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EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to arabinoxylan produced from wheat endosperm and reduction of post-prandial glycaemic responses (ID 830) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to arabinoxylan produced from wheat endosperm and reduction of post-prandial glycaemic responses (ID 830) 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 a health claim in relation to arabinoxylan produced from wheat endosperm and reduction of post-prandial glycaemic responses. 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 claim is “wheat grain fibre”. From the references and information provided, the Panel assumes that the food constituent that is responsible for the claimed effect is arabinoxylan from wheat endosperm. The Panel considers that arabinoxylan produced from wheat endosperm is sufficiently characterised in relation to the claimed effect.

The claimed effect is “carbohydrate metabolism and insulin sensitivity”. The target population is assumed to be individuals who wish to reduce their post-prandial glycaemic responses. The Panel considers that the reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) may be a beneficial physiological effect.

In weighing the evidence, the Panel took into account that one well-designed intervention study in healthy subjects showed a dose-response relationship between the intake of AX produced from wheat endosperm and reduction in post-prandial glycaemic and insulinaemic responses, that the results obtained in a longer term intervention study, which did not measure directly post-prandial glycaemic

¹ On request from the European Commission, Question No EFSA-Q-2008-1617, adopted on 25 March 2011.

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responses, were consistent with this finding, and that the mechanism by which AX produced from wheat endosperm could exert the claimed effect is well established.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of arabinoxylan produced from wheat endosperm and reduction of post-prandial glycaemic responses.

The Panel considers that in order to obtain the claimed effect, 8 g of arabinoxylan-rich fibre produced from wheat endosperm (at least 60 % arabinoxylan by weight) per 100 g of available carbohydrates should be consumed. The target population is individuals who wish to reduce their post-prandial glycaemic responses.

KEY WORDS

Arabinoxylan, fibre, post-prandial glycaemic responses, post-prandial insulinaemic responses, health claims.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

See Appendix A

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

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EFSA DISCLAIMER

See Appendix B

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 (ID 830)

The food constituent that is the subject of the health claim is “wheat grain fibre”.

From the references and information provided, the Panel assumes that the food constituent that is responsible for the claimed effect is arabinoxylan from wheat endosperm, which is a soluble and viscous fibre produced during the commercial processing of wheat flour.

Arabinoxylans are polysaccharides with a backbone of 1,4-linked xylose units with 2, 3, or 2,3-linked arabinose side chains, which can be found in many cereal grains and which may have different chemical properties depending on the source and the part of the grain used. Arabinoxylans also contain large amounts of ferulic acid and other phenolic compounds covalently linked to them.

Arabinoxylan (AX) represents 60-69 % of non-starch polysaccharides (NSPs) in wheat bran (mostly insoluble), and about 88 % of NSPs in wheat endosperm (more water soluble).

The Panel considers that the food constituent, arabinoxylan produced from wheat endosperm, which is the subject of the health claim, is sufficiently characterised in relation to the claimed effect.

2. Relevance of the claimed effect to human health (ID 830)

The claimed effect is “carbohydrate metabolism and insulin sensitivity”. The Panel assumes that the target population is individuals who wish to reduce their post-prandial glycaemic responses.

In the context of the proposed wordings, the references submitted and the clarifications provided by Member States, the Panel assumes that the claimed effect refers to the reduction of post-prandial glycaemic responses.

Post-prandial 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). Reducing post-prandial blood glucose responses may be beneficial to subjects with impaired glucose tolerance as long as

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 EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.

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

3. Scientific substantiation of the claimed effect (ID 830)

The references provided for the scientific substantiation of the claim included narrative reviews, observational and human intervention studies on various health effects of dietary fibre or cereal fibre in general, or on the effects of wheat fibre on health outcomes (e.g. bowel function and markers of inflammation) unrelated to the claimed effect. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Three intervention studies investigated the effects of AX consumption on post-prandial blood glucose and insulin responses (Lu et al., 2000; 2004; Möhlig et al., 2005).

In one sequential study by Möhlig et al. (2005), 15 volunteers (9 female) first consumed a control breakfast without AX. During the second visit, a breakfast with 6 g of AX-enriched fibre was administered. The Panel notes that the order of the intervention and control breakfasts was not randomised in this study, and that therefore the study was uncontrolled for time effects. The Panel considers that no conclusions can be drawn from this uncontrolled study for the scientific substantiation of the claim.

In the study by Lu et al. (2000), the effects of three breads containing 0, 6 or 12 g of AX-rich fibre (i.e. extracted from the by-products of wheat flour processing) on induced post-prandial glycaemic and insulinaemic responses were investigated in 14 subjects (9 female) with normal glucose tolerance using a randomised cross-over design. The breads were consumed in the context of a standard breakfast (10 g protein, 14 g fat) containing 75 g of available carbohydrates (50 g starch from bread, 25 g sugars from jam). All subjects received the three test breakfasts on a single occasion ≥ 3 days apart. The AX-rich fibre contained 70 % NSPs by weight, with a soluble:total NSP ratio of 0.62, an AX:total NSP ratio of 0.90 and an arabinose:xylose ratio of 0.60. Blood glucose and insulin concentrations were measured at baseline and 15, 30, 45, 60, 75, 90 and 120 min after each breakfast. A repeated-measures general linear model using time, meal type, and time and meal type interaction as within-subject factors was used to compare the effects of breakfast meals containing different amounts of AX-rich fibre at different time points over 2 h post-prandial. Differences in incremental areas under the curve (iAUCs) for glucose and insulin responses, as well as dose-response relationships, were also assessed. Fasting plasma glucose did not differ between the three interventions. Blood glucose concentrations peaked at 30 min after consumption of the meals, and peak post-prandial glucose concentrations after the meals containing 6 and 12 g of AX-rich fibre were significantly lower than after the control meal ($p < 0.01$ and $p < 0.001$, respectively). No significant differences were observed between meals containing 6 and 12 g of AX-rich fibre. Fasting plasma insulin did not differ between the three interventions and insulin concentrations peaked at 30 min after consumption of the three meals. Differences in blood insulin concentrations did not differ significantly between meals except for the 12 g of AX-rich fibre vs. the control meal at 45 min post-prandial ($p < 0.001$). The iAUC for glucose was significantly lower during the 6 g AX-rich fibre meal than during the control meal (-20.2 %, $p < 0.05$), and significantly lower during the 12 g AX-rich fibre meal than during the 6 g AX-rich fibre meal ($p < 0.05$) and the control meal (-41.4 %, $p < 0.01$). The iAUC for insulin was significantly lower during the 6 g AX-rich fibre meal (-17.0 %, $p < 0.05$) and that during the 12 g AX-rich fibre meal (-32.7 %, $p < 0.001$) than during the control meal. No significant differences were observed between the 6 g and the 12 g AX-rich fibre meals with respect to iAUC for insulin. A significant inverse relationship was observed between the amount of AX-rich fibre in meals and the mean iAUC for glucose ($r^2 = -0.989$, $p = 0.033$) and for insulin ($r^2 = -0.999$, $p = 0.008$). The Panel

notes that this study shows a dose-dependant effect of AX-rich fibre on the reduction of post-prandial glycaemic responses without disproportionately increasing post-prandial insulinaemic responses.

Lu et al. (2004) designed a randomised, single-blinded (subjects blinded), controlled cross-over study to assess the effects of an AX-rich fibre of the same characteristics as in the study by Lu et al. (2000) on blood glucose control in 15 subjects (9 women) with type II diabetes. Ten subjects were treated with diet only, five were on low-dose oral hypoglycaemic medications and none required insulin for blood glucose control. Two subjects were on lipid-lowering medications and nine on antihypertensive medications. No changes in medication use or dose were recorded during the study. Subjects consumed control muffins and bread (50 % whole wheat and 50 % white flour) and AX-rich muffins and bread (50 % whole wheat, 36 % white flour and 14 % AX-rich fibre) in the context of their usual diet for five weeks each with no wash-out period in between. The AX-rich foods provided 14-17 g of NSPs (of which 90 % was AX) daily compared to the control foods. Plasma glucose and insulin were assessed in fasting and at 2 hours after a 75 g oral glucose tolerance test (OGTT), both at baseline and after each study phase. Plasma concentrations of fructosamine as a surrogate marker of blood glucose control were also measured. Differences between the two arms of the cross-over design were evaluated using a General Linear Model (GLM) for cross-over designs. The sequence in which the intervention and control diets were administered had no effect on the outcome variables. Fasting plasma glucose concentrations were significantly lower after the AX-rich diet than after the control diet ($p < 0.05$). No significant differences between groups were observed with respect to fasting insulin concentrations. The 2 h glucose and insulin concentrations after the OGTT and after fructosamine concentrations were significantly lower after the AX-rich diet than after the control diet ($p < 0.001$, $p = 0.015$, and $p = 0.02$, respectively). *Post-hoc* power calculations using the data obtained in the study and $\alpha = 0.05$ indicated a power of 0.98 and 0.99 for fasting and 2 h glucose concentrations, respectively, but only of 0.57 for fructosamine. The Panel notes that although post-prandial glycaemic and insulinaemic responses following AX consumption were not measured directly in this study, the results are consistent with an effect of AX on the reduction of post-prandial glycaemic responses, as observed in the study by Lu et al. (2000).

The mechanism by which soluble fibres (including AX produced from wheat endosperm) could exert the claimed effect is well established, and relates to the increased viscosity of the meal bolus, which delays the rate of absorption of nutrients (including glucose) in the small intestine.

In weighing the evidence, the Panel took into account that one well-designed intervention study in healthy subjects showed a dose-response relationship between the intake of AX produced from wheat endosperm and reduction in post-prandial glycaemic and insulinaemic responses, that the results obtained in a longer term intervention study, which did not measure directly post-prandial glycaemic responses, were consistent with this finding, and that the mechanism by which AX produced from wheat endosperm could exert the claimed effect is well established.

The Panel concludes that a cause and effect relationship has been established between the consumption of arabinoxylan produced from wheat endosperm and reduction of post-prandial glycaemic responses.

4. Panel's comments on the proposed wording (ID 830)

The Panel considers that the following wording reflects the scientific evidence: "Consumption of arabinoxylan contributes to a reduction of the glucose rise after a meal".

5. Conditions and possible restrictions of use (ID 830)

The Panel considers that in order to obtain the claimed effect, 8 g of AX-rich fibre produced from wheat endosperm (at least 60 % AX by weight) per 100 g of available carbohydrates should be

consumed. The target population is individuals who wish to reduce their post-prandial glycaemic responses.

CONCLUSIONS

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

- The food constituent, arabinoxylan produced from wheat endosperm, which is the subject of the health claim, is sufficiently characterised in relation to the claimed effect.
- The claimed effect is “carbohydrate metabolism and insulin sensitivity”. The target population is assumed to be individuals who wish to reduce their post-prandial glycaemic responses. A 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 arabinoxylan produced from wheat endosperm and reduction of post-prandial glycaemic responses.
- The following wording reflects the scientific evidence: “Consumption of arabinoxylan contributes to a reduction of the glucose rise after a meal”.
- In order to obtain the claimed effect, 8 g of arabinoxylan-rich fibre produced from wheat endosperm (at least 60 % arabinoxylan by weight) per 100 g of available carbohydrates should be consumed. The target population is individuals who wish to reduce their post-prandial glycaemic responses.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1617). 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 arabinoxylan produced from wheat endosperm, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
830	Wheat grain fibre.	Carbohydrate metabolism and insulin sensitivity. <u>Clarification 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 ≥ 6 g/100g of wheat grain fibre.		
	Comments from Member States Health relationship defined.		

GLOSSARY AND ABBREVIATIONS

AX	Arabinoxylan
GLM	General linear model
iAUC	Incremental area under the curve
NSP	Non-starch polysaccharide
OGTT	Oral glucose tolerance test