



EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to acetic acid and maintenance of normal blood pressure (ID 1447) 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 acetic acid and maintenance of normal blood pressure (ID 1447) 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 acetic acid and maintenance of normal blood pressure. 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 that is the subject of the health claim is apple vinegar drink. From the references provided for the scientific substantiation of the claim, the Panel assumes that the food constituent which is responsible for the claimed effect is acetic acid. The Panel considers that acetic acid is sufficiently characterised.

The claimed effect is “helps maintain vascular 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 the maintenance of normal blood pressure. The Panel considers that maintenance of normal blood pressure is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that although one animal study showed an effect of acetic acid administration on systolic blood pressure, results from two human intervention studies are conflicting, and that a sustained effect of orally administered acetic acid on blood pressure is unlikely because of its rapid absorption and clearance from the circulation after consumption.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of acetic acid and maintenance of normal blood pressure.

¹ On request from the European Commission, Question No EFSA-Q-2008-2184, adopted on 08 April 2011.

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KEY WORDS

Acetic acid, blood pressure, health claims.

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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 (ID 1447)

The food that is the subject of the health claim is apple vinegar drink.

From the references provided for the scientific substantiation of the claim, the Panel assumes that the food constituent which is responsible for the claimed effect is acetic acid. Acetic acid is an organic acid produced by bacterial fermentation in the manufacturing of vinegar. Acetic acid can be measured in foods and drinks by established methods.

The Panel considers that the food constituent, acetic acid, which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health (ID 1447)

The claimed effect is “helps maintain vascular 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 the maintenance of normal blood pressure.

Blood pressure is the pressure (force per unit area) exerted by circulating blood on the walls of blood vessels. Elevated blood pressure, by convention above 140 mmHg (systolic) and/or 90 mmHg (diastolic), may compromise the normal arterial and cardiac function.

The Panel considers that maintenance of normal blood pressure is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect (ID 1447)

The references provided for the scientific substantiation of the claim included two links to web pages in Japanese, one article in Japanese reporting on a human intervention study on the effects of a drink containing vinegar on blood pressure, which could not be retrieved and for which no translation into an EU language was provided, and narrative reviews which were either not related to the claimed

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.

effect or did not contain any original data which could be used for the scientific substantiation of the claim. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

One article in Japanese with a full-text English translation was provided which reported on a human intervention study on the effects of apple and rice vinegar drinks on blood pressure (Kajimoto et al., 2003). A total of 104 adult subjects with high normal blood pressure or grade I hypertension (systolic blood pressure (SBP) between 130 and 159 mmHg, diastolic blood pressure (DBP) between 85 and 99 mmHg) were recruited. Need of emergency antihypertensive therapy, cerebrovascular disorders, history of cardiac failure, atrial fibrillation or serious arrhythmia, severe liver or kidney dysfunction, and uncontrolled diabetes were among the exclusion criteria. Medication use among participants, including the use of antihypertensive medications, was not reported. Six subjects were excluded from data analysis because of severe renal dysfunction (one), out of range blood pressure (one) and inability to start the trial due to personal reasons (four). After a two-week run-in period, subjects were randomised to consume 100 mL of a drink containing 15 g of apple vinegar (n=33, 17 female) or rice vinegar (n=34, 17 female) with acetic acid (750 mg) at a concentration of 5 % (w/v), or 100 mL of a placebo drink containing 1 g of lactic acid (n=31, 16 female) for 10 weeks, followed by a four-week observation period with no drinks. The test and placebo drinks were otherwise comparable regarding their macronutrient composition and their content of potassium, sodium, calcium and vitamin C, and subjects were not able to distinguish them on the basis of their organoleptic properties. Office blood pressure was measured after an overnight fast using a standard protocol. Data were analysed for the whole study population, and separately for subjects with high normal blood pressure and grade I hypertension. The Panel notes that it is not stated in the publication whether sub-group comparisons were pre-planned, and considers that no conclusions can be drawn from these analyses for the scientific substantiation of the claim. SBP significantly decreased in the apple and rice vinegar groups compared to placebo at weeks 2 (-6.6 mmHg and -7.6 mmHg vs. +1.0 mmHg, respectively, $p < 0.05$), 6 (-12.8 mmHg and -11.6 mmHg vs. -3 mmHg, respectively, $p < 0.01$), 8 (-11.2 mmHg and -12.9 mmHg vs. -2.2 mmHg, respectively, $p < 0.01$) and 10 of the study (-12.0 mmHg and -9.6 mmHg vs. -2.3 mmHg, $p < 0.01$ and $p < 0.05$, respectively), whereas no significant differences were observed between groups at week 4 of the study. No interaction between test drinks and intake duration on blood pressure values was observed. Follow-up values were not significantly different from baseline in any of the groups. No significant differences between the apple and the rice vinegar groups were observed at any time point. No significant differences in DBP, heart rate, body weight or body composition were observed between the three groups throughout the study.

Another human intervention study retrieved by the Panel reported on the effects on blood pressure of apple vinegar drinks containing different amounts of acetic acid (Kondo et al., 2009). After a three-week run-in period, a total of 155 adult overweight subjects (out of 175 recruited), who were not using medications, were randomised to consume 500 mL of a placebo drink containing 1,250 mg lactate (n=50, 18 female), or 500 mL of a drink containing 15 mL (n=54, 20 female) or 30 mL (n=51, 20 female) of apple vinegar daily for 10 weeks, followed by a four-week observation period with no test or placebo drinks. The acetic acid content of the drinks was 0, 750 and 1,500 mg, respectively. The test and placebo drinks were otherwise comparable regarding their macronutrient composition and their content of potassium, sodium, calcium and vitamin C, and subjects were not able to distinguish them on the basis of their organoleptic properties. Office blood pressure was measured after an overnight fast using a standard protocol. Compared to placebo SBP significantly decreased in the apple vinegar group containing 1,500 mg acetic acid at week 12 only (-4.5 mmHg vs. +0.1 mmHg, $p < 0.01$). No other significant differences on blood pressure were observed between the three groups for the entire duration of the study. The Panel notes that differences in body weight changes during the study between the high acetic acid dose group and the placebo group (reported to be about -3 kg) could account for the significant differences in SBP values observed at week 12 of the study. The Panel also notes that the results from this study are in conflict with those obtained by Kajimoto et al.

(2003), who reported a significant effect (of about -10mmHg) on SBP with 750 mg/day of acetic acid, with effects that were already statistically significant after two weeks of consumption.

One study on spontaneously hypertensive rats (SHR) was also provided (Kondo et al., 2001). Four-week old (n=18) SHR were randomised to consume standard laboratory diets with a 6.0 % solution (w/w) of either acetic acid (containing 46.2 g/L acetic acid), vinegar (containing 46.2 g/L acetic acid) or no solution (control) for eight weeks after a six-week run-in period in which only the standard diet was consumed. No significant differences in body weight, water consumption or food intake were observed between groups. SBP ($p<0.05$) and plasma renin activity ($p<0.01$) significantly decreased in the acetic acid and vinegar groups compared to placebo, whereas no significant differences were observed in angiotensin I-converting enzyme activity in various organs, or in plasma angiotensin II. Plasma aldosterone concentrations significantly decreased in the vinegar group compared to the acetic acid group and the control group ($p<0.05$). No significant differences between the acetic acid and the vinegar groups were observed during the study with respect to SBP values. It was hypothesised that acetic acid could exert the claimed effect by reducing renin secretion, and by inducing a subsequent decrease in angiotensin II. The Panel notes that this study does not provide clear evidence on a mechanism by which acetic acid could exert the claimed effect.

A recently published randomised, cross-over, human intervention study retrieved by the Panel (Sugiyama et al., 2010), addressed the bioavailability of acetate from two vinegar supplements (as capsules or drinks) compared to water as reference in 30 healthy Japanese subjects. The vinegar drink (100 mL containing 750 mg acetic acid) and water control were consumed after an overnight fast. Serum acetate concentrations increased immediately after intake of the vinegar drink, peaked at 15 min and returned to baseline at 90 min. No significant changes in serum acetate concentrations were observed after the water control. The Panel notes that acetic acid in the vinegar drink at the dose used in the human intervention study by Kajimoto et al. (2003) was rapidly absorbed and cleared from the circulation after consumption, and thus the Panel considers that an effect of orally administered acetic acid on blood pressure lasting 12 hours or more (e.g. after an overnight fast) is unlikely.

In weighing the evidence, the Panel took into account that although one animal study showed an effect of acetic acid administration on systolic blood pressure, results from two human intervention studies are conflicting, and that a sustained effect of orally administered acetic acid on blood pressure is unlikely because of the rapid absorption and clearance from the circulation after consumption.

The Panel concludes that a cause and effect relationship has not been established between the consumption of acetic acid and maintenance of normal blood pressure.

CONCLUSIONS

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

- The food constituent, acetic acid, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect is “helps maintain vascular 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 the maintenance of normal blood pressure. Maintenance of normal blood pressure is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of acetic acid and maintenance of normal blood pressure.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-2184). 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

- Kajimoto O, Ohshima Y, Tayama K, Hirata H, Nishimura A and Tsukamoto Y, 2003. Hypotensive effects of drinks containing vinegar on high normal blood pressure and mild hypertensive subjects. *Kenko Eiyo Shokuhin Kenkyu (Journal of Nutritional Food)*, 6, 51-68.
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- Sugiyama S, Fushimi T, Kishi M, Irie S, Tsuji S, Hosokawa N and Kaga T, 2010. Bioavailability of acetate from two vinegar supplements: capsule and drink. *Journal of Nutritional Science and Vitaminology*, 56, 266-269.

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 acetic acid, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
1447	Apple vinegar drink.	<p>Helps maintain vascular health.</p> <p><u>Clarification provided</u></p> <p>Apple vinegar helps to maintain a healthy blood pressure.</p>	Apple vinegar drink helps to maintain vascular health.
<p>Conditions of use</p> <ul style="list-style-type: none"> - The product should contain 15ml Apple vinegar with acidity of 5% w/v per serving. It is not advisable to take this product on an empty stomach, as irritation might be felt. 			

GLOSSARY AND ABBREVIATIONS

DBP	Diastolic blood pressure
SBP	Systolic blood pressure
SHR	Spontaneously hypertensive rats