. 26.

⁵ OJ No. L 67, 12.3.2015, p. 4.

- (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 2006⁴, as amended by Regulation (EC) No. 108/2008 of the European Parliament and of the Council of 15 January 2008⁶, Commission Regulation (EC) No. 1170/2009 of 30 November 2009⁷, Commission Regulation (EU) No. 1161/2011 of 14 November 2011⁸, Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011⁹, Commission Implementing Regulation (EU) No. 307/2012 of 11 April 2012¹⁰, Commission Regulation (EU) No. 119/2014 of 7 February 2014¹¹, Commission Regulation (EU) 2015/403 of 11 March 2015⁵, Commission Regulation 2019/649 of 24 April 2019¹, Commission Regulation 2019/650 of 24 April 2019² and Commission Regulation (EU) 2021/468 of 18 March 2021³;.”

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

“(1) A food business operator who—

- (a) adds to food or who uses in the manufacture of food—
 - (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 specified therein, or
- (b) supplies other food business operators with food not intended for the final consumer or not intended for supply 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,

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 a food which was placed on the market prior to 1 April 2021—

- (a) contains trans fats in quantities exceeding those permitted under paragraph 1(a)(ii) of this Regulation and Part B of Annex III to EC Regulation 1925/2006, or

⁶ OJ No. L 39, 13.2.2008, p. 11.

⁷ OJ No. L 314, 1.12.2009, p. 36.

⁸ OJ No. L 296, 15.11.2011, p. 29.

⁹ OJ No. L 304, 22.11.2011, p. 18.

¹⁰ OJ No. L 102, 12.4.2012, p. 2.

¹¹ OJ No. L 39, 8.2.2014, p. 44.

- (b) was supplied in a manner contrary to paragraph 1(b) of this Regulation and Part B of Annex III to EC Regulation 1925/2006.
- (3) For the purposes of paragraph (2), the food business operator shall bear the onus of proving that a food was placed on the market prior to 1 April 2021.



GIVEN under my Official Seal,
20 October, 2021.

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) 2019/649 of 24 April 2019 (concerning trans fats), Commission Regulation 2019/650 of 24 April 2019 (concerning Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille) and Commission Regulation (EU) 2021/468 of 18 March 2021 (concerning botanical species containing hydroxyanthracene derivatives). Those Regulations amend Annex III to Regulation (EC) No. 1925/2006 of the European Parliament and of the Council, by adding to or deleting from the lists of substances whose use in foods is prohibited, restricted or under Union scrutiny. Commission Regulation (EU) 2019/649 also introduces certain information requirements when food containing trans fats are supplied and makes provision for foods placed on the market before 1 April 2021.

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 2021.

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