STATUTORY INSTRUMENTS.

S.I. No. 540 of 2021

EUROPEAN COMMUNITIES (FOOD SUPPLEMENTS) (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) 2021/418 of 9 March 2021[1] hereby make the following regulations:

1. (1) These Regulations may be cited as the European Communities (Food Supplements) (Amendment) Regulations 2021.

(2) The Principal Regulations, the Regulations of 2010, the European Communities (Food Supplements) (Amendment) Regulations 2015 (S.I. No. 282 of 2015), the Regulations of 2018 and these Regulations may be cited together as the European Communities (Food Supplements) Regulations 2007 to 2021.

2. In these Regulations—

"Principal Regulations" means European Communities (Food Supplements) Regulations 2007 (S.I. No. 506 of 2007);

"Regulations of 2010" means European Communities (Food Supplements) (Amendment) Regulations 2010 (S.I. No. 355 of 2010);

"Regulations of 2018" means European Communities (Food Supplements) (Amendment) Regulations 2018 (S.I. No. 225 of 2018).

3. Regulation 2(1) of the Principal Regulation (as last amended by Regulation 3 of the Regulations of 2018) is amended by substituting for the definition of "Directive" the following definition:

"'Directive' means Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002[2], as amended by Commission Directive 2006/37/EC of 30 March 2006[3], Commission Regulation (EC) No. 1170/2009 of 30 November 2009[4], Commission Regulation (EU) No. 1161/2011 of 14 November 2011[5], Commission Regulation

[1] OJ No. L 83, 10.3.2021, p. 1.
[2] OJ No. L 183, 12.7.2002, p. 51.
[3] OJ No. L 94, 1.4.2006, p. 32.
[4] OJ No. L 314, 1.12.2009, p. 36.
[5] OJ No. L 296, 15.11.2011, p. 29.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 26*th October*, 2021.

(EU) No. 119/2014 of 7 February 2014[6], Commission Regulation (EU) No. 2015/414 of 12 March 2015[7], Commission Regulation (EU) 2017/1203 of 5 July 2017[8] and Commission Regulation (EU) 2021/418 of 9 March 2021[1].”

4. Schedule 1 to the Principal Regulations (as substituted by Regulation 3(e) of the Regulations of 2010) is amended in section “2. Minerals” by substituting for “Copper (µg)”, the following:

“Copper (mg)”.

5. Schedule 2 to the Principal Regulations (as substituted by Regulation 3(f) of the Regulations of 2010 and last amended by Regulation 4 of the Regulations of 2018) is amended by inserting —

(*a*) in Section “A Vitamins” under the heading “7. NIACIN” after “(c) ‘inositol hexanicotinate (inositol hexaniacinate)” the following:

“(d) nicotinamide riboside chloride”, and

(*b*) in section “B. Minerals” after ‘magnesium chloride’ the following:

“magnesium citrate malate”.

6. Regulation 16 of the Principal Regulations is amended by substituting for paragraph (1), the following:-

“(1)(a) Subject to subparagraph (b), a person who fails to comply with these Regulations is guilty of an offence.

(b) Without prejudice to Regulation 5(6), Schedule 1 and the fact that products containing copper may be labelled with units of measurement “mg” from the date of entry into force of Commission Regulation (EU) 2021/418 of 9 March 2021[1], products containing copper labelled with units of measurements ‘µg’ may continue to be placed on the market or so labelled until 30 September 2022 and, thereafter, marketed until existing stocks run out, and a person who complies with the foregoing shall not be guilty of an offence.

[6] OJ No. L 39, 8.2.2014, p. 44.
[7] OJ No. L 68, 13.3.2015, p. 26.
[8] OJ No. L 173, 6.7.2017, p. 9.

L.S.

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) 2021/418 of 9 March 2021 amending Directive 2002/46/EC of the European Parliament and of the Council. Under Directive 2002/46/EC, only those vitamins and minerals listed in Annex I thereto and in the forms set out in Annex II thereto, can be used in the manufacture of food supplements and the amount of the vitamin or mineral must be declared in the units specified therein. Regulation 2021/418 replaces the "µg" units of measurement for copper with "mg" in Annex I with effect from 30 September 2022 (but permits "mg" to be used from 30 March 2021 (the date of entry into force of the Regulation) and allows marketing of copper products labelled with "µg" after 30 September 2022 until existing stocks run out). It also adds nicotinamide riboside chloride and magnesium citrate malate to Annex II.

These Regulations may be cited as the European Communities (Food Supplements) (Amendment) Regulations 2021.

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