

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to resistant starch and reduction of post-prandial glycaemic responses (ID 681), “digestive health benefits” (ID 682) and “favours a normal colon metabolism” (ID 783) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2,3}

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SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to resistant starch and reduction of post-prandial glycaemic responses, “digestive health benefits” and “favours a normal colon metabolism”. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claims is resistant starch-type 2 from high amylose maize. The Panel considers that resistant starch from high amylose maize (RS2) is sufficiently characterised.

Reduction of post-prandial glycaemic responses

The claimed effect is “healthy blood glucose/sugar levels”. The target population is assumed to be individuals wishing to reduce their post-prandial glycaemic responses. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the reduction of post-prandial glycaemic responses. The Panel considers that the reduction of post-prandial glycaemic responses (as long as

¹ On request from the European Commission, Question No EFSA-Q-2008-1468, EFSA-Q-2008-1469, EFSA-Q-2008-1570, adopted on 12 November 2010.

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post-prandial insulinaemic responses are not disproportionately increased) may be a beneficial physiological effect.

In weighing the evidence, the Panel took into account that most of the studies provided reported a significant decrease in post-prandial glycaemic responses, without significantly increasing insulinaemic responses, following consumption of RS2 as a partial replacement of digestible starch in baked goods, and that the effect is generally not observed when the amount of available carbohydrates is maintained constant in the test and control products. This suggests that the replacement of digestible starch in carbohydrate-containing foods by RS2 from high amylose maize would decrease post-prandial glycaemic and insulinaemic responses due to the replacement of digestible carbohydrates by indigestible carbohydrates, so that the amount of available glucose contributing to glycaemia is reduced, whereas the addition of RS2 to carbohydrate-containing foods does not appear to modify the post-prandial glucose responses to digestible starch (i.e. when the amount of glycaemic carbohydrates is kept constant). The Panel notes that the effect of replacing digestible starch in foods with resistant starch on post-prandial glycaemic responses could be expected from all types of resistant starch, and that this effect is not specific to RS2 from high amylose maize.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of resistant starch from all sources, when replacing digestible starch in baked foods, and a reduction of post-prandial glycaemic responses.

The Panel considers that in order to bear the claim, high carbohydrate baked foods should contain at least 14 % of total starch as resistant starch in replacement to digestible starch. The target population is individuals wishing to reduce their post-prandial glycaemic responses.

“Digestive health benefits”

The claimed effect is “digestive health benefits”. The target population is assumed to be the general population.

The claimed effect is not sufficiently defined, and no further details were provided in the proposed wordings.

The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

“Favours a normal colon metabolism”

The claimed effect is “favours a normal colon metabolism”. The target population is assumed to be the general population.

The claimed effect is not sufficiently defined, and no further details were provided in the proposed wordings.

The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

KEY WORDS

Resistant starch, high amylose maize, post-prandial glycaemic responses, digestive health, colon metabolism, health claims.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

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TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

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EFSA DISCLAIMER

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006⁴ submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out⁵. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is resistant starch-type 2 from high amylose maize.

Resistant starch (RS) is defined as starch that escapes digestion and absorption in the small intestine of healthy subjects, and can be classified into four types: RS1 is physically inaccessible to digestion, RS2 describes native starch granules that are protected from digestion by the conformation or structure of the granule, RS3 refers to non-granular starch-derived materials which are generally formed during retrogradation of starch granules in food processing, and RS4 are starches not found in nature which have been chemically modified to decrease their digestibility (Nugent, 2005).

RS from high amylose maize (amylose content between 50 % and 90 %) is categorised as RS2, and is produced from a traditionally bred hybrid of high amylose maize that contains a mixture of digestible and resistant starch. The starch granules in high amylose maize are very stable, and tend not to gelatinise when subjected to the processing conditions used in the manufacture of many common foods.

Methods are available to measure these starch fractions in the laboratory (McCleary and Monaghan, 2002).

The Panel considers that the food constituent, resistant starch from high amylose maize (RS2), which is the subject of the health claims, is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Reduction of post-prandial glycaemic responses (ID 681)

The claimed effect is “healthy blood glucose/sugar levels”. The Panel assumes that the target population is individuals wishing to reduce their post-prandial glycaemic responses.

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 Briefing document for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims: <http://www.efsa.europa.eu/en/ndameetings/docs/nda100601-ax01.pdf>

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the reduction of post-prandial glycaemic responses.

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 that 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 be beneficial to subjects with, for example, impaired glucose tolerance, as long as post-prandial insulinaemic responses are not disproportionately increased. Impaired glucose tolerance is common in the general adult population.

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

2.2. “Digestive health benefits” (ID 682)

The claimed effect is “digestive health benefits”. The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined, and no further details were provided in the proposed wordings.

The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

2.3. “Favours normal colon metabolism” (ID 783)

The claimed effect is “favours a normal colon metabolism”. The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined, and no more details were provided in the proposed wordings.

The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

3. Scientific substantiation of the claimed effect

3.1. Reduction of post-prandial glycaemic responses (ID 681)

The references provided in relation to the claim included one reference on the PASSCLAIM project (Aggett et al., 2005) and one narrative review on the health properties of all types of resistant starch (Nugent, 2005). The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

One reference reported on the effects of a typical American diet containing 20 % of calories from either high-amylose corn starch or from fructose on glucose tolerance after a five-week intervention (Reiser et al., 1989). The Panel considers that no conclusions can be drawn from this reference for the scientific substantiation of the claim.

A dossier for the substantiation of an Article 13 health claim was provided (de la Hunty and Ashwell, 2008). The dossier included a systematic review (and meta-analysis where appropriate) on the effects of starch from high amylose maize in substitution of normal flour in standard food items such as

bread, muffins, cookies and corn chips on post-prandial blood glucose and insulin concentrations. A total of 16 relevant studies were identified, 15 of which had been provided as individual references for the substantiation of the claim. Ten studies were conducted in healthy men and women (Behall et al., 1988; Behall and Hallfrisch, 2002; Behall and Scholfield, 2005; Brighenti et al., 2006; Granfeldt et al., 1995; Higgins et al., 2004; Hoebler et al., 1999; Jenkins et al., 1998; Muir et al., 1994; Quilez et al., 2007), one in healthy men (Behall et al., 1989), one in healthy women (Weickert et al., 2005), one in overweight men (Behall et al., 2006a), one in overweight women (Behall et al., 2006b), one in men with hypertriglyceridaemia (Noakes et al., 1996), and one in men with hyperinsulinaemia (Behall and Howe, 1995). The Panel notes that in two studies the macronutrient composition of the test and control foods (particularly the fat content) was not comparable, which could have influenced the results obtained (Granfeldt et al., 1995; Quilez et al., 2007). The Panel considers that no conclusions can be drawn from these references, and therefore from the meta-analysis provided, for the scientific substantiation of the claim.

Most of the remaining studies used either a cross-over or Latin square design and assessed post-prandial glycaemic and insulinaemic responses after food (or meal) tests in which common baked foods (e.g. crackers, bread and muffins) were made from either regular maize or wheat flour, from high amylose (50-90 %) maize flour, or from a combination of them. Blood samples were taken for glucose and insulin analysis at 15 min and 30 min, and thereafter every 30 minutes up to at least 2 hours (except for Noakes et al., (1996) where blood sampling was up to 105 min), and generally up to 3 to 4 hours. All the studies except two (Hoebler et al., 1999; Weickert et al., 2005) included at least 10 subjects. Results are generally expressed as the difference between test and control food products (or meals) in post-prandial blood glucose and insulin concentrations at different time points, and as differences in the areas under the curve (AUC) for glucose and insulin. The Panel notes that even if in three of the studies the amount of RS2 in the test and control products has not been reported (Behall et al., 1988; 1989; Behall and Howe, 1995), this could be estimated from the amylose content of the high amylose maize starch used (Behall and Hallfrisch, 2002), and could be used as supportive evidence for the scientific substantiation of the claim.

Most of the studies provided report a statistically significant decrease in post-prandial glycaemic and insulinaemic responses when starch from high amylose maize replaces almost fully digestible starch in test products (Behall et al., 1988; 1989; Behall and Howe, 1995; Behall and Hallfrisch, 2002; Behall and Scholfield, 2005; Behall et al., 2006a; 2006b; Brighenti et al., 2006; Hoebler et al., 1999; Noakes et al., 1996), but not when the amount of available carbohydrates is maintained constant in the test and control products (Jenkins et al., 1998; Weickert et al., 2005) or when the replacement of starch by resistant starch is lower than about 14 % of total starch (Behall and Hallfrisch, 2002; Muir et al., 1994). This suggests that the replacement of digestible starch in carbohydrate-containing foods by RS2 from high amylose maize would decrease post-prandial glycaemic and insulinaemic responses due to the replacement of digestible carbohydrates by indigestible carbohydrates, so that the amount of available glucose contributing to glycaemia is reduced, whereas the addition of RS2 to carbohydrate-containing foods does not appear to modify the post-prandial glucose responses to digestible starch (i.e. when the amount of glycaemic carbohydrates is kept constant). The Panel notes that the effect of replacing digestible starch in foods with resistant starch on post-prandial glycaemic responses could be expected from all types of resistant starch, and that this effect is not specific to RS2 from high amylose maize.

Behall and Hallfrish (2002) addressed the lowest effective dose at which RS2 should be consumed as a replacement of digestible starch in order to obtain the claimed effect. In this study, 25 overweight subjects consumed breads made from maize starches with different amylose content (ranging from 30 % to 70 %). The dose of available carbohydrates linearly decreased, and the amount of resistant starch (expressed as % of total starch) significantly increased, in breads made from starches with increasing percentages of amylose. The level of RS2 needed for a significant reduction in post-prandial glucose or insulin responses was assessed. The amylose content of the starch used in

acute meals needed to be at least 60 % amylose to significantly reduce the post-prandial glucose responses. This level of amylose was equivalent to a minimum intake of 11.5 g RS2 in a serving of 80 g total carbohydrates and 68 g of available carbohydrates. The Panel notes that the amount of RS2 used to achieve the claimed effect was 14 % of total starch.

In weighing the evidence, the Panel took into account that most of the studies provided reported a significant decrease in post-prandial glycaemic responses, without significantly increasing insulinaemic responses, following consumption of RS2 as a partial replacement of digestible starch in baked foods, and that the effect is generally not observed when the amount of available carbohydrates is maintained constant in the test and control products. This suggests that the replacement of digestible starch in carbohydrate-containing foods with RS2 from high amylose maize would decrease post-prandial glycaemic and insulinaemic responses due to the replacement of digestible carbohydrates by indigestible carbohydrates, so that the amount of available glucose contributing to glycaemia is reduced, whereas the addition of RS2 to carbohydrate-containing foods does not appear to modify the post-prandial glucose responses to digestible starch (i.e. when the amount of glycaemic carbohydrates is kept constant). The Panel notes that the effect of replacing digestible starch in foods with resistant starch on post-prandial glycaemic responses could be expected from all types of resistant starch, and that this effect is not specific to RS2 from high amylose maize.

The Panel concludes that a cause and effect relationship has been established between the consumption of resistant starch from all sources, when replacing digestible starch in baked foods, and a reduction of post-prandial glycaemic responses.

4. Panel's comments on the proposed wording

4.1. Reduction of post-prandial glycaemic responses (ID 681)

The Panel considers that the following wording reflects the scientific evidence: “Replacing digestible starch with resistant starch induces a lower blood glucose rise after a meal”.

5. Conditions and possible restrictions of use

5.1. Reduction of post-prandial glycaemic responses (ID 681)

The Panel considers that in order to bear the claim, high carbohydrate baked foods should contain at least 14 % of total starch as resistant starch, in replacement to digestible starch. The target population is individuals wishing to reduce their post-prandial glycaemic responses.

CONCLUSIONS

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

- The food constituent, resistant starch from high amylose maize (RS2), which is the subject of the health claims, is sufficiently characterised.

Reduction of post-prandial glycaemic responses (ID 681)

- The claimed effect is “healthy blood glucose/sugar levels”. The target population is assumed to be subjects wishing to reduce their post-prandial glycaemic responses. The reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionately increased) may be a beneficial physiological effect.

- A cause and effect relationship has been established between the consumption of resistant starch from all sources, when replacing digestible starch in baked foods, and a reduction of post-prandial glycaemic responses.
- The following wording reflects the scientific evidence: “Replacing digestible starch with resistant starch induces a lower blood glucose rise after a meal”.
- The Panel considers that in order to bear the claim, high carbohydrate baked foods should contain at least 14 % of total starch as resistant starch, in replacement to digestible starch. The target population is individuals wishing to reduce their post-prandial glycaemic responses.

“Digestive health benefits” (ID 682)

- The claimed effect is “digestive health benefits”. The target population is assumed to be the general population.
- The claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

“Favours a normal colon metabolism” (ID 783)

- The claimed effect is “favours a normal colon metabolism”. The target population is assumed to be the general population.
- The claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1468, EFSA-Q-2008-1469, EFSA-Q-2008-1570). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: <http://www.efsa.europa.eu/panels/nda/claims/article13.htm>.

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods⁶ (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD⁷

Foods are commonly involved in many different functions⁸ of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

⁶ OJ L12, 18/01/2007

⁷ The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

⁸ The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to

describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity

- consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
 - the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
 - the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. 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 wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to resistant starch, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
681	Resistant starch- type 2 (RS) from high amylose maize	Healthy blood glucose/sugar levels.	<ul style="list-style-type: none"> - RS can help keep your blood sugar levels balanced after a meal - RS may help prevent blood sugar ‘highs’ after a meal
	<p>Conditions of use</p> <p>- Each serving of a RS fortified food should provide at least 3.4 g RS. The food must be eaten as part of healthy lifestyle and diet.</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
682	Resistant starch- type 2 (RS) from high amylose maize.	Digestive health benefits.	<p>RS promotes a healthy digestive system.</p> <p>RS delivers prebiotic activities.</p>
	<p>Conditions of use</p> <p>- Each serving of a RS fortified food should provide at least 3.4 g RS. The food must be eaten as part of healthy lifestyle and diet.</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
783	Resistant starch- type 2 (RS) from high amylose maize.	Favours a normal colon metabolism	<p>Resistant starch helps favour a normal colon metabolism;</p> <p>Resistant starch is a butyrogenic fibre, butyrate participates to a normal colonic functions and metabolism</p>
	<p>Conditions of use</p> <p>- Lebensmittel mit RS, nach Empfehlung auf dem Etikett zubereitet, sollten mindestens 4,25 g RS pro Portion enthalten. RS-haltige Lebensmittel sollten im Rahmen einer gesunden, ausgewogenen und fett- sowie cholesterinarmen Ernährung verzehrt werden (17 g/Ta</p> <p>-Where a daily value is indicated the amount per serving is typically 25% unless otherwise stated</p> <p>-17g/ day</p>		

GLOSSARY AND ABBREVIATIONS

AUC Area under the curve

PASSCLAIM Process for the Assessment of Scientific Support for Claims on Foods

RS2 Resistant starch type 2