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 (Text with EEA relevance)

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

(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,

Having consulted the European Food Safety Authority,

Whereas:

(1) Pursuant to Article 16(4) of Regulation (EC) No 1924/2006, an opinion of the European Food Safety Authority (EFSA), hereinafter referred to as the Authority, in favour of authorising a health claim should include certain particulars. Accordingly, those particulars should be set out in the Annex of authorised claims to the Regulations authorising and/or refusing to authorise certain health claims made on foods and include, as the case may be, the revised wording of the claim, specific conditions of use of the claim, and, where applicable, conditions or restrictions of use of the food and/or an additional statement or warning, in accordance with the rules laid down in Regulation (EC) No 1924/2006 and in line with the opinions of the Authority.

(2) Following two opinions of the Authority on plant stanols and plant sterols and lowering/reducing blood LDL-cholesterol (Question No EFSA-Q-2008-085 and Question No EFSA-Q-2008-118)[(2)], the Commission authorised the health claims stating that plant sterols/plant stanol esters 'have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease' in Regulation (EC) No 983/2009[(3)] with the specific conditions of use of 'Information to the consumer that the beneficial effect is obtained with a daily intake of at least 2 g of plant sterols/plant stanols'.

(3) In the context of the procedure for the authorisation of health claims under Regulation (EC) No 1924/2006, the Standing Committee on the Food Chain and Animal Health, at its meeting of 20 February 2009, concluded that, regarding the indication of a

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 376/2010. (See end of Document for details)*

quantitative effect in health claims there was a need for scientific advice from the Authority to ensure that such health claims are authorised in a way which will not mislead the consumer, and that conditions of use are set in a coherent way. To that end, the Commission submitted a request for advice to the Authority, in accordance with Article 19(2) of that Regulation.

(4) On 3 August 2009 the Commission and the Member States received the scientific opinion from the Authority (Question No EFSA-Q-2009-00530 and EFSA-Q-2009-00718)[4] which concluded that for a daily intake of 1,5-2,4 g plant sterols/stanols added to foods such as yellow fat spreads, dairy products, mayonnaise and salad dressings an average reduction of between 7 and 10,5 % can be expected and that such reduction is of biological significance. In addition, the Authority indicated that the blood LDL cholesterol lowering effect is usually established within the 2-3 weeks and can be sustained by a continued consumption of plant sterols/stanols.

(5) Therefore, taking into account the scientific opinion from the Authority and in order to ensure that such health claims referring to the magnitude of the claimed effect are authorised in a way that would not mislead the consumer, and that their conditions of use are set in a coherent way, it is necessary to amend the conditions of use set for the two authorised health claims related to the effects of plant sterols and plant stanol esters on the lowering of the blood cholesterol.

(6) Following the opinion of the Authority on essential fatty acids and in particular α-linolenic acid (ALA) and linoleic acid (LA) and normal growth and development of children (Question No EFSA-Q-2008-079)[5], the Commission, authorised the health claim 'Essential fatty acids are needed for normal growth and development of children' in Regulation (EC) No 983/2009 with the specific conditions of use of 'Information to the consumer that the beneficial effect is obtained with a daily intake of 1 % of total energy for linoleic acid and 0,2 % of total energy for α-linolenic acid'.

(7) In the context of the procedure for the authorisation of health claims under Regulation (EC) No 1924/2006, the Standing Committee on the Food Chain and Animal Health, at its meeting of 20 February 2009, concluded that the Authority should be asked to give general advice on reference values for the purpose of labelling for fatty acids to enable the review of the conditions of use for the relevant authorised health claim, in accordance with Article 19(2) of that Regulation. On 3 August 2009 the Commission and the Member States received the scientific opinion from the Authority (Question No EFSA-Q-2009-00548)[6] which concluded that the proposed labelling reference value of 2 g for the n-3 polyunsaturated fatty acid (PUFA) ALA is consistent with the recommended intakes for individuals in the general population in European countries. In addition, the Authority proposed 10 g as labelling reference intake value for n-6 PUFA LA.

(8) Therefore, taking into account the scientific opinion from the Authority and in order to set appropriate conditions of use for the health claims related to the effects of fatty acids, it is necessary to amend the conditions of use set for the authorised health claim related to the effects of essential fatty acids on normal growth and development of children.