Commission Regulation (EU) No 739/2013 of 30 July 2013 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 stabiliser 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 739/2013

of 30 July 2013

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 stabiliser 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 additives[(1)], and in particular Article 10(3) and Article 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 flavourings[(2)], 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[(3)] 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 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 2012[(4)]. 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 esters[(5)] 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 foodstuffs[(6)]. 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 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 Additives[7] 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*.

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

Done at Brussels, 30 July 2013.

For the Commission

The President

José Manuel BARROSO

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 739/2013. (See end of Document for details)*

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

(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	(80)	Only to water based ready-to-freeze alcoholic cocktails
	E 499	Stigmasterol-rich plant sterols	800	(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 (OJ L 97, 1.4.2004, p. 44) 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.