EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to “slowly digestible starch in starch-containing foods” and “reduction of postprandial glycaemic responses” pursuant to Article 13(5) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to "slowly digestible starch in starch-containing foods" and "reduction of post-prandial glycaemic responses" pursuant to Article 13(5) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Kraft Foods Europe, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, the EFSA Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to "slowly digestible starch in starch-containing foods" and "reduction of post-prandial glycaemic responses". The food constituent, "slowly digestible starch (SDS)", as defined by the applicant in applying an appropriate method (such as the method developed by Englyst et al. (1996; 1999)), which is the subject of the health claim, and the comparator food constituent, "rapidly digestible starch (RDS)", as defined by the applicant, are sufficiently characterised in relation to the claimed effect. The claimed effect, reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased), may be a beneficial physiological effect. The studies provided consistently showed that consumption of 40-50 % of digestible starch as "SDS" in cereal products containing about 55-70 % of available carbohydrates as starch and 30-45 % as sugars in the context of a meal providing at least 60 E% of available carbohydrates induced significantly lower post-prandial glycaemic responses (without leading to disproportionally increased post-prandial insulinaemic responses) than the consumption of all digestible starch as "RDS" in cereal products with a similar content of available carbohydrates, starch and sugars. Cereal products, however, providing around 30 % of digestible starch as "SDS" and containing around 70 % of available carbohydrates as starch and 30 % as sugars did not show such an effect. A cause and effect relationship has been established between the consumption of "SDS", as compared to the consumption of "RDS", in cereal products and reduced post-prandial glycaemic responses (without disproportionally increased post-prandial insulinaemic responses).

[1] On request from the Competent Authority of Belgium following an application by Kraft Foods Europe, Question No EFSA-Q-2010-00966, adopted on 30 June 2011.

[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. One member of the Panel did not participate in the discussion on the subject referred to above because of potential conflicts of interest identified in accordance with the EFSA policy on declarations of interests. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this scientific opinion: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen.

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KEY WORDS

Slowly, rapidly, digestible starch, post-prandial, glucose, responses, health claim.

SUMMARY

Following an application from Kraft Foods Europe, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to "slowly digestible starch in starch-containing foods" and "reduction of post-prandial glycaemic responses".

The scope of the application was proposed to fall under a health claim referring to a health claim based on newly developed scientific evidence and/or a health claim including a request for the protection of proprietary data.

The food constituent that is the subject of the health claim is "slowly digestible starch (SDS)" as compared to "rapidly digestible starch (RDS)" in starch-containing foods. The Panel considers that the food constituent, "SDS", as defined by the applicant in applying an appropriate method (such as the method developed by Englyst et al. (1996; 1999)), which is the subject of the health claim, and the comparator food constituent, "RDS", as defined by the applicant, are sufficiently characterised in relation to the claimed effect.

The claimed effect proposed by the applicant relates to the reduction of post-prandial glycaemic responses. The target population proposed for the claim is the general population. The Panel considers that reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) may be a beneficial physiological effect.

The applicant provided five human intervention studies (four claimed as proprietary by the applicant) for the scientific substantiation of the claim. In these studies, the effect of consuming cereal products high in "SDS" compared to consuming cereal products low in "SDS" and high in "RDS" on post-prandial blood glucose and insulin responses was investigated.

The Panel notes that the studies provided consistently showed that consumption of 40-50 % of digestible starch as "SDS" in cereal products containing about 55-70 % of available carbohydrates as starch and 30-45 % as sugars in the context of a meal providing at least 60 E% of available carbohydrates induced significantly lower post-prandial glycaemic responses (without leading to disproportionally increased post-prandial insulinaemic responses) than the consumption of all digestible starch as "RDS" in cereal products with a similar content of available carbohydrates, starch and sugars. Cereal products, however, providing around 30 % of digestible starch as "SDS" and containing around 70 % of available carbohydrates as starch and 30 % as sugars did not show such an effect. The Panel also notes that a reduction in the sugar content in these cereal products is expected to have a similar effect on post-prandial glycaemic responses.

The Panel concludes that a cause and effect relationship has been established between the consumption of "SDS", as compared to the consumption of "RDS", in cereal products and reduced post-prandial glycaemic responses (without disproportionally increased post-prandial insulinaemic responses).

The Panel could have reached the conclusion that the rate of starch digestibility assessed *in vitro* in cereal products has an effect on post-prandial glycaemic responses *in vivo* in humans without the data marked as proprietary by the applicant. However, the four unpublished studies claimed as proprietary by the applicant were required to establish conditions of use for this specific claim.

The Panel considers that the following wording reflects the scientific evidence: "Consumption of cereal products high in slowly digestible starch raises blood glucose concentrations less after a meal than cereal products low in slowly digestible starch".

The Panel considers that, in order to bear the claim, cereal products should contain at least 55 % of available carbohydrates as starch of which at least 40 % should be "SDS". The target population is individuals who wish to reduce their post-prandial blood glucose responses.

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BACKGROUND

Regulation (EC) No 1924/2006[4] harmonises the provisions that relate to nutrition and health claims and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to the reduction of disease risk and to children's development and health), which are based on newly developed scientific evidence or include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3).

According to Article 18 of this Regulation, an application for authorisation or inclusion in the Community list of permitted claims referred to in Article 13(3) shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

STEPS TAKEN BY EFSA:

- The application was received on 08/07/2010.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data.
- During the check for completeness[5] of the application, the applicant was requested to provide clarifications/additional information on 30/07/2010.
- The applicant provided the clarifications/additional information on 18/10/2010.
- The scientific evaluation procedure started on 30/10/2010.
- On 25/02/2011, the NDA Panel Working Group on Claims agreed on a list of questions for the applicant to provide additional information to accompany the application and on 01/03/2011, EFSA requested the applicant to provide this additional information. The clock was stopped from 04/03/2011 to 18/03/2011.
- The applicant submitted the responses to EFSA's request on 18/03/2011.
- On 06/04/2011, the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application and on 07/04/2011, EFSA requested the applicant to provide this additional information. The clock was stopped from 11/04/2011 to 26/04/2011.
- The applicant submitted the responses to EFSA's request on 26/04/2011.
- On 13/05/2011, the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application and on 16/05/2011, EFSA requested the applicant to provide this additional information. The clock was stopped from 17/05/2011 to 30/05/2011.
- The applicant submitted the responses to EFSA's request on 30/05/2011.

[4] 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. OJ L 404, 30.12.2006, p. 9–25.

[5] In accordance with: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. Scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim (revision 1). EFSA Journal, 9(5):2170, 36 pp.

- On 30/06/2011, the NDA Panel, after having evaluated the overall data submitted, adopted an opinion on the scientific substantiation of a health claim related to "slowly digestible starch in starch-containing foods" and "reduction of post-prandial glycaemic responses".

TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to "slowly digestible starch in starch-containing foods" and "reduction of post-prandial glycaemic responses".

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of "slowly digestible starch in starch-containing foods", a positive assessment of its safety, nor a decision on whether "slowly digestible starch in starch-containing foods" is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 18(4) of Regulation (EC) No 1924/2006.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Kraft Foods Europe - Biscuits R&D, 6 Rue Razel, 91400 Saclay - France.

The application includes a request for the protection of proprietary data in accordance with Article 21 of Regulation (EC) No 1924/2006.

Food/constituent as stated by the applicant

According to the applicant the food, which is the subject of the health claim, is "biscuits for breakfast". After clarification sought by EFSA, the applicant indicated that the food, which is the subject of the claim, is slowly digestible starch in starch-containing foods.

Health relationship as claimed by the applicant

According to the applicant the health relationship relates to the appearance, in the blood circulation, of exogenous glucose from biscuits consumed for breakfast that is moderate and stable throughout the morning. After clarification sought by EFSA, the applicant indicated that the health relationship relates to the reduction of post-prandial glycaemic responses induced by the consumption of slowly digestible starch (SDS) when consumed in replacement of rapidly digestible (RDS) starch in starch-containing foods.

Wording of the health claim as proposed by the applicant

The applicant proposes the following wording: Slowly digestible starch provides carbohydrates that are regularly and continuously absorbed and released. They contribute to a moderate post-prandial glycaemic response.

Specific conditions of use as proposed by the applicant

The applicant proposes the following conditions: A minimum of 31 % of SDS/RDS+SDS and at least 20 g of the total amount of RDS and SDS per meal.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is "slowly digestible starch (SDS)" as compared to "rapidly digestible starch (RDS)" in starch-containing foods.

SDS is defined by the applicant in this particular case by the rate and extent of starch digestion in starch-containing foods estimated by an *in vitro* method developed by Englyst et al. (1996; 1999). Briefly, food samples are analysed for free-sugar glucose (FSG) and fructose following *in vivo* chewing or mechanical mincing/crushing. Then, food samples are incubated with pancreatic enzymes (invertase, amylase, amyloglucosidase), and the amount of free glucose is measured at 20 (G_{20}) and 120 (G_{120}) minutes. Food samples are further incubated and treated to obtain the total glucose portion. The amount of RDS is calculated as the difference between G_{20} and FSG multiplied by a factor of 0.9, and the amount of SDS by the difference between G_{120} and G_{20} multiplied by a factor of 0.9. Resistant starch (RS) is calculated as the difference between total glucose and G_{120} multiplied by a factor of 0.9. The Panel notes that this application refers to the digestible fraction of starch.

The Panel considers that the food constituent, "SDS", as defined by the applicant in applying an appropriate method (such as the method developed by Englyst et al. (1996; 1999)), which is the subject of the health claim, and the comparator food constituent, "RDS", as defined by the applicant, are sufficiently characterised in relation to the claimed effect.

2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant relates to the reduction of post-prandial glycaemic responses. The target population proposed for the claim is the general population.

Postprandial glycaemia is interpreted as the elevation of blood glucose concentrations after consumption of a food and/or meal. This function is a normal physiological response which varies in magnitude and duration, and which may be influenced by the chemical and physical nature of the food or meal consumed, as well as by individual factors (Venn and Green, 2007). Decreasing post-prandial glycaemic responses may, for example, be beneficial to individuals with impaired glucose tolerance, as long as post-prandial insulinaemic responses are not disproportionally increased. Impaired glucose tolerance is common in the general population of adults.

The Panel considers that reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) may be a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The applicant provided four unpublished human intervention studies (identified as proprietary data) and one published human intervention study, all of which compared the effect of consuming cereal products high in "SDS" to consuming cereal products low in "SDS" and high in "RDS" on post-prandial blood glucose concentrations in healthy subjects.

In an open-label, randomised, controlled cross-over study (Rabasa-Lhoret et al., 2007, unpublished) the effect of three different breakfast biscuits and one extruded wheat flake cereal product (control) consumed with breakfast on post-prandial blood glucose and insulin responses was investigated in 19 healthy females (19-26 years) after an overnight fast. The intervention breakfasts consisted of 71.8 g breakfast biscuits and 150 mL skimmed milk. The control breakfast was composed of 66 g extruded wheat flakes, 150 mL skimmed milk and 4.5 g of a 50/50 rapeseed oil/palm olein oil mixture. Subjects were allowed to consume a maximum of 300 mL decaffeinated/detheinated unsweetened coffee or tea with the breakfasts. The four breakfasts, which provided around 380 kcal of energy, were comparable with respect to macronutrient composition and dietary fibre content. The cereal products tested were comparable for total digestible starch (biscuits: 33-37 g, wheat flakes: 34.1 g), total sugars (biscuits: 14.6-18.5 g, wheat flakes: 17.4 g) and total fructose (biscuits: 7.1-9.9 g, wheat flakes: 8.9 g). The biscuits contained 41.9-46.4 % of total digestible starch as "SDS" while this value for the control breakfast was 0.3 %. Breakfasts were consumed on four occasions separated by a 28±3 day wash-out period. Blood glucose and insulin concentrations were measured at baseline, every 15 min up to 90 min and thereafter every 30 min up to 270 min. Four subjects dropped out during the study. Data from one of the four subjects, who did not complete the study but attended all but one visit, were taken into account in the analysis. The incremental area under the curve (iAUC) for blood glucose concentrations (T0-T120 min) was significantly lower after the consumption of the intervention breakfasts than after the control breakfast (mean±SEM 153.9±14.7, 137.1±12.3, 150.7±16.4 *vs*. 224.2±22.0 mmol/L/min; $p=0.003$, $p<0.001$, $p=0.002$) as was the iAUC for insulin (T0-T120 min; mean±SEM 2166±227, 2224±196, 2301±226 *vs*. 3351±296 IU/L/min; $p=0.002$ for all comparisons). The Panel notes that the consumption of 40 % of digestible starch as "SDS" induced significantly lower post-prandial glycaemic responses (without leading to disproportionally increased post-prandial insulinaemic responses) than the consumption of all digestible starch as "RDS" in cereal products containing about 67 % of available carbohydrates as starch and 33 % as sugars.

In an open-label, randomised, controlled cross-over study (Brand-Miller et al., 2006, unpublished) the effect of breakfast biscuits and an extruded wheat flake product consumed with breakfast on post-prandial blood glucose and insulin responses after an overnight fast was investigated in 13 healthy adult men (21.3-26.4 years). The two breakfasts were consumed on two separate occasions separated by a wash-out period of at least one day. The intervention breakfast consisted of 70 g breakfast biscuits and 250 mL semi-skimmed milk. The control breakfast was composed of 70 g extruded wheat flakes and 250 mL of full fat milk. Subjects were allowed to consume a maximum of 300 mL unsweetened coffee or tea with the breakfasts. The breakfasts, which provided around 450 kcal of energy, were comparable with respect to macronutrient composition and dietary fibre content. The cereal products tested were comparable for total digestible starch (biscuits: 37.1 g, wheat flakes: 41.3 g), total sugars (biscuits: 15.4 g, wheat flakes: 16.5 g) and total fructose (biscuits: 7.5 g, wheat flakes: 8.0 g). The biscuits contained 39.9 % of total digestible starch as "SDS", while this value for the control breakfast was 1.5 %. Blood glucose and insulin concentrations were measured at baseline, at 15 min, at 20 min, every 10 min up to 60 min, every 15 min up to 120 min, every 30 min up to 180 min, every 15 min up to 240 min and at 270 min. All subjects completed the study. The iAUC for blood glucose concentrations (T0-T120 min) was significantly lower after the consumption of the intervention breakfast than after the control breakfast (mean±SEM 100.6±11.3 *vs*. 142.7±11.3 mmol/L/min; p=0.01) as was the iAUC for insulin (T0-T120 min; mean±SEM 3528±358 *vs*. 2517±358 IU/L/min; p<0.01). The Panel notes that the consumption of 40 % of digestible starch as "SDS" induced significantly lower post-prandial glycaemic responses (without leading to disproportionally increased post-prandial insulinaemic responses) than the consumption of all digestible starch as "RDS" in cereal products containing about 70 % of available carbohydrates as starch and 30 % as sugars.

In an open-label, randomised, controlled cross-over study (Vinoy et al., 2000, unpublished) the effect of breakfast biscuits and chocolate flavoured cereals consumed with breakfast on post-prandial blood glucose and insulin responses after an overnight fast was investigated in 12 healthy subjects (6 females, 18-40 years). Breakfasts were consumed on two occasions separated by a seven-day wash-out period. The intervention breakfast consisted of 62.5 g honey-plain breakfast biscuits with chocolate chips and 180 mL skimmed milk. The control breakfast was composed of 56 g chocolate flavoured cereals and 180 mL full fat milk. Each breakfast also contained 10 g chocolate powder and 80 mL orange juice. The breakfasts, which provided around 400 kcal of energy, were comparable with respect to macronutrient composition and dietary fibre content. The cereal products tested were comparable for total digestible starch (biscuits: 24.0 g, cereal: 21.3 g), total sugars (biscuits: 18.6 g, cereal: 23.9 g) and total fructose (biscuits: 8.4 g, cereal: 11.4 g). The biscuits contained 40.0 % of total digestible starch as "SDS" while this value for the control breakfast was 2.3 %. Blood glucose and insulin concentrations were measured at baseline, at 15 min, at 30 min and thereafter every 30 min up to 240 min. All subjects completed the study. The iAUC for blood glucose concentrations (T0-T120 min) was significantly lower after the consumption of the intervention breakfast than after the control breakfast (mean±SEM 50.6±10.8 *vs*. 89.3±16.9 mmol/L/min; p=0.03) as was the iAUC for insulin (T0-T120 min; mean±SEM 5123±291 *vs*. 6938±550 IU/L/min; p=0.004). The Panel notes that the consumption of 40 % of digestible starch as "SDS" induced significantly lower post-prandial glycaemic responses (without leading to disproportionally increased post-prandial insulinaemic responses) than the consumption of all digestible starch as "RDS" in cereal products containing about 55 % of available carbohydrates as starch and 45 % as sugars.

In a randomised, controlled parallel trial (Nazare et al., 2009) the effects of breakfast biscuits and wheat flakes consumed with breakfast on post-prandial blood glucose and insulin responses after an overnight fast were investigated in 38 overweight subjects (19 women, 23-57 years). The intervention breakfast consisted of 80 g biscuits and 180 mL semi-skimmed milk. The control breakfast was composed of 80 g breakfast cereals and 180 mL semi-skimmed milk. Subjects were allowed to consume a maximum of 300 mL of calorie-free hot beverage. The breakfasts, which provided around 430 kcal of energy, were comparable with respect to macronutrient composition and dietary fibre content. The cereal products tested were comparable for total digestible starch (biscuits: 39.7 g,

cereal: 39.1 g), total sugars (biscuits: 18.9 g, cereal: 19.5 g) and total fructose (biscuits: 9.2 g, cereal: 9.6 g). The biscuits contained 53.1 % of total digestible starch as "SDS" while this value for the control breakfast was 2.0 %. Blood glucose and insulin concentrations were measured at baseline, every 15 min up to 90 min and thereafter every 30 min up to 270 min. The iAUC for blood glucose concentrations (T0-T120 min) was significantly lower after the consumption of the intervention breakfast than after the control breakfast (mean±SEM 95.5±15.9 *vs*. 152.7±13.5 mmol/L/min; p=0.01). No significant differences were observed with respect to the iAUC for insulin (T0-T120 min). The Panel notes that the consumption of 50 % of digestible starch as "SDS" induced significantly lower post-prandial glycaemic responses (without leading to disproportionally increased post-prandial insulinaemic responses) than the consumption of all digestible starch as "RDS" in cereal products containing about 70 % of available carbohydrates as starch and 30 % as sugars.

In an open-label, randomised, controlled cross-over study (Laville et al., 2005, unpublished) the effect of breakfast biscuits and wheat flakes consumed with breakfast and after an overnight fast on post-prandial blood glucose and insulin responses were investigated in 12 healthy men (18-40 years). Breakfasts were consumed on two occasions separated by a two-week wash-out period and a 3-week run-in period in which the respective breakfasts were consumed. The intervention breakfast consisted of 70 g biscuits and 250 mL semi-skimmed milk. The control breakfast was composed of 70 g wheat flakes and 250 mL full fat milk. Subjects were allowed to consume a maximum of 300 mL of unsweetened tea or coffee. The breakfasts, which provided around 440 kcal of energy, were comparable with respect to macronutrient composition and dietary fibre content. The cereal products tested were comparable for total digestible starch (biscuits: 34.7 g, cereal: 39.4 g), total sugars (biscuits: 15.7 g, cereal: 17.5 g) and total fructose (biscuits: 7.4 g, cereal: 10.0 g). The biscuits contained 34.6 % of total digestible starch as "SDS" while this value for the control breakfast was 2.3 %. Blood glucose and insulin concentrations were measured at baseline and every 30 min up to 270 min. No significant differences were observed under the conditions of the study with respect to the iAUC for blood glucose or insulin concentrations (T0-T120 min). The Panel notes that the consumption of 30 % of digestible starch as "SDS" did not induce significantly lower post-prandial glycaemic responses (without leading to disproportionally increased post-prandial insulinaemic responses) than the consumption of all digestible starch as "RDS" in cereal products containing about 70 % of available carbohydrates as starch and 30 % as sugars.

The Panel notes that the studies provided consistently showed that consumption of 40-50 % of digestible starch as "SDS" in cereal products containing about 55-70 % of available carbohydrates as starch and 30-45 % as sugars in the context of a meal providing at least 60 E% of available carbohydrates induced significantly lower post-prandial glycaemic responses (without leading to disproportionally increased post-prandial insulinaemic responses) than the consumption of all digestible starch as "RDS" in cereal products with a similar content of available carbohydrates, starch and sugars. Cereal products, however, providing around 30 % of digestible starch as "SDS" and containing around 70 % of available carbohydrates as starch and 30 % as sugars did not show such an effect. The Panel also notes that a reduction in the sugar content in these cereal products is expected to have a similar effect on post-prandial glycaemic responses.

The Panel concludes that a cause and effect relationship has been established between the consumption of "SDS", as compared to the consumption of "RDS", in cereal products and reduced post-prandial glycaemic responses (without disproportionally increased post-prandial insulinaemic responses).

The Panel notes that other *in vitro* methods (in addition to the method developed by Englyst et al. (1996; 1999) following *in vivo* chewing to determine the rate of starch (and carbohydrate) digestibility in starchy foods have been developed, described, and modified by different authors (reviewed by Woolnough et al., 2008), and that many of these methods have been validated *in vivo* (e.g. Brighenti et al., 1995; Granfeldt et al., 1992; Seal et al., 2003) with respect to the post-prandial glycaemic and insulinaemic responses induced by such foods in different population sub-groups (e.g.

healthy subjects, subjects with type 2 diabetes on diet only and under hypoglycaemic medications, subjects with celiac disease) (e.g. Berti et al., 2004; Giacco et al., 2001; Holm and Bjorck, 1992; Seal et al., 2003). The Panel also notes that, although these methods encompass simulations of oral, gastric and intestinal digestion processes, the way in which physiological conditions are simulated differs considerably, and that these differences may have a substantial influence on the post-prandial glycaemic responses predicted for a particular food, and that there is currently no consensus on a single *in vitro* method for the measurement of the rate of starch (and carbohydrate) digestibility in starch-containing foods providing the highest predictive values with respect to the induced post-prandial glycaemic (and insulinaemic) responses *in vivo* in humans (Woolnough et al., 2008). No inter-laboratory comparison is available at present for any of these methods.

Therefore, the Panel could have reached the conclusion that the rate of starch digestibility assessed *in vitro* (e.g. by the method developed by Englyst et al. (1996; 1999)) in cereal products has an effect on post-prandial glycaemic responses *in vivo* in humans without the data marked as proprietary by the applicant. However, the four unpublished studies claimed as proprietary by the applicant were required to establish conditions of use for this specific claim.

4. Panel's comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence: "Consumption of cereal products high in slowly digestible starch raises blood glucose concentrations less after a meal than cereal products low in slowly digestible starch".

5. Conditions and restrictions of use

The Panel considers that, in order to bear the claim, cereal products should contain at least 55 % of available carbohydrates as starch of which at least 40 % should be "SDS". The target population is individuals who wish to reduce their post-prandial blood glucose responses.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, "slowly digestible starch (SDS)", as defined by the applicant in applying an appropriate method (such as the method developed by Englyst et al. (1996; 1999)), which is the subject of the health claim, and the comparator food constituent, "rapidly digestible starch (RDS)", as defined by the applicant, are sufficiently characterised in relation to the claimed effect.

- The claimed effect proposed by the applicant relates to the reduction of post-prandial glycaemic responses. The target population proposed for the claim is the general population. Reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) may be a beneficial physiological effect.

- A cause and effect relationship has been established between the consumption of "SDS", as compared to the consumption of "RDS", in cereal products and reduced post-prandial glycaemic responses (without disproportionally increased post-prandial insulinaemic responses).

- The following wording reflects the scientific evidence: "Consumption of cereal products high in slowly digestible starch raises blood glucose concentrations less after a meal than cereal products low in slowly digestible starch".

- In order to bear the claim, cereal products should contain at least 55 % of available carbohydrates as starch of which at least 40 % should be "SDS". The target population is individuals who wish to reduce their post-prandial blood glucose responses.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on "slowly digestible starch in starch-containing foods" and "reduction of post-prandial glycaemic responses" pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0284_BE). October 2010. Submitted by Kraft Foods Europe.

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GLOSSARY AND ABBREVIATIONS

FSG	Free-sugar glucose
iAUC	Incremental area under the curve
RDS	Rapidly digestible starch
SDS	Slowly digestible starch