

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to whole grain (ID 831, 832, 833, 1126, 1268, 1269, 1270, 1271, 1431) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

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

European Food Safety Authority (EFSA), Parma, Italy

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 related to whole grain. 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 constituents that are the subject of this opinion are “whole grain”, “whole grain flour”, “whole grain foods”, and “diets rich in whole grain”, related to the following claimed effects: “gut health”/“bowel function”, “weight control”, “blood glucose”/“insulin levels”, “weight management”, “blood cholesterol”, “satiety”, “glycaemic index”, “digestive function” and “cardiovascular health”.

Whole grain foods (including whole grain flour) are defined differently across countries, also within the EU. In the UK and the USA whole grain foods must contain ≥ 51 % whole grain ingredients by wet weight, whereas in Sweden and Denmark the requirement is ≥ 50 % whole grain ingredients on a dry matter basis. In Germany, whole grain bread must be 90 % whole grain.

The information in the consolidated list and the references provided do not allow the Panel to characterise the food constituent, whole grain, that is the subject of the health claims. The Panel

¹ On request from the European Commission, Question No EFSA-Q-2008-1619, EFSA-Q-2008-1865, adopted on 11 February 2010 and Question No EFSA-Q-2008-1618, EFSA-Q-2008-1620, EFSA-Q-2008-2006, EFSA-Q-2008-2007, EFSA-Q-2008-2008, EFSA-Q-2008-2009, EFSA-Q-2008-2168, adopted on 30 April 2010.

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considers that the food constituent, whole grain, which is the subject of this opinion is not sufficiently characterised in relation to the claimed effects considered in this opinion.

On the basis of the data presented, the Panel concludes that a cause and effect relationship cannot be established between the consumption of whole grain and the claimed effects considered in this opinion.

KEY WORDS

Whole grain, health claims.

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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

The approach used in the evaluation of Article 13(1) health claims is explained in the briefing document for stakeholders published by EFSA⁶.

In assessing each specific food/health relationship that forms the basis of a health claim the NDA Panel considers the extent to which:

1. the food/constituent is defined and characterised;
2. the claimed effect is defined and is a beneficial physiological effect (“beneficial to human health”);
3. a cause and effect relationship is established between the consumption of the food/constituent and the claimed effect (for the target group under the proposed conditions of use).

Substantiation of the claim is dependent on a favourable outcome of the assessment of 1, 2 and 3 above. Thus, a cause and effect relationship is considered not to be established if the outcome of any one of these assessments is unfavourable.

For a claim, each relationship between a food/constituent and a claimed effect is assessed separately and individual assessments are combined, as appropriate, to form coherent opinions.

Characterisation of the food/constituent (ID 831, 832, 833, 1126, 1268, 1269, 1270, 1271, 1431)

The food constituents that are the subject of this opinion are “whole grain”, “whole grain flour”, “whole grain foods”, and “diets rich in whole grain”, related to the following claimed effects: “gut health”/“bowel function”, “weight control”, “blood glucose”/“insulin levels”, “weight management”, “blood cholesterol”, “satiety”, “glycaemic index”, “digestive function” and “cardiovascular health”.

Whole grain has been defined as grains of the Gramineae family that “consist of the intact, ground, cracked or flaked caryopsis, whose principal anatomical components - the starchy endosperm, germ and bran - are present in the same relative proportions as they exist in the intact caryopsis” (AACC,

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>

⁶ See footnote 5

1999). Since then, several definitions of whole grains have been proposed, and no consensus has been reached at the European level. The same concept applies to diets rich in whole grain.

Whole grain foods (including whole grain flour) are defined differently across countries, also within the EU. In the UK (JHCI, 2002) and the USA (FDA, 1999) whole grain foods must contain ≥ 51 % whole grain ingredients by wet weight, whereas in Sweden and Denmark the requirement is ≥ 50 % whole grain ingredients on a dry matter basis (SNF, 2004; Mejborn et al., 2008). In Germany, whole grain bread must be 90 % whole grain (Deutsches Lebensmittelbuch, 1993).

Among the references submitted, five references reported on randomised controlled trials (RCTs) in humans addressing the effects of whole grain intake on body weight (Katcher et al., 2008; Saltzman et al., 2001; Melanson et al., 2006; Pereira et al., 2002; Jang et al., 2001). In the study by Katcher et al. (2008), a grain product was identified as “whole grain” if whole grain was listed as the first ingredient on the food label; Saltzman et al. (2001) used oatmeal as the intervention; in the study by Melanson et al. (2006), subjects in the whole grain group were asked to consume the fibre-rich whole grain cereals provided by the investigators, containing an average of 7.7 g, 6.7 g, and 1.0 g per serving of total, insoluble, and soluble fibre, respectively; in the study by Pereira et al. (2002) the whole grain multigrain group was advised to consume commercially available whole grain items containing bran, germ, and fibre, most of which were ground to flour; the intervention in the study by Jang et al. (2001) consisted of whole grains and legume powder containing 66.6 % whole grains, 22.2 % legumes, 5.6 % seeds, and 5.6 % vegetables, composed of brown rice (22.2 %), glutinous brown rice (11.1 %), barley (22.2 %), black beans (22.2 %), sesame (5.6 %), and Job’s tears (11.1 %). The Panel notes that each intervention study used a different definition of (and therefore a different intervention with) whole grain foods. On the other hand, several of the epidemiological studies provided have defined whole grain foods as those products with 25 % or more of whole grain or bran weight (Jacobs et al., 2001; Liu et al., 2000; Fung et al., 2002; McKeown et al., 2002).

Other references submitted in relation to these claims are general reviews and consensus opinions as well as observational and intervention studies on the effects of dietary fibre in general, of different types of dietary fibre (e.g. rye bran, wheat bran, oat bran, oat gum), or of whole grain using various definitions (e.g. 25 % or more of whole grain or bran by weight; whole grain derived from dark breads and high-fibre cooked cereals, etc.) on different health outcomes (e.g. faecal bulk, incidence of metabolic syndrome, type 2 diabetes, cardiovascular disease).

The Panel therefore considers that the food constituent, whole grain, which is the subject of this opinion is not sufficiently characterised in relation to the claimed effects considered in this opinion.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of whole grain and the claimed effects considered in this opinion.

CONCLUSIONS

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

- The food constituent, whole grain, that is the subject of this opinion is not sufficiently characterised in relation to the claimed effects considered in this opinion.
- A cause and effect relationship cannot be established between the consumption of whole grain and the claimed effects considered in this opinion.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1618, EFSA-Q-2008-1619, EFSA-Q-2008-1620, EFSA-Q-2008-1865, EFSA-Q-2008-2006, EFSA-Q-2008-

2007, EFSA-Q-2008-2008, EFSA-Q-2008-2009, EFSA-Q-2008-2168). 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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- Pereira MA, Jacobs DR, Jr., Pins JJ, Raatz SK, Gross MD, Slavin JL and Seaquist ER, 2002. Effect of whole grains on insulin sensitivity in overweight hyperinsulinemic adults. *American Journal of Clinical Nutrition*, 75, 848-855.
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improves lipid profile beyond effects of weight loss in men and women. *Journal of Nutrition*, 131, 1465-1470.

SNF (Swedish Nutrition Foundation), 2004. Health claims in the labelling and marketing of food products. The food sector's code of practice.

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 foods⁷ (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 FOOD⁸

Foods are commonly involved in many different functions⁹ 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.

⁷ OJ L12, 18/01/2007

⁸ The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

⁹ 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 whole grain, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
831	Wholegrain	Gut health <u>Clarifications provided</u> Promotes bowel function. Helps to maintain normal bowel function.	Promotes gut activity.
		Conditions of use - Bakery products with whole-grain content given as % of the cereal raw material. More than 50% of the cereal raw material must be whole-grain to present the claim (US FDA, Swedish SNF). Criterion: Fibre > 6%	
ID	Food or Food constituent	Health Relationship	Proposed wording
832	Wholegrain	Weight control	Helps with weight control. For a long-lasting sense of satiety. Releases energy slowly.
		Conditions of use - Bakery products with whole-grain content given as % of the cereal raw material. More than 50% of the cereal raw material must be whole-grain to present the claim (US FDA, Swedish SNF). Lean dough: Fat max 7g/100g Mono- and disaccharides max 10g/100g Sodium max (salt 1.3%) Lean dough (moisture max 15%): Fat max 7g/100g Mono- and disaccharides max 10g/100g Sodium max (salt 1.7%) Rich dough: Fat max 12g/100g Saturated fat max 4g/100g Mono- and disaccharides max 16g/100g	
ID	Food or Food constituent	Health Relationship	Proposed wording
833	Whole-grain	Carbohydrate metabolism and insulin sensitivity <u>Clarifications provided</u> Helps to balance blood glucose/insulin. Helps to maintain normal blood glucose/insulin levels.	Balances sugar metabolism.
		Conditions of use - Bakery products with whole-grain content given as % of the cereal raw material. More than 50% of the cereal raw material must be whole-grain to present the claim (US FDA, Swedish SNF).	
ID	Food or Food constituent	Health Relationship	Proposed wording
1126	Whole grain foods	Weight management	People who eat more whole grain foods tend to have a healthier body weight and gain less weight over time (as part of a low fat diet & healthy lifestyle).

<p>Conditions of use</p> <ul style="list-style-type: none"> - FDA: 'at least 3 servings of whole grain per day' - Flour and grain/granules: 100% wholegrain. Foods made of wholegrain mixed with other ingredients: whole grain > 51% of dry material. - Bakery products with wholegrain content given as % of the cereal raw material. More than 50% of the cereal raw material must be whole-grain to present the claim (US FDA, Swedish SNF). - 100g enthalten 14g Ballaststoffe 			
ID	Food or Food constituent	Health Relationship	Proposed wording
1268	Whole grain, whole grain flour	Whole grain products' impact on blood cholesterol level.	<p>Täisteratoodete tarbimine reguleerib vere kolesteroolitaset.</p> <p><u>Clarifications provided</u></p> <p>Consuming whole grain products regulates blood cholesterol level.</p>
	<p>Conditions of use</p> <ul style="list-style-type: none"> - Täistera või täisterajahu sisaldus tootes 50 g/100 g. 		
	<p>Comments from Member States</p> <p>Consuming whole grain products regulates blood cholesterol level.</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
1269	Whole grain, whole grain flour	Consumption of whole grain products increases satiety, prolongs satiety.	<p>Täisteratoodete tarbimine suurendab küllastustunnet ehk täiskõhutunnet. Täisteratoodete tarbimine pikendab küllastustunde ehk täiskõhutunde säilimist.</p> <p><u>Clarifications provided</u></p> <p>Consuming whole grain products increases satiety. Consuming whole grain products prolongs the feeling of satiety.</p>
	<p>Conditions of use</p> <ul style="list-style-type: none"> - Täistera või täisterajahu sisaldus tootes 50 g/100 g. 		
	<p>Comments from Member States</p> <p>Consuming whole grain products increases satiety. Consuming whole grain products prolongs the feeling of satiety.</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
1270	Whole grain, whole grain flour	Whole grain products' low glycaemic index.	<p>Täisteratooteid iseloomustab madal glükeemiline indeks.</p> <p><u>Clarifications provided</u></p> <p>Whole grain products are characterised by low glycaemic index.</p>
	<p>Conditions of use</p>		

	- Täistera või täisterajahu sisaldus tootes 50 g/100 g.		
	Comments from Member States Whole grain products are characterised by low glycaemic index.		
ID	Food or Food constituent	Health Relationship	Proposed wording
1271	Whole grain, whole grain flour	Consumption of whole grain products improves digestive function.	Täisteratoodete tarbimine soodustab seedimist. Täisteratoodete tarbimine aitab soodustada seedimist.
	Conditions of use - Täistera või täisterajahu sisaldus tootes 50 g/100 g.		
	Comments from Member States Consuming whole grain products promotes digestion, improves digestive function.		
ID	Food or Food constituent	Health Relationship	Proposed wording
1431	Diet rich in whole grain	Heart health <u>Clarifications provided</u> Contribute to cardiovascular/heart health (see also WHO Report 2003, cpt 5.4, table 10) (Diet including at least 3 portions a day of whole grain. One portion being at least 15g of whole grain). EFSA advice sought prior to final suggestion	-diets rich in whole grain foods promote heart health.
	Conditions of use - 3 portion per of whole grain food day		
	Comments from Member States WHO report 2003 was initially in the list of references, for unknown reason is not there anymore. Please consider this report too. EFSA advice is sought prior to final suggestion.		