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Subject:	COMMISSION REGULATION (EU) No .../.. of XXX amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of Stigmasterol-rich plant sterols as a stabilizer in ready-to-freeze alcoholic cocktails, and the Annex to Commission Regulation (EU) No 231/2012 as regards specifications for Stigmasterol-rich plant sterols food additive

Delegations will find attached Commission document D026576/03.

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COMMISSION REGULATION (EU) No .../..

of **XXX**

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of Stigmasterol-rich plant sterols as a stabilizer in ready-to-freeze alcoholic cocktails, and the Annex to Commission Regulation (EU) No 231/2012 as regards specifications for Stigmasterol-rich plant sterols food additive

(Text with EEA relevance)

COMMISSION REGULATION (EU) No .../..

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amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of Stigmasterol-rich plant sterols as a stabilizer in ready-to-freeze alcoholic cocktails, and the Annex to Commission Regulation (EU) No 231/2012 as regards specifications for Stigmasterol-rich plant sterols food additive

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives¹, and in particular Articles 10(3) and 14 thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings², and in particular Article 7(5) thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.
- (2) Commission Regulation (EU) No 231/2012 of 9 March 2012³ lays down specifications for food additives listed in Annex II to Regulation (EC) No 1333/2008.
- (3) Those lists may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application.
- (4) An application for the authorisation of use of Stigmasterol-rich plant sterols as a stabiliser in ready-to-freeze alcoholic cocktails was submitted on 11 February 2011 and was made available to the Member States.
- (5) There is a technological need for the use of Stigmasterol-rich plant sterols as a stabiliser, ice nucleating agent, to generate and maintain the presence of ice dispersions within a range of ready-to-freeze alcoholic cocktails. These products are

¹ OJ L 354, 31.12.2008, p. 16.

² OJ L 354, 31.12.2008, p. 1.

³ OJ L 83, 22.3.2012, p. 1.

designed to be purchased by the consumer in liquid form and placed in domestic freezers to produce a semi-frozen beverage. Stigmasterol-rich plant sterols when added to the cocktails as an ice-nucleating agent (stabiliser) ensure that the cocktails will freeze and produce a satisfactory semi-frozen beverage in the consumer's freezer. Without the use of stigmasterol-rich plant sterols, supercooling of the beverage can occur and ice formation cannot be guaranteed resulting in product failure.

- (6) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission is to seek the opinion of the European Food Safety Authority in order to update the Union list of food additives set out in Annex II to Regulation (EC) No 1333/2008.
- (7) The European Food Safety Authority evaluated the safety of Stigmasterol-rich plant sterols when used as a food additive in ready-to-freeze alcoholic cocktails and expressed its opinion on 14 May 2012⁴. It considered that the toxicological data available for stigmasterol-rich plant sterols are insufficient to establish an acceptable daily intake. However, based on the available data, it concluded that the proposed use and use levels of stigmasterol-rich plant sterols as a stabiliser in ready-to-freeze alcoholic cocktails are not of a safety concern. Furthermore, the Authority considers that the average daily intake, taking into account the estimated exposure to plant sterols from all sources (i.e. from new applications, from natural sources and added as novel food ingredient) will not exceed 3 g/day.
- (8) Therefore, it is appropriate to authorise the use of Stigmasterol-rich plant sterols as a stabiliser in ready-to-freeze alcoholic cocktails and to assign E 499 as an E-number to that food additive.
- (9) Phytosterols, phytostanols and their esters have been previously evaluated by several scientific authorities, including the Scientific Committee for Food, the Joint FAO/WHO Expert Committee on Food Additives and the European Food Safety Authority and are approved for use in various foods within the Union at levels of intake of up to 3 g/day. Those substances are used as novel food ingredients with the purpose of helping hypercholesterolaemic individuals control their LDL-cholesterol blood levels.
- (10) Commission Regulation (EC) No 608/2004 of 31 March 2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters⁵ provides for mandatory particulars on the labelling of such foods, in addition to those listed in Article 3 of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs⁶. Those labelling requirements relate to the effects of phytosterols, phytosterol esters, phytostanols and/or phytostanol esters on blood cholesterol levels.
- (11) As the levels of stigmasterol-rich plant sterols for the intended use on alcoholic beverages are not sufficient to affect blood cholesterol levels, ready-to-freeze alcoholic cocktail beverages containing the stigmasterol-rich plant sterols should be exempted

⁴ EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the safety of stigmasterol-rich plant sterols as food additive. EFSA Journal 2012;10(5):2659.

⁵ OJ L 97, 1.4.2004, p. 44.

⁶ OJ L 109, 6.5.2000, p. 29.

from complying with the labelling requirements laid down by Regulation (EC) No 608/2004.

- (12) The specifications for stigmasterol-rich plant sterols should be included in Regulation (EU) No 231/2012.
- (13) The European Food Safety Authority's opinion on the safety of Stigmasterol-rich plant sterols of 14 May 2012 considered the specifications for that food additive as proposed by the applicant and as laid down in Annex II to this Regulation. It concluded that the specifications are based on the ones established for phytosterols, phytostanols, and their esters by the Joint FAO/WHO Expert Committee on Food Additives⁷ and results from analysis of stigmasterol-rich plant sterols verified that the production process produces a consistent product that falls within the proposed specifications.
- (14) When updating specifications laid down in Regulation (EU) No 231/2012, it is necessary to take into account the specifications and analytical techniques for additives set out in the Codex Alimentarius as drafted by the Joint FAO/WHO Expert Committee on Food Additives.
- (15) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.
- (16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with Annex I to this Regulation.

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

⁷ Joint FAO/WHO Expert Committee on Food Additives, 2008. Phytosterols, phytostanols and their esters. In: Compendium of Food Additive Specifications. Prepared at the 69th JECFA (2008), FAO JECFA Monographs 5.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
José Manuel BARROSO

ANNEX I

Annex II to Regulation (EC) No 1333/2008 is amended as follows:

- (1) In point 3 of Part B, the following entry for E 499 is inserted after the entry for E 495:

"

E 499	Stigmasterol-rich plant sterols
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"

- (2) Part E, food category 14.2.8 "Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol" is amended as follows:

- (a) the following entries for E 499 are inserted after the entry for E 481-482:

"

E 499	Stigmasterol-rich plant sterols	80 mg/l	(80)	Only to water based ready-to-freeze alcoholic cocktails
E 499	Stigmasterol-rich plant sterols	800 mg/l	(80)	Only to cream based ready-to-freeze alcoholic cocktails

"

- (b) the following footnote is added:

"(80) The labelling requirements set out by Commission Regulation (EC) No 608/2004 shall not apply."

ANNEX II

In the Annex to Regulation (EU) No 231/2012 the following entry for E 499 is inserted after the entry for E 495:

"E 499 STIGMASTEROL-RICH PLANT STEROLS

Synonyms	
Definition	Stigmasterol-rich plant sterols are derived from soybeans and are a chemically defined simple mixture that comprises not less than 95% of plant sterols (stigmasterol, β -sitosterol, campesterol and brassicasterol), with stigmasterol representing not less than 85% of the stigmasterol-rich plant sterols.
Einecs	
Chemical name	
Stigmasterol	(3S,8S,9S,10R,13R,14S,17R)-17-(5-ethyl-6-methyl-hept-3-en-2-yl)-10,13-dimethyl-2,3,4,7,8,9,11,12,14,15,16,17-dodecahydro-1Hcyclopenta[a]phenanthren-3-ol
β -Sitosterol	(3S,8S,9S,10R,13R,14S,17R)-17-[(2S,5S)-5-ethyl-6-methylheptan-2-yl]-10,13-dimethyl-2,3,4,7,8,9,11,12,14,15,16,17-dodecahydro-1Hcyclopenta[a]phenanthren-3-ol
Campesterol	(3S,8S,9S,10R,13R,14S,17R)-17-(5,6-dimethylheptan-2-yl)-10,13-dimethyl-2,3,4,7,8,9,11,12,14,15,16,17-dodecahydro-1Hcyclopenta[a]phenanthren-3-ol
Brassicasterol	(3S,8S,9S,10R,13R,14S,17R)-17-[(E,2R,5R)-5,6-dimethylhept-3-en-2-yl]-10,13-dimethyl-2,3,4,7,8,9,11,12,14,15,16,17-dodecahydro-1Hcyclopenta[a]phenanthren-3-ol
Chemical formula	
Stigmasterol	C ₂₉ H ₄₈ O
β -Sitosterol	C ₂₉ H ₅₀ O
Campesterol	C ₂₈ H ₄₈ O
Brassicasterol	C ₂₈ H ₄₆ O
Molecular weight	
Stigmasterol	412.6 g/mol
β -Sitosterol	414.7 g/mol
Campesterol	400.6 g/mol
Brassicasterol	398.6 g/mol

Assay (products containing only free sterols and stanols)	Content not less than 95 % on a total free sterol/stanol basis on the anhydrous basis
Description	Free-flowing, white to off-white powders, pills or pastilles; colourless to pale yellow liquids
Identification	
Solubility	Practically insoluble in water. Phytosterols and phytostanols are soluble in acetone and ethyl acetate.
Stigmasterol content	Not less than 85% (w/w)
Other plant sterols/stanols: either singularly or in combination including Brassicasterol, campestanol, campesterol, Δ -7-campesterol, cholesterol, chlerosterol, sitostanol and β -sitosterol.	Not more than 15% (w/w)
Purity	
Total Ash	Not more than 0.1%
Residual Solvents	Ethanol: Not more than 5000 mg/kg Methanol: Not more than 50 mg/kg
Water content	Not more than 4 % (Karl Fischer method)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 1 mg/kg
Microbiological criteria	
Total plate count	Not more than 1000 CFU/g
Yeasts	Not more than 100 CFU/g
Moulds	Not more than 100 CFU/g
<i>Escherichia coli</i>	Not more than 10 CFU/g
<i>Salmonella</i> spp.	Absent in 25 g