COMMISSION REGULATION (EU) No 851/2013

of 3 September 2013

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 established 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 are to 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 GlaxoSmithKline Services Unlimited, 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 the effects of a reformulated acidic non-alcoholic drink on reduction of tooth demineralisation (Question No EFSA-Q-2010-00784) [3]. The claim proposed by the applicant was worded as follows: ' "Toothkind" drinks help to maintain healthy teeth'.

(7) On 16 December 2010, the Commission and the Member States received the scientific opinion from the Authority which concluded that on the basis of the data presented, a cause and effect relationship had been established between the consumption of typical conventional juice drinks at an exposure frequency of four times per day and of typical sugar-containing beverages (8-12 g sugars/100 ml) at an exposure frequency of seven times per day and tooth demineralisation. Furthermore, it concluded that replacement of those beverages with 'toothkind' drinks may contribute to reduced tooth demineralisation.

(8) Following consultation with the Member States, the Commission requested additional advice from the Authority, inter alia, on whether the beneficial effect is shown or expected to be shown for less frequent consumers of conventional juice drinks and typical sugar-containing non-alcoholic beverages. The Authority in its opinion of 8 July 2011 (Question No EFSA-Q-2011-00781) [4] concluded that a beneficial effect on maintaining tooth mineralisation may be expected for people who consume conventional juice drinks or sugar-containing non-alcoholic beverages and who are also frequent consumers of sugars and/or acids from other beverages or foods that can contribute to tooth demineralisation, if one or more servings of conventional juice drinks or sugar-containing non-alcoholic beverages are substituted by an equivalent number of servings of 'toothkind' juice drink. Furthermore, it was clarified that 'reduction of tooth demineralisation' has a similar meaning to 'maintenance of tooth mineralisation'. Accordingly, a health claim reflecting this conclusion and accompanied by specific conditions of use should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and it should be included in the Union list of permitted claims, established by Regulation (EU) No 432/2012.

(9) The Authority indicated in its opinion that its conclusions could not have been reached without considering 15 studies claimed by the applicant as proprietary. Those studies are the following:

[1] OJ L 404, 30.12.2006, p. 9.
[2] 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 health (OJ L 136, 25.5.2012, p. 1).
[3] The EFSA Journal 2010; 8(12):1884.
[4] The EFSA Journal 2011; 9(7):2293.

— Adams G, North M, De'Ath J. Principal Investigator: West NX, 2004. An investigation into the Erosive Effect of Hot Drinks. GlaxoSmithKline Report NHCMA0303, UK,

— Adams G, North M. Principal Investigator Duggal MS, 2003. Development of Intra-Oral Cariogenicity (ICT) Model #3. GlaxoSmithKline Report NHCMA0301, UK,

— Adnitt C, Adams G, North M. Principal Investigator Toumba KJ., 2005. Development of Intra-Oral Cariogenicity (ICT) Model #4. GlaxoSmithKline Report NHCMA0302, UK,

— Broughton J, North, M, Roman L. Principal Investigator Toumba KJ., 2006. Development of Intra-Oral Cariogenicity (ICT) Model #5. GlaxoSmithKline Report NHCMA0401, UK,

— De'Ath, J, North M, Smith S. Principal Investigator: Ong TJ., 2002a. A single blind, four-way crossover study to investigate the effect of two formulations of fruit drinks in comparison to a positive control (sucrose) and a negative control (sorbitol) on the pH of dental plaque. GlaxoSmithKline Report N1760182, UK,

— De'Ath J, North M, Smith S. Principal Investigator: Jackson R, 2002b. A single blind, four-way crossover study to investigate the effect of two formulations of fruit drinks in comparison to a positive control (sucrose) and a negative control (sorbitol) on the pH of dental plaque. GlaxoSmithKline Report N1760183, UK,

— De'Ath J, North M, Smith S. Principal Investigator: Preston A, 2002c. A single blind, four-way crossover study to investigate the effect of two formulations of fruit drinks in comparison to a positive control (sucrose) and a negative control (sorbitol) on the pH of dental plaque. GlaxoSmithKline Report N1760184, UK,

— De'Ath J, Moohan M, Smith S. Principal Investigator: Toumba KJ, 2003. A single blind, four-way crossover study to investigate the effect of two formulations of fruit drinks in comparison to a positive control (sucrose) and a negative control (sorbitol) on the pH of dental plaque. GlaxoSmithKline Report N1010201, UK,

— Gard'ner K, Moohan M, Smith S. Principal Investigator: Ong TJ, 2003a. A single blind, four-way crossover study to investigate the effect of two formulations of fruit drinks in comparison to a positive control (sucrose) and a negative control (sorbitol) on the pH of dental plaque. GlaxoSmithKline Report N1010199, UK,

— Gard'ner K, Moohan M, Smith S. Principal Investigator: Jackson R, 2003b. A single blind, four-way crossover study to investigate the effect of two formulations of fruit drinks in comparison to a positive control (sucrose) and a negative control (sorbitol) on the pH of dental plaque. GlaxoSmithKline Report N1010200, UK,

— Hollas M, McAuliffe T, Finke M. Principal Investigator: West NX, 2005. An investigation into the effect of a modified blackcurrant drink on tooth enamel with and without additional tooth brushing. GlaxoSmithKline Report NMA0501, UK,

— May R, and Hughes JM. Principal Investigator: Toumba KJ, 1998c. A single blind, five-way crossover study to investigate the effect of three new formulations of fruit drinks in comparison to a positive control (sucrose) and a negative control (sorbitol) on the pH of dental plaque. GlaxoSmithKline Report N1010068, UK,

— May R, and Moohan M. Principal Investigator: Duggal MS, 1999. A single blind, three-way crossover study to investigate the effect of a new formulation of fruit drink in comparison to a positive control (sucrose) and a negative control (sorbitol) on the pH of dental plaque in children. GlaxoSmithKline Report N1010104, UK,

— May R, Darby-Dowan A, Smith S. Principal Investigator: Curzon M, 1998a. A single blind, five-way crossover healthy volunteer study to investigate the effect of a new orange and a new strawberry formulation of fruit drink in comparison to a blackcurrant

fruit drink and two control treatments on the pH of dental plaque. GlaxoSmithKline Report N1010021, UK,

— May R, Hughes JM. Principal Investigator: Duggal MS, 1998b. A single blind, five-way crossover study to investigate the effect of three new formulations of fruit drinks in comparison to a positive control (sucrose) and a negative control (sorbitol) on the pH of dental plaque. GlaxoSmithKline Report N1010067, UK.

(10) All the justifiable information provided by the applicant has been assessed by the Commission and it is considered that the requirements laid down in Article 21(1) of Regulation (EC) No 1924/2006 are fulfilled for all 15 studies claimed as proprietary. By letter dated 12 June 2013, the applicant informed the Commission that there have been some changes to the structure and location of its business. Therefore, the applicant formally requested that protection of proprietary data is granted to GlaxoSmithKline Services Unlimited and its affiliates, GSK House, 980 Great West Road, Brentford, TW89GS, United Kingdom. Accordingly, the scientific data and other information included in those studies may not be used for the benefit of a subsequent applicant for a period of five years from the date of authorisation, under the conditions laid down in Article 21(1) of Regulation (EC) No 1924/2006.

(11) Following an application from Kraft Foods Europe — Biscuits R & D 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 the effects of slowly digestible starch (SDS) in starch-containing foods and reduction of post-prandial glycaemic responses (Question No EFSA-Q-2010-00966) ([1]). The claim proposed by the applicant was worded as follows: 'Slowly digestible starch provides carbohydrates that are regularly and continuously absorbed and released. They contribute to a moderate post-prandial glycaemic response'.

(12) On 21 July 2011, the Commission and the Member States received the scientific opinion from the Authority which concluded that on the basis of the data presented, a cause and effect relationship had been established between the consumption of SDS, as compared to the consumption of rapidly digestible starch (RDS), in cereal products and reduced post-prandial glycaemic responses. 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.

(13) The Authority indicated in its opinion that the four studies claimed as proprietary by the applicant were required to establish conditions of use for this specific claim. Those studies are the following:

— Brand-Miller JC, Holt S, Atkinson F, Fuzellier G and Agnetti V, 2006. Determination of the postprandial responses to two cereal foods eaten alone or as part of a mixed meal,

— Laville M, Rabasa-Lhoret R, Normand S and Braesco V, 2005. Measurement of metabolic outcome of carbohydrates of two types of cereal products,

— Rabasa-Lhoret R, Peronnet F, Jannot C, Fuzellier G and Gausseres N, 2007. Metabolic fate of four cereal products consumed as part of a breakfast by healthy female subjects,

— Vinoy S, Aubert R and Chapelot D, 2000. A cereal product high in slowly available glucose increases subsequent satiety feelings and decreases glucose and insulin responses.

(14) All the justifiable information provided by the applicant has been assessed by the Commission and it is considered that the requirements laid down in Article 21(1) of Regulation (EC) No 1924/2006 are fulfilled for the studies claimed as proprietary. By letter dated 1 October 2012, the applicant informed the Commission about the restructuring process, by means of which the Kraft Foods group span off its business, thereby creating two fully independent groups, one of them being the Mondelēz International group. As from 1 October 2012, Kraft Foods Europe — Biscuits R & D belongs to the Mondelēz International group, and the applicant formally requested that the protection of proprietary data is granted to the Mondelēz International group. Accordingly, the scientific data and other information included in those studies may not be used for the benefit of a subsequent applicant for a period of five years from the date of authorisation, under the conditions laid down in Article 21(1) of Regulation (EC) No 1924/2006.

(15) Following an application from Barry Callebaut Belgium NV 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 the effects of cocoa flavanols on endothelium-dependent vasodilation (Question No EFSA-Q-2012-00002) ([2]). The claim proposed by the applicant was worded as follows: 'Cocoa flavanols help maintain endothelium-dependent vasodilation which contributes to healthy blood flow'.

(16) On 17 July 2012, the Commission and the Member States received the scientific opinion from the Authority which concluded that on the basis of the data presented a cause and effect relationship had been established between the consumption of cocoa flavanols and the claimed effect. 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.

(17) The Authority indicated in its opinion that its conclusions could not have been reached without considering one human intervention study claimed by the applicant as proprietary. That study is Grassi D, Desideri G, Necozione S, Di Giosia P, Cheli P, Barnabei

([1]) The EFSA Journal 2011; 9(7):2292.

([2]) The EFSA Journal 2012; 10(7):2809.

R, Allegaert L, Bernaert H and Ferri C, 2011. Cocoa consumption dose-dependently improves flow-mediated dilation and arterial stiffness and decreases blood pressure in healthy subjects.

(18) All the justifiable information provided by the applicant has been assessed by the Commission and it is considered that the requirements laid down in Article 21(1) of Regulation (EC) No 1924/2006 are fulfilled for the study claimed as proprietary. Accordingly, the scientific data and other information included in that study may not be used for the benefit of a subsequent applicant for a period of five years from the date of authorisation, under the conditions laid down in that Article.

(19) 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, they should be subject to the same conditions of use as those listed in the Annex to this Regulation.

(20) 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.

(21) Since the applicants claim protection of proprietary data, it is considered appropriate to restrict the use of these claims in favour of the applicants for a period of five years. However, the authorisation of these claims restricted for the use of an individual operator does not prevent other applicants from applying for authorisation to use the same claims in case the application is based on data and studies other than those protected under Article 21 of Regulation (EC) No 1924/2006.

(22) 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.

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

(24) The Member States have been consulted,

HAS ADOPTED THIS REGULATION:

Article 1

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.

2. The use of health claims referred to in paragraph 1 shall be restricted to the applicants for a period of five years after the entry into force of this Regulation. After the expiry of that period, those health claims may be used, in conformity with the conditions applying to them, by any food business operator.

Article 2

The scientific data and other information included in the applications, which are claimed by the applicants as proprietary and without the submission of which the health claims could not have been authorised, are restricted for use for the benefit of the applicants for a period of five years from the date of entry into force of this Regulation under the conditions laid down in Article 21(1) of Regulation (EC) No 1924/2006.

Article 3

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

Article 4

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, 3 September 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX

In the Annex to Regulation (EU) No 432/2012, the following entries are inserted in an alphabetical order:

Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA Journal number	Relevant entry number in the Consolidated List submitted to EFSA for its assessment
'Reformulated, non-alcoholic, acidic drink with: — less than 1 g fermentable carbohydrate per 100 ml (sugars and other carbohydrates except polyols), — calcium in a range from 0,3 to 0,8 mol per mol acidulant, — display of pH between 3,7-4,0.	Replacing sugar-containing, acidic drinks, such as soft drinks (typically 8-12 g sugars/100 ml), with reformulated drinks contributes to the maintenance of tooth mineralisation (*)	In order to bear the claim, reformulated acidic drinks shall comply with the description of the food subject to the claim	—	2010;8(12):1884	—
Slowly digestible starch	Consumption of products high in slowly digestible starch (SDS) raises blood glucose concentration less after a meal compared to products low in SDS (**)	The claim may be used only on food where the digestible carbohydrates provide at least 60 % of the total energy and where at least 55 % of those carbohydrates is digestible starch, of which at least 40 % is SDS	—	2011;9(7):2292	—
Cocoa flavanols	Cocoa flavanols help maintain the elasticity of blood vessels, which contributes to normal blood flow (***)	Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 200 mg of cocoa flavanols. The claim can be used only for cocoa beverages (with cocoa powder) or for dark chocolate which provide at least a daily intake of 200 mg of cocoa flavanols with a degree of polymerisation 1-10	—	2012;10(7):2809	—

(*) Authorised on 24.9.2013 restricted to the use of GlaxoSmithKline Services Unlimited and its affiliates, GSK House, 980 Great West Road, Brentford, TW89GS, United Kingdom, for a period of five years.
(**) Authorised on 24.9.2013 restricted to the use of Mondelēz International group, Three Parkway North Deerfield, IL 60015, United States of America, for a period of five years.
(***) Authorised on 24.9.2013 restricted to the use of Barry Callebaut Belgium NV, Aalstersestraat 122, B-9280 Lebbeke-Wieze, Belgium, for a period of five years.'