Commission Implementing Regulation (EU) 2016/854 of 30 May 2016 authorising certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No 432/2012 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2016/854

of 30 May 2016

authorising certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No 432/2012

(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 18(4) thereof,

Whereas:

(1) Regulation (EC) No 1924/2006 provides that health claims made on food are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.

(2) Pursuant to Article 13(3) of Regulation (EC) No 1924/2006 Commission Regulation (EU) No 432/2012[(2)] was adopted, which establishes 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 health.

(3) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority', for a scientific assessment, as well as to the Commission and the Member States for information.

(4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.

(5) In order to stimulate innovation, health claims which are based on newly developed scientific evidence and/or which include a request for the protection of proprietary data shall undergo an accelerated type of authorisation.

(6) Following an application from Roquette Frères, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to Nutriose® which should replace fermentable carbohydrates

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in foods or beverages in order to obtain the claimed effect, i.e. maintenance of tooth mineralisation by reducing tooth demineralisation (Question No EFSA-Q-2013-00040[3]). The claim proposed by the applicant was worded as follows: 'Frequent consumption of sugars contributes to tooth demineralisation. Consumption of food/drinks containing Nutriose® instead of sugar may help maintain tooth mineralisation by decreasing tooth demineralisation'.

(7) On 26 July 2013, the Commission and the Member States received the scientific opinion from the Authority which concluded that the characteristic which is most relevant to the claimed effect (i.e. not lowering plaque pH below 5,7 during and up to 30 minutes after consumption) is not unique to the food subject to the claim[4], but common to other non-fermentable carbohydrates (e.g. polyols, D-tagatose, isomaltulose, and polydextrose). The Authority added that a claim on sugar replacers xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose and polydextrose and maintenance of tooth mineralisation by decreasing tooth demineralisation had already been assessed with a favourable outcome[5]. The Authority concluded that a cause and effect relationship had been established between the consumption of foods or beverages containing fermentable carbohydrates at an exposure frequency of four or more times daily and increased tooth demineralisation, and that the consumption of foods or beverages containing non-fermentable carbohydrates instead of fermentable carbohydrates may maintain tooth mineralisation by decreasing tooth demineralisation, provided that such foods or beverages do not lead to dental erosion. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006 and should be included in the Union list of permitted claims, established by Regulation (EU) No 432/2012.

(8) Following an application from Beneo-Orafti SA, Sensus BV and Cosucra-Groupe Warcoing SA, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to fructo-oligosaccharides (FOS) from inulin and a reduction of postprandial glycaemic responses (Question No EFSA-Q-2013-00615[6]). The claim proposed by the applicant was worded, inter alia, as follows: 'Consumption of foods/drinks containing oligofructose from chicory instead of sugars induces a lower blood glucose rise'.

(9) On 10 January 2014, the Commission and the Member States received the scientific opinion from the Authority which noted that the characteristic which is most relevant to the claimed effect (i.e. reduction of postprandial glycaemic responses by replacing sugars in foods and beverages) is not unique to FOS but common to other non-digestible carbohydrates (e.g. non-starch polysaccharides, resistant oligosaccharides, resistant starch) because, similarly to FOS, non-digestible carbohydrates are resistant to hydrolysis and absorption in the small intestine and therefore do not contribute to postprandial glycaemia. The Authority also noted that a claim related to sugar replacers and reduction of postprandial glycaemic responses had already been assessed by the Authority with a favourable outcome[7]. The Authority concluded that on the basis of the data presented, a cause and effect relationship has been established between the consumption of foods or beverages containing non-digestible carbohydrates instead of sugars and a reduction of postprandial glycaemic responses as compared to sugar-

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containing foods or beverages. Accordingly, a health claim reflecting that conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006 and should be included in the Union list of permitted claims, established by Regulation (EU) No 432/2012.

(10) Following an application from Olygose, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to AlphaGOS® and a reduction of postprandial glycaemic responses (Question No EFSA-Q-2014-00044[8]). The claim proposed by the applicant was worded as follows: 'Consumption of foods or drinks containing AlphaGOS® instead of sugar induces a lower blood glucose rise after their consumption compared to sugar-containing foods or drinks'.

(11) On 8 October 2014, the Commission and the Member States received the scientific opinion from the Authority which noted that the characteristic which is most relevant to the claimed effect (i.e. reduction of postprandial glycaemic responses by replacing sugars in foods and beverages) is not unique to α-galacto-oligosaccharides (α-GOS) but is common to other non-digestible carbohydrates (e.g. non-starch polysaccharides, resistant starch) because, similarly to α-GOS, non-digestible carbohydrates are resistant to hydrolysis and absorption in the small intestine and therefore do not contribute to postprandial glycaemia. In that opinion, the Authority also noted that a claim on non-digestible carbohydrates and reduction of postprandial glycaemic responses had already been assessed by the Authority with a favourable outcome[9] and concluded that a cause and effect relationship had been established between the consumption of foods or beverages containing non-digestible carbohydrates and a reduction of postprandial glycaemic responses as compared with sugar-containing foods or beverages. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006 and should be included in the Union list of permitted claims established by Regulation (EU) No 432/2012.

(12) Following an application from Roquette Italia SpA, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to Nutriose®06 and a reduction of postprandial glycaemic responses (Question No EFSA-Q-2014-00073[10]). The claim proposed by the applicant was worded as follows: 'Consumption of foods/drinks containing Nutriose®06 instead of high-glycaemic carbohydrates induces a lower blood glucose rise after their consumption compared to high-glycaemic carbohydrate-containing foods/drinks'.

(13) On 8 October 2014, the Commission and the Member States received the scientific opinion from the Authority in which it noted that the characteristic which is most relevant to the claimed effect (i.e. reduction of postprandial glycaemic responses by replacing glycaemic carbohydrates in foods and beverages) is the non-digestibility of the resistant dextrin contained in the food subject to the claim[11]. The Authority also considered that this characteristic, which is relevant to the claimed effect, is not unique to resistant dextrin but is common to other non-digestible carbohydrates (e.g. non-starch

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polysaccharides and resistant oligosaccharides) because, similarly to resistant dextrin, non-digestible carbohydrates are resistant to hydrolysis and absorption in the small intestine and therefore do not contribute to postprandial glycaemia. In that opinion, the Authority noted that a claim on non-digestible carbohydrates and reduction of postprandial glycaemic responses had already been assessed by the Authority with a favourable outcome[12] and it concluded that a cause and effect relationship had been established between the consumption of foods or beverages containing non-digestible carbohydrates, and a reduction of postprandial glycaemic responses as compared with foods or beverages containing glycaemic carbohydrates. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006 and should be included in the Union list of permitted claims established by Regulation (EU) No 432/2012.

(14) One of the objectives of Regulation (EC) No 1924/2006 is to ensure that health claims are truthful, clear and reliable and useful to the consumer, and that the wording and the presentation are taken into account in that respect. Therefore, where the wording of claims used by the applicant has the same meaning for consumers as that of an authorised health claim, because they demonstrate the same relationship that exists between a food category, a food or one of its constituents and health, these claims should be subject to the same conditions of use as those listed in the Annex to this Regulation.

(15) In accordance with Article 20 of Regulation (EC) No 1924/2006, the Register of nutrition and health claims containing all authorised health claims should be updated in order to take into account this Regulation.

(16) The comments from one of the applicants 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.

(17) Regulation (EU) No 432/2012 should therefore be amended accordingly.

(18) The Member States have been consulted,

HAS ADOPTED THIS REGULATION:

Article 1

The health claims set out in the Annex to this Regulation shall be included in the Union list of permitted claims as provided for in Article 13(3) of Regulation (EC) No 1924/2006.

Article 2

The Annex to Regulation (EU) No 432/2012 is amended in accordance with the Annex to this Regulation.

Article 3

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.

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Done at Brussels, 30 May 2016.

For the Commission

The President

Jean-Claude JUNCKER