

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to wheat bran fibre and increase in faecal bulk (ID 3066), reduction in intestinal transit time (ID 828, 839, 3067, 4699) and contribution to the maintenance or achievement of a normal body weight (ID 829) 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 in relation to wheat bran fibre and increase in faecal bulk, reduction in intestinal transit time and contribution to the maintenance or achievement of a normal body weight. 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 wheat bran fibre. The Panel considers that wheat bran fibre is sufficiently characterised.

Increase in faecal bulk

The claimed effect is “intestinal health: faecal bulking”. The target population is assumed to be the general population. The Panel considers that an increase in faecal bulk might be a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the majority of the human intervention studies showed a consistent effect of wheat bran fibre on faecal bulk and that no threshold dose for the effect can be established. A linear dose dependent relationship was demonstrated in several studies.

¹ On request from the European Commission, Question No EFSA-Q-2008-1626, EFSA-Q-2008-3798, EFSA-Q-2008-3799, adopted on 30 April 2010 and Question No EFSA-Q-2008-1615, EFSA-Q-2008-1616, EFSA-Q-2010-00652, adopted on 10 September 2010.

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On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of wheat bran fibre and an increase in faecal bulk.

The following wording reflects the scientific evidence: “Wheat bran fibre contributes to an increase in faecal bulk”.

The Panel considers that in order to bear the claim a food should be at least “high in fibre” as per Annex to Regulation (EC) No 1924/2006. The target population is the general population.

Reduction in intestinal transit time

The claimed effects are “gut health” and “intestinal transit time, intestinal health”. The target population is assumed to be the general population. In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect refers to a reduction in intestinal transit time. The Panel considers that a reduction in intestinal transit time within the normal range might be a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the studies provided consistently indicated that wheat bran fibre consumed at an amount of at least 10 g per day decreased intestinal transit time.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of wheat bran fibre and a reduction in intestinal transit time.

The following wording reflects the scientific evidence: “Wheat bran fibre contributes to a reduction in intestinal transit time”.

The Panel considers that in order to obtain the claimed effect at least 10 g per day of wheat bran fibre should be consumed in one or more servings. The target population is the general population.

Contribution to the maintenance or achievement of a normal body weight

The claimed effect is “weight control”. The target population is assumed to be the general population. The Panel considers that contribution to the maintenance or achievement of a normal body weight is a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of wheat bran fibre and contribution to the maintenance or achievement of a normal body weight.

KEY WORDS

Wheat bran fibre, intestinal transit time, faecal bulk, weight management, 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 claims is “wheat grain fibre”, “wheat bran and wheat bran products”, and “Triticum aestivum – wheat bran”. The Panel assumes that the active food constituent is wheat bran fibre.

Wheat bran fibre is a component of wheat bran, which consists of the outer coat (pericarp, testa and aleuron layer) of the wheat grain (*Triticum aestivum* L). Wheat bran is separated from the other parts of the wheat kernel by milling and the chemical composition of wheat bran varies with the extraction rate. Wheat bran is predominantly composed of non-starch polysaccharides (~38 %), starch (~19 %), protein (~18 %) and lignin (~6 %), with the non-starch polysaccharides being primarily ~70 % arabinoxylans, ~19 % cellulose and ~6 % β -(1,3)/ β -(1,4)-glucan. Wheat bran typically contains approximately 45 % of dietary fibre, of which about 95 % is non-soluble fibre (Cornell and Hoveling, 1998; Pomeranz, 1988). Wheat bran products may differ with regard to chemical composition and particle size depending on the milling process.

The Panel considers that the food constituent, wheat bran fibre, which is the subject of the health claims, is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Increase in faecal bulk (ID 3066)

The claimed effect is “intestinal health: faecal bulking”. The Panel assumes that the target population is the general population.

The Panel considers that an increase in faecal bulk might be a beneficial physiological effect.

2.2. Reduction in intestinal transit time (ID 828, 839, 3067, 4699)

The claimed effects are “gut health” and “intestinal transit time, intestinal health”. The Panel assumes that the target population is the general population.

In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect refers to a reduction in intestinal transit time.

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>

The Panel considers that a reduction in intestinal transit time within the normal range might be a beneficial physiological effect.

2.3. Contribution to the maintenance or achievement of a normal body weight (ID 829)

The claimed effect is “weight control”. The Panel assumes that the target population is the general population.

Weight management can be interpreted as the contribution to the maintenance of a normal body weight. In this context even a moderate weight loss in overweight subjects without achieving a normal body weight is considered to be a beneficial physiological effect.

The Panel considers that contribution to the maintenance or achievement of a normal body weight is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

Forty seven studies were cited for the scientific substantiation of two claimed effects: “increase in faecal bulk” and “reduction in intestinal transit time”.

Several studies were considered as not being pertinent for the scientific substantiation of the claimed effects evaluated in sections 3.1 and 3.2: a study with patients with severe constipation following spinal cord injury (Cameron et al., 1996), a study measuring the effect of wheat bran on faecal bile acid concentration (Alberts et al., 1996) and publications targeted for the general public (Medical News Today; Mindell, 1994). The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effects. The data from two references were identical (Fuchs et al., 1976; Floch and Fuchs, 1978) and were treated as one study. The text of the unpublished study was not available to the Panel (Dodi, unpublished).

3.1. Increase in faecal bulk (ID 3066)

The effect of wheat bran fibre on stool bulk was evaluated in 32 human intervention studies.

In 29 out of 32 studies, a statistically significant increase of wet and/or dry stool weight was found. In the remaining three studies statistically significant differences were also demonstrated but were limited to the higher doses of wheat bran fibre (Spiller et al., 1986) or coarse wheat bran (Smith et al., 1981; Wyman et al., 1976).

In several studies a dose dependent effect of wheat bran on faecal bulk was demonstrated. Jenkins et al. (1987) estimated that 1 g of wheat bran produced a mean increase of 2.7 g in faecal weight and Cummings calculated that 1 g of dietary fibre from wheat bran increased stool weight by about 5.3 g (SEM±0.7g) (Cummings, 1976). Chen et al. (1998) found an increase in mean wet stool weight of 4.5 g for each additional gram of wheat fibre consumed, while Stephen et al. (1986) calculated that 1 g of non-starch polysaccharides (the main component of dietary fibre) from wheat bran increased stool weight by 5 g/day. The effect is independent of the initial daily faecal weight.

The results of a meta-analysis of 20 studies also showed that wheat bran fibre increased stool weight (Muller-Lissner, 1988), and this effect is also supported by an animal study (Kahlon et al., 2001).

The insoluble components of fibre are minimally degraded by colonic bacteria, and thus remain to trap water, thereby increasing faecal bulk (Graham et al., 1982).

In weighing the evidence, the Panel considered that the majority of the human intervention studies showed a consistent effect of wheat bran fibre on faecal bulk, and that no threshold dose for the effect can be established. A linear dose dependent relationship was demonstrated in several studies.

The Panel concludes that a cause and effect relationship has been established between the consumption of wheat bran fibre and an increase in faecal bulk.

3.2. Reduction in intestinal transit time (ID 828, 839, 3067, 4699)

In 23 human intervention studies the effect of wheat bran fibre on intestinal transit time was evaluated.

The studies differed by design (randomised controlled trials, single or double-blind, cross-over design, non-randomised). Different doses of wheat bran fibre were used and the dose used was expressed in different ways (e.g. dose of wheat bran, dose of fibre given or administered, portion of food enriched by wheat bran); different methods were used to assess transit time (several radio-opaque markers and scintigraphic methods) and different methods were applied to calculate the results (e.g. mean transit time, time needed to pass 50 %, 75 % or 80 % of pellets, number of pellets in first two stools passed at least 24 h after ingestion of the marker, percent of pellets in faeces within three days after marker intake). Taking into account the different designs of the studies presented, it is not possible to compare all of these results directly.

From the 23 studies provided, the results of 14 studies (with the dose of wheat bran fibre from 4 to 27 g daily) demonstrated a statistically significant decrease of intestinal transit time (Arffmann et al., 1985; Badiali et al., 1995; Cummings et al., 1976; Graham et al., 1982; Lampe et al., 1993; Lewis and Heaton, 1997; Melcher et al., 1991; Mortensen et al., 1987; Muir et al., 2004; Rees et al., 2005; Spiller et al., 1986; Stephen et al., 1986; Stevens et al., 1988; Tomlin and Read, 1988). In three studies, administration of wheat bran (with the dose of fibre from 6 to 8 g daily) did not significantly affect transit time (Eastwood et al., 1973, 1983; Vincent et al., 1995). The remaining six studies measured multiple endpoints and their results were not consistent (Ziegenhagen et al., 1991; Balasubramanian et al., 1987; Hebden et al., 2002; Wrick et al., 1983; Wyman et al., 1976; Smith et al., 1981).

A meta-analysis of 20 cross-over studies (with wheat bran fibre 5–18 g/day) demonstrated an effect of wheat bran fibre on decreasing intestinal transit time but the dose effect was not assessed (Muller-Lissner, 1988).

The amount of at least 10 g/day of wheat bran fibre was connected with a statistically significant decrease in intestinal transit time in 14 out of 16 studies submitted. In another two studies, only some of the methods used for assessing intestinal transit time showed an effect (Wrick et al. 1983; Ziegenhagen et al., 1991).

The results of nine studies in which wheat bran fibre was used at the daily dose of 4-9.9 g revealed inconsistent results. In four studies a decrease in intestinal transit time was found (Spiller et al., 1986; Muir et al., 2004; Rees et al., 2005; Graham et al. 1982) while in another three studies, no effect on transit time could be demonstrated (Eastwood et al., 1973, 1983; Vincent et al., 1995). In the remaining two studies, intestinal transit time was measured by several methods and only the results of part of the measurements showed a statistically significant effect (Wyman et al., 1976; Smith et al., 1981).

The Panel notes the dose-dependency of the results and that trials with daily doses of wheat bran fibre below 10 g resulted in inconsistent outcomes.

Wheat bran fibre increases water holding capacity of the content of the intestine, increases intestinal and pancreatic fluid secretion and thus increases the velocity of chyme displacement through the intestine (Jenkins et al., 1987).

In weighing the evidence, the Panel took into account that the studies provided consistently indicated that wheat bran fibre consumed at an amount of at least 10 g/day decreased intestinal transit time.

The Panel concludes that a cause and effect relationship has been established between the consumption of wheat bran fibre and a reduction in intestinal transit time.

3.3. Contribution to the maintenance or achievement of a normal body weight (ID 829)

None of the references provided for the scientific substantiation of the claimed effect addressed the effect of consumption of wheat bran fibre on maintenance or achievement of a normal body weight.

One human study submitted for the scientific substantiation of another claim evaluated in this opinion (ID 828) dealt with the effect of a formula diet providing 692 kcal per day, consisting of 50.7 g of protein, 13.6 g of fat and 91.3 g of carbohydrates, and containing 14.3 g of wheat bran and 3 g of apple pectin, on the reduction of body weight in eight obese subjects (Matzkies et al., 1982). The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of wheat bran fibre and contribution to the maintenance or achievement of a normal body weight.

4. Panel's comments on the proposed wording

4.1. Increase in faecal bulk (ID 3066)

The Panel considers that the following wording reflects the scientific evidence: "Wheat bran fibre contributes to an increase in faecal bulk".

4.2. Reduction in intestinal transit time (ID 828, 839, 3067, 4699)

The Panel considers that the following wording reflects the scientific evidence: "Wheat bran fibre contributes to a reduction in intestinal transit time".

5. Conditions and possible restrictions of use

5.1. Increase in faecal bulk (ID 3066)

The Panel considers that in order to bear the claim a food should be at least "high in fibre" as per Annex to Regulation (EC) No 1924/2006. The target population is the general population.

5.2. Reduction in intestinal transit time (ID 828, 839, 3067, 4699)

The Panel considers that in order to obtain the claimed effect at least 10 g per day of wheat bran fibre should be consumed in one or more servings. The target population is the general population.

CONCLUSIONS

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

- The food constituent, wheat bran fibre, which is the subject of the health claims, is sufficiently characterised.

Increase in faecal bulk (ID 3066)

- The claimed effect is "intestinal health: faecal bulking". The target population is assumed to be the general population. An increase in faecal bulk might be a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of wheat bran fibre and an increase in faecal bulk.

- The following wording reflects the scientific evidence: “Wheat bran fibre contributes to an increase in faecal bulk”.
- In order to bear the claim a food should be at least “high in fibre” as per Annex to Regulation (EC) No 1924/2006. The target population is the general population.

Reduction in intestinal transit time (ID 828, 839, 3067, 4699)

- The claimed effects are “gut health” and “intestinal transit time, intestinal health”. The target population is assumed to be the general population. A reduction in intestinal transit time within the normal range might be a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of wheat bran fibre and a reduction in intestinal transit time.
- The following wording reflects the scientific evidence: “Wheat bran fibre contributes to a reduction in intestinal transit time”.
- In order to obtain the claimed effect at least 10 g per day of wheat bran fibre should be consumed in one or more servings. The target population is the general population.

Contribution to the maintenance or achievement of a normal body weight (ID 829)

- The claimed effect is “weight control”. The target population is assumed to be the general population. Contribution to the maintenance or achievement of a normal body weight is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of wheat bran fibre and contribution to the maintenance or achievement of a normal body weight.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1626, EFSA-Q-2008-3798, EFSA-Q-2008-3799, EFSA-Q-2008-1615, EFSA-Q-2008-1616, EFSA-Q-2010-00652). 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.

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

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).

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 wheat bran fibre, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
828	Wheat grain fibre	Gut health. <u>Clarification provided</u> Promotes bowel function. Helps to maintain normal bowel function.	Promotes gut activity
ID	Food or Food constituent	Health Relationship	Proposed wording
829	Wheat grain fibre	Weight control <u>Clarification provided</u> Weight management	Helps with weight control
ID	Food or Food constituent	Health Relationship	Proposed wording
839	Wheat Bran and Wheat Bran Enriched Foods	Intestinal transit time; Intestinal health	Regular consumption of wheat bran significantly reduces intestinal transit time. Wheat bran promotes intestinal health by significantly decreasing intestinal transit time.
ID	Food or Food constituent	Health Relationship	Proposed wording
3066	Wheat Bran and Wheat Bran Enriched Foods	Faecal bulking; intestinal health	Regular wheat bran consumption significantly increases faecal bulk. Wheat bran promotes intestinal health by significantly increasing faecal bulk.
ID	Food or Food constituent	Health Relationship	Proposed wording
3067	Wheat Bran and Wheat Bran Enriched Foods	Intestinal transit time; Intestinal health	Regular consumption of wheat bran significantly reduces intestinal transit time.

			Wheat bran promotes intestinal health by significantly decreasing intestinal transit time.
Conditions of use <ul style="list-style-type: none"> - Contains at least 25g wheat bran per portion. - 9g dietary fibre from wheat bran per portion compliance measure. 			
ID	Food or Food constituent	Health Relationship	Proposed wording
4699	Triticum sativum – wheat bran – wheat	Large intestine health	Are useful in cases of low dietary fibre content and slow intestinal transit
		<u>Clarification provided</u> Bowel function	
Conditions of use <ul style="list-style-type: none"> - Tablets: 6 tablets, 3 times a day before the main meals / equivalent of 1.26g of insoluble dietary fibres. Granules: one single dose little bag a day/ equivalent of 2.11g of insoluble dietary fibres. 			