



**EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to sodium alginate and reduction of post-prandial glycaemic responses (ID 1868, 1881) 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 sodium alginate and reduction of post-prandial glycaemic responses (ID 1868, 1881) pursuant to Article 13(1) of Regulation (EC) No 1924/2006<sup>1</sup>

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2, 3</sup>

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 sodium alginate 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 “sodium alginate and *Ascophyllum nodosum*”. From the references provided, the Panel assumes that the food constituent that is the subject of the health claim is sodium alginate. The Panel considers that sodium alginate with an M/G ratio of 1.50 is sufficiently characterised in relation to the claimed effect.

The claimed effect is “alginate can reduce the activity of digestive enzymes and reduce glucose absorption”. The target population is assumed to be subjects who wish to reduce their post-prandial glycaemic responses. The Panel considers that the reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionately increased) may be a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the one human intervention study provided from which conclusions could be drawn for the scientific substantiation of the claim did not show a reduction in post-prandial glycaemic responses without a disproportionate increase in post-prandial insulinaemic responses following consumption of sodium alginate.

<sup>1</sup> On request from the European Commission, Question No EFSA-Q-2008-2601, EFSA-Q-2008-2614, adopted on 25 March 2011.

<sup>2</sup> Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: [nda@efsa.europa.eu](mailto:nda@efsa.europa.eu)

<sup>3</sup> Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Weight Management/Satiety/Glucose and Insulin Control/Physical Performance: Kees de Graaf, Joanne Harrold, Mette Hansen, Mette Kristensen, Anders Sjødin and Inge Tetens.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of sodium alginate and the reduction of post-prandial glycaemic responses without disproportionately increasing post-prandial insulinaemic responses.

**KEY WORDS**

Sodium alginate, post-prandial glycaemic response, insulin, 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 1924/2006<sup>4</sup> 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 out<sup>5</sup>. 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 1868, 1881)

The food constituent that is the subject of the health claim is “sodium alginate and *Ascophyllum nodosum*”.

Sodium alginate is the sodium salt of alginic acid. Sodium alginate is extracted from the cell walls of brown algae. It is authorised for use as a food additive<sup>6</sup> (E 401) for its thickening and emulsifying properties.

Alginate is an anionic polysaccharide, a linear copolymer with homopolymeric blocks of (1-4)-linked  $\beta$ -D-mannuronate (M) and its epimer  $\alpha$ -glucuronate (G) residues, which are linked covalently in different sequences. Commercial varieties of sodium alginate are extracted from *Marocystis pyrifera*, *Ascophyllum nodosum* and various types of *Laminaria*. Different sources yield alginates that differ in monomeric composition and block structure, and a given alginate has its own characteristic calcium reactivity and gelation properties. Alginates are usually referred to as high M or high G, depending on the proportions of M and G they contain. Although the food constituent that is the subject of the health claim is indicated to be sodium alginate from *Ascophyllum nodosum*, the human studies provided for the scientific substantiation of the health claim do not indicate the source of the sodium alginate used.

From the references provided, the Panel assumes that the food constituent that is the subject of the health claims is sodium alginate with an M/G ratio of 1.50. This opinion refers to sodium alginate with an M/G ratio of 1.50 from all sources.

The Panel considers that the food constituent, sodium alginate, which is the subject of the health claim, is sufficiently characterised in relation to the claimed effect.

### 2. Relevance of the claimed effect to human health (ID 1868, 1881)

The claimed effect is “alginate can reduce the activity of digestive enzymes and reduce glucose absorption”, and “polyphenols found in *Ascophyllum nodosum* inhibit enzyme activity and reduce the

<sup>4</sup> 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.

<sup>5</sup> 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.

<sup>6</sup> European Parliament and Council Directive 95/2/EC of 20 February 1995, on food additives other than colours and sweeteners. OJ L 61, 18.3.1995, p. 1–40.

glycaemic load of meals". 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 is a normal physiological response that varies in magnitude and duration, and which may be influenced by the chemical and physical nature of the food or meal consumed, as well as by individual factors (Venn and Green, 2007). Reducing post-prandial blood glucose responses may be beneficial to subjects with, for example, impaired glucose tolerance, as long as post-prandial insulinaemic responses are not disproportionately increased. Impaired glucose tolerance and hyperinsulinaemia are common in the general population of adults.

The Panel considers that the 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 1868, 1881)**

Among the references provided were one narrative review and three animal studies which were not related to the claimed effect, and one animal study which did not address the food constituent that is the subject of the claim. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

One placebo-controlled, cross-over intervention study (Torsdottir et al., 1991) investigated the effects of 5 g sodium alginate (M/G ratio of 1.50) consumed in a meal on post-prandial glycaemic and insulinaemic responses in seven men with non-insulin dependent diabetes mellitus. Three of the subjects were treated with sulfonylurea. The evidence provided does not establish that subjects with non-insulin dependent diabetes mellitus under treatment with sulfonylurea are representative of the target population with respect to their insulinaemic responses to carbohydrate-containing meals. The Panel considers that no conclusions can be drawn from this reference for the scientific substantiation of the claim.

In a double-blind, placebo-controlled, cross-over intervention study (Wolf et al., 2002), 30 healthy adult subjects (19 women) consumed a 250 g glucose-based beverage containing 1.5 g sodium alginate with an M/G ratio of 1.50/100 g beverage, and the same beverage containing no sodium alginate but 1.2 g gum Arabic and 0.3 g guar gum/100 g beverage after an overnight 12 h fast, on two different occasions, 12 days apart. Subjects were instructed to eat a high carbohydrate diet (at least 200 g/day) for the three days before each testing session and were allowed to drink 250 mL water during the 3 h test. Subjects consumed the test and control beverages within 10 min, and blood sampling was performed at baseline and 15, 30, 60, 90, 120 and 180 minutes post-prandial. Incremental peak glucose response was used for power calculations, and was the primary outcome of the study. Net incremental areas under the curve (AUC) for blood glucose and insulin concentrations were calculated with the trapezoidal rule, ignoring the area below fasting blood glucose values. Mean incremental peak glucose response was not significantly different between beverages, whereas the mean incremental peak insulin response was significantly higher with the test compared to the control beverage ( $p < 0.05$ ). The net incremental AUC for glucose was significantly lower for the test than for the control ( $p < 0.01$ ). The time at which peak glucose was reached was not significantly different, but incremental glucose concentrations were significantly lower at 60 and 150 min for the test compared to the control ( $p < 0.05$ ). No significant differences were observed between beverages with respect to the net incremental AUC for insulin. However, incremental insulin concentrations were significantly higher at 90 min for the test compared to the control ( $p < 0.01$ ). The Panel notes that this study does not

show an effect of sodium alginate on the reduction of post-prandial blood glucose responses without disproportionately increasing post-prandial insulin responses.

One animal study investigated a possible mechanism by which sodium alginate could exert an effect on post-prandial glycaemic responses. The Panel considers that evidence provided in animal studies is not sufficient to predict the occurrence of an effect of sodium alginate consumption on the reduction of post-prandial glycaemic responses in humans.

In weighing the evidence, the Panel took into account that the one human intervention study provided from which conclusions could be drawn for the scientific substantiation of the claim did not show a reduction in post-prandial glycaemic responses without a disproportionate increase in post-prandial insulinaemic responses following consumption of sodium alginate.

The Panel concludes that a cause and effect relationship has not been established between the consumption of sodium alginate and the reduction of post-prandial glycaemic responses without disproportionately increasing post-prandial insulinaemic responses.

## CONCLUSIONS

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

- The food constituent, sodium alginate (with an M/G ratio of 1.50), which is the subject of the health claim, is sufficiently characterised in relation to the claimed effect.
- The claimed effect is “alginate can reduce the activity of digestive enzymes and reduce glucose absorption”. The target population is assumed to be individuals who wish to reduce their post-prandial glycaemic responses. A reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionately increased) may be a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of sodium alginate and the reduction of post-prandial glycaemic responses without disproportionately increasing post-prandial insulinaemic responses.

## DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-2601, EFSA-Q-2008-2614). 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

- Torsdottir I, Alpsten M, Holm G, Sandberg AS and Tolli J, 1991. A small dose of soluble alginate-fiber affects postprandial glycemia and gastric emptying in humans with diabetes. *Journal of Nutrition*, 121, 795-799.
- Wolf BW, Lai CS, Kipnes MS, Ataya DG, Wheeler KB, Zinker BA, Garleb KA and Firkins JL, 2002. Glycemic and insulinemic responses of nondiabetic healthy adult subjects to an experimental acid-induced viscosity complex incorporated into a glucose beverage. *Nutrition*, 18, 621-626.

## 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 foods<sup>7</sup> (hereinafter "the Regulation") entered into force on 19<sup>th</sup> 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 FOOD<sup>8</sup>

Foods are commonly involved in many different functions<sup>9</sup> 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.

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<sup>7</sup> OJ L12, 18/01/2007

<sup>8</sup> The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

<sup>9</sup> 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 sodium alginate, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
1868	<p>Name of Food product: Product-specific claim: sodium alginate and ascophyllum nodosum.</p>	<p>Health benefits of food: Alginate can reduce the activity of digestive enzymes and reduce glucose absorption. Polyphenols found in ascophyllum nodosum inhibit enzyme activity and reduce the glycaemic load of meals.</p> <p>Do benefits relate to a disease risk factor: Yes.</p> <p>Target group: Adults aged 18 years and over with some exceptions.</p> <p>If exceptions describe: Pregnant, lactating women and children. People with brittle bones or calcium deficiency.</p> <p>Reasons for excluding these groups: Sodium alginate may decrease the absorption of calcium if taken concomitantly therefore it should be avoided by pregnant, lactating women and children and those with brittle bones or calcium deficiency.</p>	<p>Exact wording of claim as it appears on product: Helps manage blood glucose levels.</p> <p>Examples of any alternative wording that may be used in relation to claim: Reduces heightened glycaemic index/Blunts glucose elevation/Reduces glycaemic load of a meal/Helps maintain a normal blood glucose level as part of a healthy lifestyle/Contributes to normal glucose metabolism/Helps control blood glucose levels/Supports maintenance of normal glucose levels.</p>
<p><b>Conditions of use</b></p>			
<p>– Number of nutrients/other substances that are essential to claimed effect: 2. Names of nutrient/other substances and Quantity in Average daily serving: 5 grams sodium alginate, 1 gram ascophyllum nodosum. Weight of average daily food serving: 150 millilitre(s). Daily amount to be consumed to produce claimed effect: 300 millilitre(s). Number of food portions this equates to in everyday food portions: 1.00. Are there factors that could interfere with bioavailability: No. Length of time after consumption for claimed effect to become apparent: 4 weeks. Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No. Where applicable outline nutritional composition (g per 100g) of food: Total Fat: .01, Saturated Fat: .00, Trans Fat: .00, Sugar: .31, Salt: .00, Sodium: .01 Other conditions for use: This beverage should be consumed as part of a varied, balanced, healthy lifestyle. Two beverages are to be consumed daily in order to gain benefit. The entire beverage must be consumed. This product should be avoided by pregnant and lactating women, children and those brittle bones and calcium deficiency.</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
1881	<p>Name of Food product: Product-specific claim: Sodium alginate and</p>	<p>Health benefits of food: Alginate can reduce the activity of digestive enzymes and reduce</p>	<p>Exact wording of claim as it appears on product: Helps manage blood glucose and</p>

	<p>ascophyllum nodosum.</p>	<p>glucose absorption. Polyphenols found in ascophyllum nodosum inhibit enzyme activity and reduce the glycemic load of meals.</p> <p>Do benefits relate to a disease risk factor: Yes.</p> <p>Target group: Adults aged 18 years and over with some exceptions.</p> <p>If exceptions describe: Pregnant, lactating women and children. People with brittle bones or calcium deficiency.</p> <p>Reasons for excluding these groups: Sodium alginate may decrease the absorption of calcium if taken concomitantly therefore it should be avoided by pregnant, lactating women and children and those with brittle bones or calcium deficiency.</p>	<p>insulin levels.</p> <p>Examples of any alternative wording that may be used in relation to claim: Reduces heightened glycaemic index/Blunts glucose and insulin elevation/Reduces the glycaemic load of a meal/Helps maintain a normal blood glucose level as part of a healthy lifestyle/Contributes to normal blood glucose levels as part of a healthy lifestyle/Contributes to normal glucose/insulin metabolism/Helps control blood glucose levels/Supports maintenance of normal glucose levels.</p> <p>Is claim a picture: No.</p>
<p><b>Conditions of use</b></p> <p>– Number of nutrients/other substances that are essential to claimed effect: 2. Names of nutrient/other substances and Quantity in Average daily serving: 5 grams sodium alginate, 1 grams ascophyllum nodosum. Weight of average daily food serving: 150 millilitre(s). Daily amount to be consumed to produce claimed effect: 300 millilitre(s). Number of food portions this equates to in everyday food portions: 1. Are there factors that could interfere with bioavailability: No. Length of time after consumption for claimed effect to become apparent: 4 weeks. Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No. Where applicable outline nutritional composition (g per 100g) of food: Total Fat: .01, Saturated Fat: .00, Trans Fat: .00, Sugar: .31, Salt: .00, Sodium: .01 Other conditions for use: This beverage should be consumed as part of a varied, balanced and healthy lifestyle. Two beverages are to be consumed daily in order to gain benefit. The entire beverage must be consumed. This product should be avoided by pregnant and lactating women, children and those with brittle bones and calcium deficiency.</p>			

## GLOSSARY AND ABBREVIATIONS

AUC            Areas under the curve

M/G ratio    (1-4)-linked  $\beta$ -D-mannuronate/ $\alpha$ -glucuronate ratio