



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 16 April 2013

8481/13

**DENLEG 34
AGRI 240**

COVER NOTE

from:	European Commission
date of receipt:	11 April 2013
to:	Secretariat General of the Council

No Cion doc.:	D025414/03
Subject:	COMMISSION REGULATION (EU) No .../. of XXX amending Regulation (EC) No 608/2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters

Delegations will find attached Commission document D025414/03.

Encl.: D025414/03



Brussels, **XXX**
SANCO/12876/2012 Rev. 1
(POOL/E4/2012/12876/12876R1-
EN.doc) D025414/03
[...](2012) **XXX** draft

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

of **XXX**

amending Regulation (EC) No 608/2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters

(Text with EEA relevance)

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

of XXX

amending Regulation (EC) No 608/2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytosterols and/or phytosterol esters

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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 foodstuffs¹, and in particular Article 4(3) thereof,

Whereas:

- (1) Following the Opinion of the Scientific Committee on Food (SCF) of 26 September 2002² and in order to ensure that consumers receive adequate information when purchasing foods and food ingredients with added phytosterols, phytosterol esters, phytosterols and phytosterol esters, Commission Regulation (EC) No 608/2004 of 31 March 2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytosterols and/or phytosterol esters³ provides for mandatory particulars in addition to those listed in Article 3 of Directive 2000/13/EC on the labelling of such foods.
- (2) Regulation (EC) No 608/2004 provides that the labelling of such foods and food ingredients shall contain, amongst others, a statement that the product is intended exclusively for people who want to lower their blood cholesterol level. The purpose of this mandatory statement is to ensure that the product reaches its target group, and thus avoid unnecessary consumption by non-targeted groups.
- (3) The voluntary inclusion of nutrition or health claims on food labels is governed by Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods⁴. Accordingly, Commission Regulation (EC) No 983/2009 of 21 October 2009 on the authorisation

¹ OJ L 109, 6.5.2000, p. 29.

² Opinion of the SCF titled 'General view on the long-term effects of the intake of elevated levels of phytosterols from multiple dietary sources'.

³ OJ L 97, 1.4.2004, p. 44.

⁴ OJ L 404, 30.12.2006, p. 9.

and refusal of authorisation of certain health claims made on food and referring to the reduction of disease risk and to children's development and health⁵, Commission Regulation (EU) No 384/2010 of 5 May 2010 on the authorisation and refusal of authorisation of certain health claims made on foods and referring to the reduction of disease risk and to children's development and health⁶ and Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health⁷ have authorised health claims relating to the reduction and maintenance of blood cholesterol with respect to foods containing plant sterols and plant stanols, subject to certain conditions of use.

- (4) Commission Regulation (EC) No 983/2009 authorised, under certain conditions of use, the following health claims: "Plant sterols have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease" and "Plant stanol esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease".
- (5) Commission Regulation (EU) No 384/2010 authorised, under certain conditions of use, the following health claim: "Plant sterols and plant stanol esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease."
- (6) Commission Regulation (EU) 432/2012 authorised, under certain conditions of use, the following health claim: "Plant sterols/stanols contribute to the maintenance of normal blood cholesterol levels".
- (7) The wording of the authorised health claims in combination with the mandatory statement relating to the target group laid down in Regulation (EC) No 608/2004 could potentially lead consumers who do not need to control their blood cholesterol level to use the product. Therefore, with a view to ensure consistency of the information provided on the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters, it is appropriate to amend the mandatory statement laid down in Regulation (EC) No 608/2004 while ensuring that its wording serves adequately the informative purpose for which it was initially introduced.
- (8) In order to enable food business operators to adapt the labelling of their products to the requirements introduced by this Regulation, it is important to provide for an appropriate transition period for the application of this Regulation.
- (9) 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],

⁵ OJ L 277, 22.10.2009, p. 3.

⁶ OJ L 113, 6.5.2010, p. 6.

⁷ OJ L 136, 25.5.2012, p. 1.

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Regulation (EC) No 608/2004

In Article 2 of Commission Regulation (EC) No 608/2004, point 3 is replaced by the following:

- '3. there shall be a statement that the product is not intended for people who do not need to control their blood cholesterol level.'

Article 2

Transitional measures

Food and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters placed on the market or labelled prior to [six months from entry into force] which do not comply with the requirements of this Regulation may be marketed until the stocks of the foods are exhausted.

Article 3

Entry into force

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,

For the Commission
The President
José Manuel BARROSO