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EUROPEAN
COMMISSION

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COMMISSION REGULATION (EU) No …/..

of XXX

amending Regulation (EC) No 983/2009 and Regulation (EU) No 384/2010, on the modification of the conditions of use of certain health claims related to the effect of plant sterols and plant stanols on lowering blood LDL-cholesterol

(Text with EEA relevance)

COMMISSION REGULATION (EU) No …/..

of XXX

amending Regulation (EC) No 983/2009 and Regulation (EU) No 384/2010 as regards the conditions of use of certain health claims related to the lowering effect of plant sterols and plant stanols on blood LDL-cholesterol

(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 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods[1], and in particular Article 17(3) thereof,

Whereas:

(1) Regulation (EC) No 1924/2006 provides that applications for authorisations of health claims are to be sent to the national competent authority of the respective Member State. The national competent authority is to forward those applications to the European Food Safety Authority (EFSA), hereinafter referred to as "the Authority". The Authority is to give an opinion on the health claim and to forward it to the Commission who is to decide on the authorisation of the health claim taking into account the opinion delivered by the Authority.

(2) Pursuant to Article 16(4) of Regulation (EC) No 1924/2006, an opinion of the Authority in favour of authorising a health claim may include specific conditions of use of the claim.

(3) The authorisation of health claims may be amended following a request by the applicant or user according to Article 19(1) of Regulation (EC) No 1924/2006 or following an opinion of the Authority issued on its own initiative or following a request from a Member State or from the Commission according to Article 19(2) of Regulation (EC) No 1924/2006.

(4) Following the opinion of the Authority, based on a request of the Commission and a similar request from France, regarding the possibility to indicate a quantitative effect in health claims related to the lowering effects of plant sterols/plant stanols esters on LDL-cholesterol **(Question No EFSA-Q-2009-00530 and Q-2009-00718)**[2], the Commission amended, by Regulation (EU) No 376/2010[3], the conditions of use of two health claims related to the lowering effects of plant sterols and plant stanol esters on

1 OJ L 404, 30.12.2006, p. 9.

2 The EFSA Journal, (2009) 1175, 1-9.

3 Commission Regulation (EU) No 376/2010 of 3 May 2010 amending Regulation (EC) No 983/2009 on the authorisation 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 health (OJ L 111, 4.5.2010, p. 3-4).

blood cholesterol, as laid down in Commission Regulation (EC) No 983/2009[4], by indicating a quantitative effect. Moreover, based on the same opinion of the Authority, the Commission authorised, by Regulation (EU) No 384/2010[5], a health claim related to the lowering effects of plant sterols/plant stanol esters on LDL-cholesterol, establishing conditions of use related to the indication of a quantitative effect.

(5) Following an application from Raisio Nutrition Ltd., submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the lowering effects of plant stanols as plant stanol esters on blood LDL-cholesterol concentrations **(Question No EFSA-Q-2011-00851)[6]**. The claim proposed by the applicant, related to the amendment of an already authorised health claim on plant stanol esters[7], was worded as follows: "The daily consumption of 3 g plant stanols in ester form has been shown to reduce blood cholesterol by 12%. High cholesterol is a risk factor in the development of coronary heart disease". The applicant further requested that the minimum duration to obtain the effect be stated to be one to two weeks, and that an authorisation be given for claims for an extended range of foods, including yellow fat spreads, dairy products, cheese, rye bread, oatmeal, fermented soy milk based products (drinkable and spoonable yoghurt-type products), and oat based milk drinks.

(6) On the basis of the data presented, the Authority concluded in its opinion, received by the Commission and the Member States on 16 May 2012, that plant stanol esters at a daily intake of 3 g (range 2,7 – 3,3 g) lower LDL-cholesterol by 11,4% (95% Confidence Interval (CI): 9,8-13,0), and that the minimum duration required to achieve the maximum effect of plant stanol esters on LDL-cholesterol lowering is two to three weeks. Moreover, the Authority concluded that while plant stanol esters added to foods such as margarine-type spreads, mayonnaise, salad dressings and to dairy products such as milk, yoghurts including low-fat yoghurts, and cheese have been shown consistently to lower blood LDL-cholesterol levels, the extent of the cholesterol-lowering effect of plant stanols added to other food formats is less well established.

(7) Unilever PLC and Unilever NV submitted an application pursuant to Article 19 of Regulation (EC) No 1924/2006, for the modification of the conditions of use of the health claims related to the lowering effects of plant sterols and plant stanols on blood LDL-cholesterol **(Question No EFSA-Q-2012-01241)[8]**. The modification concerns the magnitude of the lowering effect on blood LDL-cholesterol (7-12%) for a daily intake of plant sterols and plant stanols between 1,5 and 3 g. The applicant further requested that the minimum duration to obtain the effect be stated to be one to two weeks.

(8) On the basis of the data presented, the Authority concluded in its opinion, received by the Commission and the Member States on 16 May 2012, that plant sterols and plant stanol esters at a daily intake of 3 g (range 2,6-3,4 g) lower LDL-cholesterol by 11,3% (95% Confidence Interval (CI): 10,0-12,5), and that the minimum duration required to

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4 Commission Regulation (EC) No 983/2009 of 21 October 2009 on the authorisation 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 health (OJ L 277, 22.10.2009, p. 3).

5 OJ L113, 6.5.2010, p. 6.

6 The EFSA Journal 2012; 10(5):2692.

7 Commission Regulation (EC) No 983/2009, (OJ L 277, 22.10.2009, p. 3).

8 The EFSA Journal 2012; 10(5):2693.

achieve the maximum effect of plant sterols and stanols on LDL-cholesterol is two to three weeks. The Authority also noted in its assessment that plant sterols and plant stanols at a daily intake of up to 3 g per day have a similar efficacy on lowering blood LDL-cholesterol.

(9) Accordingly, taking into account the scientific opinions from the Authority and other legitimate factors, it is necessary to amend the conditions of use of the authorised health claims on plant sterols, plant stanol esters and plant sterols/stanol esters referring to the reduction of a risk factor in the development of a disease, in order to ensure that by referring to the magnitude of the claimed effect those claims would not confuse and mislead the consumer, and that their conditions of use are set in a coherent way.

(10) Regulations (EC) No 983/2009 and (EU) No 384/2010 should therefore be amended accordingly.

(11) The comments from the applicants and the members of the public received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006 have been considered when setting the measures provided for in this Regulation.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1
Amendments to Regulation (EC) No 983/2009

Annex I to Regulation (EC) No 983/2009 is amended as follows:

(1) The first entry (concerning the health claim: *"Plant sterols have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease"*), is amended as follows:

(a) The text in the fifth column (conditions of use of the claim) is replaced by the following:

"Information to the consumer that the beneficial effect is obtained with a daily intake of 1,5-3 g plant sterols. Reference to the magnitude of the effect may only be made for foods within the following categories: yellow fat spreads, dairy products, mayonnaise and salad dressings. When referring to the magnitude o7f the effect, the range '7 to 10%' for foods that provide a daily intake of 1,5-2,4g plant sterols or the range '10 to 12,5%' for foods that provide a daily intake of 2,5-3g plant sterols and the duration to obtain the effect 'in 2 to 3 weeks' must be communicated to the consumer."

(b) The text in the seventh column (EFSA opinion reference) is replaced by the following:

"Q-2008-085
Q-2009-00530 and Q-2009-00718
Q-2011-01241"

(2) The second entry (concerning the health claim: *"Plant stanol esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease"*) is amended as follows:

(a) The text in the fifth column (conditions of use of the claim), is replaced by the following:

"Information to the consumer that the beneficial effect is obtained with a daily intake of 1,5-3 g plant stanols. Reference to the magnitude of the effect may only be made for foods within the following categories: yellow fat spreads, dairy products, mayonnaise and salad dressings. When referring to the magnitude of the effect, the range '7 to 10%' for foods that provide a daily intake of 1,5-2,4g plant stanols or the range '10-12,5%' for foods that provide a daily intake of 2,5-3g plant stanols and the duration to obtain the effect 'in 2 to 3 weeks' must be communicated to the consumer."

(b) The text in the seventh column (EFSA opinion reference) is replaced by the following:

"Q-2008-118
Q-2009-00530 and Q-2009-00718
Q-2011-00851
Q-2011-01241".

Article 2
Amendments to Regulation (EU) No 384/2010

Annex I to Regulation (EU) No 384/2010 is amended as follows

The first entry (concerning the 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"*) is amended as follows:

(a) The text in the fifth column (conditions of use of the claim) is replaced by the following:

"Information to the consumer that the beneficial effect is obtained with a daily intake of 1,5-3 g plant sterols/stanols. Reference to the magnitude of the effect may only be made for foods within the following categories: yellow fat spreads, dairy products, mayonnaise and salad dressings. When referring to the magnitude of the effect, the range '7 to 10%' for foods that provide a daily intake of 1,5-2,4g plant sterols/stanols or the range '10 to 12,5%' for foods that provide a daily intake of 2,5-3g plant sterols/stanols and the duration to obtain the effect 'in 2 to 3 weeks' must be communicated to the consumer."

(b) The text in the seventh column (EFSA opinion reference) is replaced by the following:

"Q-2008-779
Q-2009-00530 and Q-2009-00718
Q-2011-01241".

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