

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to fructose and reduction of post-prandial glycaemic responses (ID 558) 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 fructose and reduction of post-prandial glycaemic responses. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claim is fructose. From the information provided, the Panel assumes that fructose should replace sucrose or glucose in foods or beverages in order to obtain the claimed effect. The Panel considers that fructose, and the food constituents which fructose should replace in foods or beverages in order to obtain the claimed effect, sucrose and glucose, are sufficiently characterised.

The claimed effect is “carbohydrate metabolism and insulin sensitivity”. The Panel assumes that the target population is individuals who wish to reduce their post-prandial glycaemic responses. In the context of the proposed wordings and the references provided, the Panel assumes that the claimed effect refers to the reduction of post-prandial glycaemic responses. The Panel considers that reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionately increased) may be a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the few intervention studies in healthy and type 2 diabetic subjects provided showed a consistent significant reduction in post-prandial glycaemic

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responses, without disproportionately increasing post-prandial insulinaemic responses, following fructose consumption in foods or beverages compared with sucrose and glucose, and that the mechanism by which fructose (in place of sucrose or glucose) in food or beverages could exert the claimed effect is well established.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of fructose in place of sucrose or glucose in foods or beverages and reduction of post-prandial glycaemic responses.

The Panel considers that in order to bear the claim, glucose or sucrose should be replaced by fructose in sugar sweetened foods or beverages. The target population is individuals who wish to reduce their post-prandial glycaemic responses. The Panel notes that high intakes of fructose may lead to metabolic complications such as dyslipidaemia, insulin resistance and increased visceral adiposity.

KEY WORDS

Fructose, glucose, sucrose, post-prandial glycaemic response, 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 558)

The food constituent that is the subject of the health claim is fructose.

Fructose (a ketohexose) is a 6-carbon monosaccharide with the same molecular formula ($C_6H_{12}O_6$) as glucose (an aldohexose), but with a different structure. Fructose is found in many foods, especially fruits. Purified fructose is a white solid which dissolves easily in water. Together with glucose, fructose is a component of sucrose. Fructose is derived from the digestion of sucrose, and absorbed directly in the small intestine (Vasankari and Vasankari, 2006).

From the information provided, the Panel assumes that fructose should replace sucrose or glucose in foods or beverages in order to obtain the claimed effect. Fructose is used commercially in foods and beverages because of its sweet taste, which is about 1.3-1.7 times as sweet as sucrose. Fructose, sucrose, and glucose can be determined quantitatively in foods and beverages by established methods.

The Panel considers that the food constituent which is the subject of the health claim, fructose, and the food constituents which fructose should replace in foods or beverages in order to obtain the claimed effect, sucrose and glucose, are sufficiently characterised.

2. Relevance of the claimed effect to human health (ID 558)

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

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

Postprandial glycaemia is interpreted as the elevation of blood glucose concentrations after consumption of a food and/or meal. This function is a normal physiological response which varies in magnitude and duration, and which may be influenced by the chemical and physical nature of the food or meal consumed, as well as by individual factors (Venn and Green, 2007). Decreasing post-prandial glycaemic responses may be beneficial to individuals with, for example, impaired glucose tolerance as

⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

⁵ EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.

long as post-prandial insulinaemic responses are not disproportionately increased. Impaired glucose tolerance is common in the general population of adults.

The Panel considers that reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionately increased) may be a beneficial physiological effect.

3. Scientific substantiation of the claimed effect (ID 558)

The references provided in relation to the claim included two narrative reviews and an internet page which did not provide original data that 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.

Two human intervention studies investigated the effects of fructose on post-prandial glycaemic and insulinaemic responses compared to other carbohydrates (Bantle et al., 1983; Crapo et al., 1980).

In a test meal study by Bantle et al. (1983), 10 healthy subjects, 12 patients with type 1 diabetes, and 10 patients with type 2 diabetes (none taking oral hypoglycaemic medications) received in a random order five test breakfasts containing 42-43 g of different test carbohydrates (glucose, fructose, sucrose, potato starch and wheat starch) and nearly identical amounts of energy (685-742 kcal), of total carbohydrates (84-89 g), of protein (31-38 g) and of fat (25-26 g). Blood samples were obtained at 0, 15, 30, 60, 90, 120, 180 and 240 minutes after each breakfast. In healthy and type 2 diabetic subjects, the breakfast containing fructose induced significantly smaller peak increments in post-prandial blood glucose concentrations when compared to glucose, but not to sucrose. Similar results were obtained in healthy and type 2 diabetic subjects for the mean incremental area under the curve. No significant differences between carbohydrate sources were observed with respect to post-prandial insulin responses. The Panel notes that in this study fructose replaced sucrose and glucose in solid foods.

In another test meal study by Crapo et al. (1980), 9 healthy subjects, 10 subjects with impaired glucose tolerance, and 17 type 2 diabetic subjects received in a random order 50 g loads of glucose, sucrose and fructose, given alone in a drink or in combination with protein and fat, in a liquid formula meal. Diabetic subjects on oral hypoglycemic agents had discontinued medications two weeks before testing. Blood samples were obtained at 0, 15, 30, 45, 60, 120 and 180 minutes after each meal. Fructose consumption induced significantly lower blood glucose and insulin responses than sucrose or glucose consumption in all study groups, either when given alone or in the test meal, with the exception of post-prandial insulin responses, which in the diabetic group were flat and not significantly different for all three sugars. The post-prandial blood glucose response to fructose was directly proportional to the degree of glucose intolerance (i.e. post-prandial glycaemic responses to fructose were significantly higher in glucose-intolerant and type 2 diabetic subjects). The Panel notes that this study shows a significant decrease in post-prandial blood glucose responses when fructose replaces either sucrose or glucose in liquid meals or beverages.

Another reference provided was “the international table of glycemic index and glycemic load values: 2002” (Foster-Powell et al., 2002), which provides glycaemic index values from individual studies or groups of studies on a variety of foods, including fructose and fructose-containing beverages. Post-prandial glycaemic response expressed as the glycaemic index for fructose using glucose dissolved in water as a reference has a mean value of 19 ± 2 , and using white bread as a reference 27 ± 4 , whereas such values for sucrose were 68 ± 5 and 97 ± 7 , respectively. The Panel notes that these values support a significant decrease in post-prandial blood glucose responses when fructose replaces either sucrose or glucose.

The Panel notes that fructose induces lower glycaemic and insulinaemic responses compared to other hexoses, including glucose, and compared to sucrose, both when consumed alone or with other macronutrients.

Regarding the mechanism by which fructose could exert the claimed effect, fructose is more slowly absorbed in the gastro-intestinal tract than glucose, and the rapid entry of fructose into the liver, as well as its initial steps of metabolism, are insulin independent. Fructose is converted into glucose or triglycerides in the liver, and most of the glucose is stored as glycogen, resulting in only a modest increase in blood glucose concentrations.

Some recent short- and longer-term intervention studies, which compared the consumption of beverages sweetened with fructose, glucose or sucrose, have shown that high fructose intakes ($\geq 25\%$ of total energy) induce dyslipidaemia, insulin resistance and increased visceral adiposity in healthy and in hyperinsulinaemic insulin-resistant subjects (reviewed in Le and Tappy, 2006; Stanhope and Havel, 2008; Stanhope et al., 2009; Stanhope and Havel, 2010; Tappy and Le, 2010). However, these effects are generally not observed at lower doses of fructose intake (about 40-50 g/day in place of starch or sucrose (reviewed in Wolever, 2006)). Whether free fructose and fructose in sucrose have different metabolic effects is a matter of debate.

In weighing the evidence, the Panel took into account that the few intervention studies in healthy and type 2 diabetic subjects provided showed a consistent significant reduction in post-prandial glycaemic responses following fructose consumption compared with sucrose and glucose, without disproportionately increasing post-prandial insulinaemic responses, and that the mechanism by which fructose (in place of sucrose or glucose) could exert the claimed effect is well established.

The Panel concludes that a cause and effect relationship has been established between the consumption of fructose in place of sucrose or glucose in foods or beverages and reduction of post-prandial glycaemic responses.

4. Panel's comments on the proposed wording (ID 558)

The Panel considers that the following wording reflects the scientific evidence: "Consumption of fructose leads to a lower blood glucose rise than consumption of sucrose or glucose".

5. Conditions and possible restrictions of use (ID 558)

The Panel considers that in order to bear the claim, glucose or sucrose should be replaced by fructose in sugar-sweetened foods or beverages. The target population is individuals who wish to reduce their post-prandial glycaemic responses.

The Panel notes that high intakes of fructose may lead to metabolic complications such as dyslipidaemia, insulin resistance and increased visceral adiposity.

CONCLUSIONS

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

- The food constituent, fructose, which is the subject of the health claim and the food constituents which fructose should replace in foods or beverages in order to obtain the claimed effect, sucrose and glucose, are sufficiently characterised.
- The claimed effect is "carbohydrate metabolism and insulin sensitivity". The target population is assumed to be individuals who wish to reduce their post-prandial glycaemic

responses. In the context of the proposed wordings and the references provided, it is assumed that the claimed effect refers to the reduction of post-prandial glycaemic responses. Reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionately increased) may be a beneficial physiological effect.

- A cause and effect relationship has been established between the consumption of fructose in place of sucrose or glucose in food or beverages and reduction of post-prandial glycaemic responses.
- The following wording reflects the scientific evidence: “Consumption of fructose leads to a lower blood glucose rise than consumption of sucrose or glucose”.
- In order to bear the claim, glucose or sucrose should be replaced by fructose in sugar-sweetened foods or beverages. The target population is individuals who wish to reduce their post-prandial glycaemic responses. High intakes of fructose may lead to metabolic complications such as dyslipidaemia, insulin resistance and increased visceral adiposity.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1345). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: <http://www.efsa.europa.eu/panels/nda/claims/article13.htm>.

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods⁶ (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD⁷

Foods are commonly involved in many different functions⁸ of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

⁶ OJ L12, 18/01/2007

⁷ The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

⁸ The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to

describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to fructose, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
558	Fructose.	Carbohydrate metabolism and insulin sensitivity.	<p>When there are no rapid drops in blood sugar, people feel more active.</p> <p>Fructose releases energy into the body slowly and therefore prevents the feeling of tiredness due to “sugar peek” drop.</p>
	<p>Conditions of use</p> <ul style="list-style-type: none"> - Citrus drink with carbohydrate content of 2.3g/100g, 11.5g/serving, of which sugars 2g/100g, 10g/serving, of which fructose 1g/100g, 5g/1 serving - Beverage and bakery products and dairy products with 1/3 of fructose of the amount of saccharose used (because sweeter than saccharose). Fructose behaves like saccharose in the processing. 		