

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to activated charcoal and reduction of excessive intestinal gas accumulation (ID 1938) and reduction of bloating (ID 1938) 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 activated charcoal and the reduction of excessive intestinal gas accumulation and reduction of bloating. 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 activated charcoal. The Panel considers that activated charcoal is sufficiently characterised in relation to the claimed effect.

Reduction of excessive intestinal gas accumulation

The claimed effect is “gastrointestinal 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 reducing excessive intestinal gas accumulation. The Panel considers that reduction of excessive intestinal gas accumulation is a beneficial physiological effect.

In weighing the evidence, the Panel took into account the results of three human intervention studies, which consistently showed an effect of activated charcoal on decreasing the amount of intestinal gas accumulation. The studies showed the effectiveness of activated charcoal with different methods (e.g. hydrogen breath test and numbers of flatus events) and in different populations (US and India).

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The Panel also notes the plausibility of the mechanism of action by which activated charcoal could exert the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between consumption of activated charcoal and reduction of excessive intestinal gas accumulation.

The Panel considers that, in order to obtain the claimed effect, the intake of activated charcoal should be 1 g at least 30 minutes before consumption of a meal and 1 g after the meal.

Reduction of bloating

The claimed effect is “gastrointestinal 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 reducing bloating. The Panel considers that reduction of bloating 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 consumption of activated charcoal and reduction of bloating.

KEY WORDS

Activated charcoal, intestinal gas, bloating, 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 activated charcoal.

Charcoal is a type of carbon made from wood, vegetables and other materials which have been exposed to very high temperatures in an airless environment. Activated charcoal is usually derived from charcoal, which is then specially processed by reheating with oxidising gas or other chemicals, in order to increase its degree of micro-porosity and surface area. The processing results in a highly porous charcoal. The tiny holes can give the charcoal a surface area of up to 1500 m²/g, allowing liquids or gases to pass through the charcoal and interact with the exposed carbon. Several factors may influence the properties/effectiveness of activated charcoal. Pore size and distribution varies depending on the source of the carbon and the manufacturing process.

Different types of activated charcoals are available on the market with various purported properties and a wide range of reported applications (e.g. industrial use and medical use, including over-the-counter products). For over-the-counter products, activated charcoal is available in different forms, e.g. in liquid, powder or granulated form, in tablets, capsules, or biscuits.

The Panel considers that the food constituent, activated charcoal, which is the subject of the health claims, is sufficiently characterised in relation to the claimed effects.

2. Relevance of the claimed effect to human health

2.1. Reduction of excessive intestinal gas accumulation (ID 1938)

The claimed effect is “gastrointestinal 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 reducing excessive intestinal gas accumulation.

Excessive intestinal gas accumulation may cause abdominal pain and discomfort.

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 reduction of excessive intestinal gas accumulation is a beneficial physiological effect.

2.2. Reduction of bloating (ID 1938)

The claimed effect is “gastrointestinal 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 reducing bloating. Bloating may cause abdominal pain and discomfort.

The Panel considers that reduction of bloating is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

3.1. Reduction of excessive intestinal gas accumulation (ID 1938)

The references provided for the scientific substantiation of the claim included review articles, a textbook and a case series study on the acceptability of activated charcoal for home use. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

Three human intervention studies, which addressed outcomes related to the claimed effect (Hall et al., 1981; Jain et al., 1986a; 1986b), were cited. In these studies, capsules of activated charcoal were used (194 mg or 260 mg/capsule).

In a double-blind randomised trial (Jain et al., 1986a) in two healthy population groups in the United States (n=30; 20 males, 10 females) and India (n=69; 62 males, 7 females) in which lactulose was used as the substrate for fermentation, breath hydrogen levels were measured (at 30 min intervals for 4 h 30 min) to quantify the amount of gas produced in the colon. Each subject was tested with identical capsules of a non-carbohydrate (gelatine) placebo or activated charcoal (260 mg/capsule) on two days. Subjects fasted (except for water *ad libitum*) for 10 hours before being tested, and abstained from smoking for two hours before and during the test. After collecting the first (fasting) breath sample, four coded capsules were given to each subject and the same dose repeated one hour later. Lactulose (15 mL) was given half an hour after the first dose of capsules. Symptoms of bloating, abdominal cramps and diarrhoea experienced by the volunteers during and for four hours after collection of the last breath sample were recorded. The study was repeated one week later with the second set of coded capsules; those who received placebo the first time were given activated charcoal subsequently. Non-lactulose fermenting subjects (i.e. in whom lactulose ingestion did not produce a rise in breath hydrogen) were excluded from data analysis (remaining sample: 28 in the United States and 62 in India). In comparison to a placebo, activated charcoal significantly ($p < 0.05$) reduced breath hydrogen in both population groups. In relation to subjective outcome measures, the Panel notes that no evidence was provided that the questionnaire used to score bloating and abdominal cramps was validated.

In a double-blind, randomised study by Jain et al. (1986b) ten healthy adults (mean age: 28.3 years; 7 men, 3 women) were tested with identical-looking capsules of a non-carbohydrate placebo, activated charcoal (260 mg/capsule) and simethicone (20 mg/capsule). On each test day 20 mL end-expiratory fasting breath samples were collected from each subject. Four coded capsules were then given to each volunteer and the same dose repeated one hour later. Thirty minutes after the first dose, subjects consumed baked beans. Serial breath samples were subsequently collected at 30 minute intervals for seven hours. Symptoms of bloating and abdominal discomfort were recorded using a questionnaire.

One subject did not produce hydrogen (H_2), thus the results of only nine subjects were analysed. Compared to placebo, activated charcoal significantly reduced peak breath hydrogen levels ($p=0.002$) and the mean (0-7 hours) area under the curve ($p<0.003$). These effects were observed between 2.5 and 3 hours, and between 4.5 and 6.5 hours, after charcoal ingestion. Symptom scores of bloating and gastrointestinal discomfort were recorded, but the Panel notes that no information about the validation of the questionnaire used to score symptoms of bloating and abdominal discomfort was given.

In a double-blind, placebo-controlled trial, Hall et al. (1981) analysed the effect of activated charcoal in decreasing the amount of intestinal gas following a gas-producing meal among healthy subjects (age 18-40 years). Subjects were assigned either a “normal” meal (selected by the subjects and containing no known “gas forming” items: no further information was given) or a “bean” meal (i.e. cooked beans, two slices of white bread toast, orange juice and sliced peaches: containing approximately 144 g of carbohydrate, 25 g protein, 18 g fat and 770 calories). The breath hydrogen levels and number of flatus events were measured in two separate studies. Thirteen subjects consumed a “bean” meal on two separate occasions, with a period of at least two days between meals. Subjects were given either six capsules of activated charcoal (194 mg/capsule) or placebo (identical-appearing starch filled capsule); three capsules were administered immediately after the meal and three capsules two hours after the meal. Additionally, seven subjects were administered two capsules of activated charcoal only two hours after the meal. Subjects were asked to keep an accurate record on a time chart of the number of flatus passed each hour following the meal for the next seven hours; all subjects were asked not to eat lunch or have any snacks during this period. Baseline data on flatus events were recorded after consumption of the “normal” meal in 13 subjects. In a separate study, breath hydrogen concentrations were measured in ten subjects, who were assigned to either a “normal” meal or a “bean” meal. Subjects who were assigned to the bean meal were supplemented with either charcoal or placebo capsules. Each subject consumed three capsules immediately after the meal followed by three capsules every 30 minutes during the following two hours (15 capsules in total). The seven subjects who were given two capsules of activated charcoal two hours after the meal suffered more flatus events during the first three hours than those receiving three capsules immediately after the meal and additional three capsules two hours later ($p<0.05$). This difference was not observed during the remaining four hours of observation. Overall, results from this study showed that orally administered activated charcoal capsules were effective in preventing the increase in the number of flatus events ($p<0.01$), and the increase in breath hydrogen concentrations ($p<0.001$), which normally occur after consumption of a gas-producing meal when compared with placebo capsules. The Panel notes the lack of information on the method used for the statistical analysis of the results.

The Panel also notes the plausibility of the mechanism of action (adsorption of gas accumulated in the colon) by which activated charcoal could exert the effect.

In weighing the evidence, the Panel took into account the results of three human intervention studies, which consistently showed an effect of activated charcoal on decreasing the amount of intestinal gas accumulation. The studies showed the effectiveness of activated charcoal with different methods (e.g. hydrogen breath test and numbers of flatus events) and in different populations (US and India). The Panel also notes the plausibility of the mechanism of action by which activated charcoal could exert the claimed effect.

The Panel concludes that a cause and effect relationship has been established between consumption of activated charcoal and reduction of excessive intestinal gas accumulation.

3.2. Reduction of bloating (ID 1938)

All the references provided in relation to this claim have already been described in section 3.1.

In two of the references provided the effect of consumption of activated charcoal on symptom scores of bloating and gastrointestinal discomfort (Jain et al., 1986a; Jain et al., 1986b) was reported. The Panel notes that no evidence was provided on whether the questionnaire used to score subjective symptoms (bloating and abdominal cramps) was validated, and considers that no conclusions can be drawn from the studies presented for the scientific substantiation of the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between consumption of activated charcoal and reduction of bloating.

4. Panel's comments on the proposed wording

4.1. Reduction of excessive intestinal gas accumulation (ID 1938)

The Panel considers that the following wording reflects the scientific evidence: "Activated charcoal contributes to the reduction of excessive intestinal gas accumulation".

5. Conditions and possible restrictions of use

5.1. Reduction of excessive intestinal gas accumulation (ID 1938)

The Panel considers that, in order to obtain the claimed effect, the intake of activated charcoal should be 1 g at least 30 minutes before consumption of a meal and 1 g after the meal.

CONCLUSIONS

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

- The food constituent, activated charcoal, which is the subject of the health claim, is sufficiently characterised in relation to the claimed effect.

Reduction of excessive intestinal gas accumulation (ID 1938)

- The claimed effect is "gastrointestinal health". The target population is assumed to be the general population. In the context of the clarifications provided by Member States, it is assumed that the claimed effect refers to reducing excessive intestinal gas accumulation. Reduction of excessive intestinal gas accumulation is a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of activated charcoal and reduction of excessive intestinal gas accumulation.
- The following wording reflects the scientific evidence: "Activated charcoal contributes to the reduction of excessive intestinal gas accumulation".
- In order to obtain the claimed effect, the intake of activated charcoal should be 1 g at least 30 minutes before consumption of a meal and 1 g after the meal.

Reduction of bloating (ID 1938)

- The claimed effect is "gastrointestinal health". The target population is assumed to be the general population. In the context of the clarifications provided by Member States, it is

assumed that the claimed effect refers to reducing bloating. Reduction of bloating is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of activated charcoal and reduction of bloating.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-2671). 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>.

REFERENCES

- Hall RG, Jr., Thompson H and Strother A, 1981. Effects of orally administered activated charcoal on intestinal gas. *American Journal of Gastroenterology*, 75, 192-196.
- Jain NK, Patel VP and Pitchumoni CS, 1986a. Efficacy of activated charcoal in reducing intestinal gas: a double-blind clinical trial. *American Journal of Gastroenterology*, 81, 532-535.
- Jain NK, Patel VP and Pitchumoni S, 1986b. Activated charcoal, simethicone, and intestinal gas: a double-blind study. *Annals of Internal Medicine*, 105, 61-62.

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 activated charcoal, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
1938	Activated charcoal	Gastro-intestinal health <u>Clarification provided</u> Reduce importance of gases from intestinal fermentations. Relax the gastrointestinal tract. Reduce bloating	Traditionally used to contribute to good digestive comfort Usually known for its contribution to good digestive
Conditions of use <ul style="list-style-type: none"> - Powder Equivalent of 400 mg of drug daily - Consommation dans le cadre d'une alimentation normale/1,8g/jour 			