SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to the sugar replacers xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose and polydextrose and maintenance of tooth mineralisation by decreasing tooth demineralisation (ID 463, 464, 563, 618, 647, 1182, 1591, 2907, 2921, 4300), and reduction of post-prandial glycaemic responses (ID 617, 619, 669, 1590, 1762, 2903, 2908, 2920) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

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 the sugar replacers xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose and polydextrose and maintenance of tooth mineralisation by decreasing tooth demineralisation, 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.

[1] On request from the European Commission, Question No EFSA-Q-2008-1404, EFSA-Q-2008-1406, EFSA-Q-2008-1456, EFSA-Q-2008-2327, EFSA-Q-2008-2495, EFSA-Q-2008-3636, EFSA-Q-2008-3641, EFSA-Q-2008-3653, adopted on 12 November 2010, and EFSA-Q-2008-1250, EFSA-Q-2008-1251, EFSA-Q-2008-1350, EFSA-Q-2008-1405, EFSA-Q-2008-1434, EFSA-Q-2008-1921, EFSA-Q-2008-2328, EFSA-Q-2008-3640, EFSA-Q-2008-3654, EFSA-Q-2010-00253, adopted on 28 January 2011.

[2] 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

[3] 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 Bone/Teeth/Connective Tissue: Rikke Andersen, Olivier Bruyère, Albert Flynn, Ingegerd Johansson, Jukka Meurman and Hildegard Przyrembel. 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 Sjödin and Inge Tetens.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to the sugar replacers xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose and polydextrose and maintenance of tooth mineralisation by decreasing tooth demineralisation (ID 463, 464, 563, 618, 647, 1182, 1591, 2907, 2921, 4300), and reduction of post-prandial glycaemic responses (ID 617, 619, 669, 1590, 1762, 2903, 2908, 2920) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2076. [25 pp.]. doi:10.2903/j.efsa.2011.2076. Available online: www.efsa.europa.eu/efsajournal

© European Food Safety Authority, 2011

The food constituents that are the subject of the health claims are "carbohydrates - non-cariogenic e.g. isomaltulose; tagatose, polyols, polydextrose, absence of, or low, fermentable carbohydrates", "polydextrose", "xylitol in candy and bakery industry products and in dairy products", "polyols", "isomaltulose", "isomalt", "D-tagatose" and "sucralose". In the context of the proposed wordings and conditions of use, the Panel assumes that the food constituents that are the subject of the health claim are xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose and polydextrose, which should replace sugars in foods in order to obtain the claimed effect. The Panel considers that the sugar replacers xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose and polydextrose are sufficiently characterised in relation to the claimed effects.

Maintenance of tooth mineralisation by decreasing tooth demineralisation

The claimed effects are "dental health", "mouth, teeth", "remineralisation of teeth", "not cariogenic", and "do not promote tooth decay". The target population is assumed to be the general population. In the context of the proposed wordings, conditions of use and references provided in the consolidated list, the Panel assumes that the claimed effects refer to the maintenance of tooth mineralisation by decreasing tooth demineralisation. The Panel considers that the maintenance of tooth mineralisation by reducing tooth demineralisation resulting from acid production in plaque through the fermentation of carbohydrates is a beneficial physiological effect, provided that it is not accompanied by tooth demineralisation resulting from erosive properties of a food.

The evidence provided by consensus opinions, reports from authoritative bodies and reviews also indicates that the decrease in pH in plaque as a consequence of metabolic acid production by saccharolytic bacteria when exposed to fermentable carbohydrates (i.e. sugars and starches) may promote demineralisation and prevent remineralisation of the hydroxyapatite crystals.

The evidence provided in relation to the claim also establishes that in the absence of other fermentable carbohydrate-containing foods, foods containing the sugar replacers considered in this opinion do not promote dental caries because they do not lower plaque pH to the level associated with enamel demineralisation.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of sugar-containing foods/drinks at an exposure frequency of four times daily or more and an increased tooth demineralisation, and that the consumption of foods/drinks containing xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose or polydextrose, instead of sugar in sugar-containing foods/drinks, may maintain tooth mineralisation compared with sugar-containing foods, provided that such foods/drinks do not lead to dental erosion.

The Panel considers that in order to bear the claim, sugars should be replaced in foods or drinks (which reduce plaque pH below 5.7) by xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose or polydextrose, or a combination of them, so that consumption of such foods or drinks does not lower plaque pH below 5.7 during and up to 30 minutes after consumption, and does not lead to dental erosion.

If excessive amounts of bulk sweeteners (polyols) are consumed, laxative effects may occur. In order to ensure that consumers receive adequate information, the labelling of foods containing more than 10 % added polyols must include the advisory statement "excessive consumption may produce laxative effects" (Commission Directive 94/54/EC).

Reduction of post-prandial glycaemic responses

The claimed effects are "low glycaemic properties", "reduced speed of digestion and absorption results in lower glycaemic response", and "post-prandial blood glucose". The target population is assumed to be individuals wishing to reduce their post-prandial glycaemic responses. In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the reduction of post-prandial glycaemic responses. The Panel considers that the reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) may be a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the food constituents xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose or polydextrose decrease post-prandial blood glucose (or insulinaemic) responses compared with sugars on a weight by weight basis owing to their reduced/delayed digestion/absorption and/or to a decrease in the amount of available carbohydrates, and that the consumption of foods/drinks in which xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose or polydextrose replaced sugars induced lower post-prandial glycaemic and insulinaemic responses than sugar-containing foods/drinks.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of foods/drinks containing xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose or polydextrose instead of sugar and reduction in post-prandial blood glucose responses (without disproportionally increasing post-prandial insulinaemic responses) as compared to sugar-containing foods/drinks.

The Panel considers that in order to bear the claim, sugars should be replaced in foods or drinks by xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose or polydextrose, or a combination of them, so that foods or drinks contain reduced amounts of sugars as per Annex of Regulation (EC) No 1924/2006 and in accordance with the Guidance on the implementation of Regulation (EC) No 1924/2006 of the Standing Committee on the Food Chain and Animal Health for comparative nutrition claims made on foods (section 2.2.3).

If excessive amounts of bulk sweeteners (polyols) are consumed, laxative effects may occur. In order to ensure that consumers receive adequate information, the labelling of foods containing more than 10% added polyols must include the advisory statement "excessive consumption may produce laxative effects" (Commission Directive 94/54/EC).

KEY WORDS

Polyols, xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose, polydextrose, tooth mineralisation, tooth demineralisation, post-prandial glycaemic response, health claims.

TABLE OF CONTENTS

Summary 1
Table of contents 4
Background as provided by the European Commission 5
Terms of reference as provided by the European Commission 5
EFSA Disclaimer 5
Information as provided in the consolidated list 6
Assessment 6
1. Characterisation of the food/constituent 6
2. Relevance of the claimed effect to human health 6
2.1. Maintenance of tooth mineralisation by decreasing tooth demineralisation (ID 463, 464, 563, 618, 647, 1182, 1591, 2907, 2921, 4300) 6
2.2. Reduction of post-prandial glycaemic responses (ID 617, 619, 669, 1590, 1762, 2903, 2908, 2920) 7
3. Scientific substantiation of the claimed effect 7
3.1. Maintenance of tooth mineralisation by decreasing tooth demineralisation (ID 463, 464, 563, 618, 647, 1182, 1591, 2907, 2921, 4300) 7
3.2. Reduction of post-prandial glycaemic responses (ID 617, 619, 669, 1590, 1762, 2903, 2908, 2920) 8
4. Panel's comments on the proposed wording 9
4.1. Maintenance of tooth mineralisation by decreasing tooth demineralisation (ID 463, 464, 563, 618, 647, 1182, 1591, 2907, 2921, 4300) 9
4.2. Reduction of post-prandial glycaemic responses (ID 617, 619, 669, 1590, 1762, 2903, 2908, 2920) 9
5. Conditions and possible restrictions of use 9
5.1. Maintenance of tooth mineralisation by decreasing tooth demineralisation (ID 463, 464, 563, 618, 647, 1182, 1591, 2907, 2921, 4300) 9
5.2. Reduction of post-prandial glycaemic responses (ID 617, 619, 669, 1590, 1762, 2903, 2908, 2920) 10
Conclusions 10
Documentation provided to EFSA 12
References 12
Appendices 14

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

See Appendix A

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

See Appendix A

EFSA DISCLAIMER

See Appendix B

INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006[4] 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[5]. 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 constituents that are the subject of the health claims are "carbohydrates - non-cariogenic e.g. isomaltulose; tagatose, polyols, polydextrose, absence of, or low, fermentable carbohydrates", "polydextrose", "xylitol in candy and bakery industry products and in dairy products", "polyols", "isomaltulose", "isomalt", "D-tagatose" and "sucralose".

In the context of the proposed wordings and conditions of use, the Panel assumes that the food constituents, which are the subject of the health claims, are xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose and polydextrose, which should replace sugars in foods in order to obtain the claimed effects.

The Panel considers that the food constituents, the sugar replacers xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose and polydextrose, which are the subject of the health claims, are sufficiently characterised in relation to the claimed effects.

2. Relevance of the claimed effect to human health

2.1. Maintenance of tooth mineralisation by decreasing tooth demineralisation (ID 463, 464, 563, 618, 647, 1182, 1591, 2907, 2921, 4300)

The claimed effects are "dental health", "mouth, teeth", "remineralisation of teeth", "not cariogenic", and "do not promote tooth decay". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, conditions of use and references provided in the consolidated list, the Panel assumes that the claimed effects refer to the maintenance of tooth mineralisation by decreasing tooth demineralisation.

Demineralisation of tooth tissues can occur following acid production through the fermentation of carbohydrates by acid-producing bacteria in dental biofilms. The effect may be balanced by remineralisation when pH is neutralised and a state of calcium and phosphate supersaturation is met.

[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

If demineralisation is not balanced by remineralisation then net demineralisation of tooth tissues results, which, if sustained, can lead to dental caries. Demineralisation of tooth tissues can also occur as a result of consumption of dietary acids in foods or beverages, and frequent consumption can lead to dental erosion. Dental caries and dental erosion are diseases with a high prevalence in the EU.

The Panel considers that the maintenance of tooth mineralisation by reducing tooth demineralisation resulting from acid production in plaque through the fermentation of carbohydrates is a beneficial physiological effect, provided that it is not accompanied by tooth demineralisation resulting from the erosive properties of a food.

2.2. Reduction of post-prandial glycaemic responses (ID 617, 619, 669, 1590, 1762, 2903, 2908, 2920)

The claimed effects are "low glycaemic properties", "reduced speed of digestion and absorption results in lower glycaemic response", and "post-prandial blood glucose". The Panel assumes that the target population is individuals wishing to reduce their post-prandial glycaemic responses.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer 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). Reducing post-prandial glycaemic responses may be beneficial to subjects with, for example, impaired glucose tolerance, as long as post-prandial insulinaemic responses are not disproportionally increased. Impaired glucose tolerance is 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 disproportionally increased) may be a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

3.1. Maintenance of tooth mineralisation by decreasing tooth demineralisation (ID 463, 464, 563, 618, 647, 1182, 1591, 2907, 2921, 4300)

The evidence provided by consensus opinions, reports from authoritative bodies and reviews shows that an increased risk of dental caries in children is associated with a high frequency (more than about four times daily) of intake of "cariogenic" sugars (mainly sucrose, glucose and fructose), rather than with the total amount of dietary sugars, and that frequent consumption of sweets, confectionery products and sugar-containing drinks is associated with a higher risk of caries (Anderson et al., 2009; DoH, 1991; EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010; IoM, 2005; Moynihan and Petersen, 2004). Foods rich in starch may also contribute, especially when the starch molecule is easily available to degradation by amylase (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010; FDA, 1996).

The evidence provided by consensus opinions, reports from authoritative bodies and reviews also indicates that the decrease in pH in plaque as a consequence of metabolic acid production by saccharolytic bacteria when exposed to fermentable carbohydrates (i.e. sugars and starches) may promote demineralisation and prevent remineralisation of the hydroxyapatite crystals. Tooth hydroxyapatite crystals are very resistant to dissolution at neutral pH, but their solubility drastically increases as pH drops. Typically, the critical pH for dental enamel is around 5.5. The Panel notes that

demineralisation of tooth tissues can also occur as a result of consumption of dietary acids in foods or beverages, and that frequent consumption can lead to dental erosion.

Xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose and polydextrose are slowly metabolised by bacteria in the mouth. The rate and amount of acid production from these food constituents is significantly less than that from sucrose. Although frequent or long-term use of some sugar alcohols (e.g. sorbitol, mannitol and xylitol), especially as part of a daily diet containing other carbohydrates which are preferentially metabolised by oral bacteria, may result in some adaptation by the bacteria to these substances, the effect would not be such that consumption of sugar alcohols would cause the loss of minerals from tooth enamel (Edgar, 1998; FDA, 1996, 2010; Imfeld, 1999; Touger-Decker and van Loveren, 2003).

The evidence provided in relation to this claim also establishes that in the absence of other fermentable carbohydrate-containing foods, foods containing the sugar replacers considered in this opinion do not promote dental caries because they do not lower plaque pH to the level associated with enamel demineralisation. The Panel considers that foods lowering plaque pH below a conservative value of 5.7 by bacterial fermentation during and up to 30 minutes after consumption, as determined *in vivo* or *in situ* by pH telemetry, may promote demineralisation and prevent remineralisation of the hydroxyapatite crystals (FDA, 1996).

The Panel concludes that a cause and effect relationship has been established between the consumption of sugar-containing foods/drinks at an exposure frequency of four times daily or more and an increased tooth demineralisation, and that the consumption of foods/drinks containing xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose or polydextrose, instead of sugar in sugar-containing foods/drinks, may maintain tooth mineralisation by decreasing tooth demineralisation compared with sugar-containing foods, provided that such foods/drinks do not lead to dental erosion.

3.2. Reduction of post-prandial glycaemic responses (ID 617, 619, 669, 1590, 1762, 2903, 2908, 2920)

Postprandial glycaemic and insulinaemic responses following consumption of the sugar alcohols considered in this opinion are significantly lower compared to glucose or sucrose on a weight basis in healthy and diabetic subjects when consumed in liquid form at doses between 10 and 50 g. The addition of the sugar alcohols to simple and complex meals compared to the addition of glucose or sucrose leads to similar results. The reduced post-prandial blood glucose response of sugar alcohols compared to glucose or sucrose is explained by the interference of the alcohol group that replaces the carbonyl group with digestion and absorption, and the occurrence of saccharide linkages other than the alpha-1-4 and alpha-1-6 glycosidic bonds present in available carbohydrates (Livesey, 2003).

Postprandial glycaemic and insulinaemic responses following consumption of isomaltulose have been shown to be significantly lower in healthy subjects compared to sucrose on a weight basis when consumed in water (Achten et al., 2007; Kawai et al., 1985; MacDonald and Daniel, 1983), and compared to dextrin when consumed in a liquid diet for enteral nutrition (14 % protein, 31 % fat and 55 % carbohydrate), with or without a standard breakfast in which isomaltulose replaced about 55 % of dextrin (Arai et al., 2007). The reduced rate of digestion and absorption, and subsequent reduced post-prandial blood glucose response of isomaltulose compared with sucrose or dextrin, is explained by the slower hydrolysis of the disaccharide alpha-1,6-glycosidic bonds by isomaltase compared with other disaccharides (Achten et al., 2007; Arai et al., 2007).

The effects of D-tagatose (the C-4 epimer of D-fructose) on post-prandial blood glucose and insulin responses have been shown to be about 3 % of those of glucose on a weight by weight basis when administered in liquid solution (SUGiRS, 2004). Polydextrose, a glucose polymer with sorbitol end

groups and randomly branched chains (average degree of polymerisation of 12), which is indigestible in the small intestine, and sucralose, an intense sweetener with no energy value, are also likely to induce lower post-prandial glycaemic and insulinaemic responses than glucose or disaccharides on a weight basis.

No evidence has been provided that adding the sugar replacers considered in this opinion to available carbohydrate-containing foods affects the post-prandial glycaemic or insulinaemic responses to those foods.

In weighing the evidence, the Panel took into account that the food constituents xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose or polydextrose resulted in reduced post-prandial blood glucose (or insulinaemic) responses compared with sugars on a weight by weight basis owing to their reduced/delayed digestion/absorption and/or to a decrease in the amount of available carbohydrates, and that the consumption of foods/drinks in which xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose or polydextrose replaced sugars induced lower post-prandial glycaemic and insulinaemic responses than sugar-containing foods/drinks.

The Panel concludes that a cause and effect relationship has been established between the consumption of foods/drinks containing xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose or polydextrose instead of sugar and reduction in post-prandial blood glucose responses (without disproportionally increasing post-prandial insulinaemic responses) as compared to sugar-containing foods/drinks.

4. Panel's comments on the proposed wording

4.1. Maintenance of tooth mineralisation by decreasing tooth demineralisation (ID 463, 464, 563, 618, 647, 1182, 1591, 2907, 2921, 4300)

The Panel considers that the following wording reflects the scientific evidence: "Frequent consumption of sugars contributes to tooth demineralisation. Consumption of foods/drinks containing <name of sugar replacer> instead of sugar may help maintain tooth mineralisation by decreasing tooth demineralisation".

4.2. Reduction of post-prandial glycaemic responses (ID 617, 619, 669, 1590, 1762, 2903, 2908, 2920)

The Panel considers that the following wording reflects the scientific evidence: "Consumption of foods/drinks containing <name of sugar replacer> instead of sugar induces a lower blood glucose rise after meals compared to sugar-containing foods/drinks".

5. Conditions and possible restrictions of use

5.1. Maintenance of tooth mineralisation by decreasing tooth demineralisation (ID 463, 464, 563, 618, 647, 1182, 1591, 2907, 2921, 4300)

The Panel considers that in order bear the claim, sugars should be replaced in foods or drinks (which reduce plaque pH below 5.7) by xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose or polydextrose, or a combination of them, so that consumption of such foods or drinks does not lower plaque pH below 5.7 during and up to 30 minutes after consumption, and does not lead to dental erosion.

If excessive amounts of bulk sweeteners (polyols) are consumed, laxative effects may occur. In order to ensure that consumers receive adequate information, the labelling of foods containing more than 10 % added polyols must include the advisory statement "excessive consumption may produce laxative effects" (Commission Directive 94/54/EC[6]).

5.2. Reduction of post-prandial glycaemic responses (ID 617, 619, 669, 1590, 1762, 2903, 2908, 2920)

The Panel considers that in order to bear the claim, sugars should be replaced in foods or drinks by xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose or polydextrose, or a combination of them, so that foods or drinks contain reduced amounts of sugars as per Annex of Regulation (EC) No 1924/2006 and in accordance with the Guidance on the implementation of Regulation (EC) No 1924/2006 of the Standing Committee on the Food Chain and Animal Health for comparative nutrition claims made on foods[7] (section 2.2.3).

If excessive amounts of bulk sweeteners (polyols) are consumed, laxative effects may occur. In order to ensure that consumers receive adequate information, the labelling of foods containing more than 10°% added polyols must include the advisory statement "excessive consumption may produce laxative effects" (Commission Directive 94/54/EC).

CONCLUSIONS

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

- The food constituents, the sugar replacers xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose and polydextrose, which are the subject of the health claims, are sufficiently characterised in relation to the claimed effects.

Maintenance of tooth mineralisation by decreasing tooth demineralisation (ID 463, 464, 563, 618, 647, 1182, 1591, 2907, 2921, 4300)

- The claimed effects are "dental health", "mouth, teeth", "remineralisation of teeth", "not cariogenic", and "do not promote tooth decay". The target population is assumed to be the general population. In the context of the proposed wordings, conditions of use and references provided in the consolidated list, it is assumed that the claimed effects refer to the maintenance of tooth mineralisation by decreasing tooth demineralisation. Maintenance of tooth mineralisation by reducing tooth demineralisation resulting from acid production in plaque through the fermentation of carbohydrates is a beneficial physiological effect, provided that it is not accompanied by tooth demineralisation resulting from erosive properties of a food.

- A cause and effect relationship has been established between the consumption of sugar-containing foods/drinks at an exposure frequency of four times daily or more and an increased tooth demineralisation, and that the consumption of foods/drinks containing xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose or polydextrose, instead of sugar in sugar-containing foods/drinks, may maintain tooth mineralisation by decreasing tooth demineralisation compared with sugar-containing foods, provided that such foods/drinks do not lead to dental erosion.

[6] Commission Directive 94/54/EC of 18 November 1994 concerning the compulsory indication on the labelling of certain foodstuffs of particulars other than those provided for in Council Directive 79/112/EEC. OJ L 300, 23.11.1994, pp. 14–15.

[7] Guidance on the implementation of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods – Conclusions of the Standing Committee on the Food Chain and Animal Health, 14 December 2007.

- The following wording reflects the scientific evidence: "Frequent consumption of sugars contributes to tooth demineralisation. Consumption of foods/drinks containing <name of sugar replacer> instead of sugar may help maintain tooth mineralisation by decreasing tooth demineralisation".

- In order to bear the claim, sugars should be replaced in foods or drinks (which reduce plaque pH below 5.7) by xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose or polydextrose, or a combination of them, so that consumption of such foods or drinks does not lower plaque pH below 5.7 during and up to 30 minutes after consumption, and does not lead to dental erosion.

- If excessive amounts of bulk sweeteners (polyols) are consumed, laxative effects may occur. In order to ensure that consumers receive adequate information, the labelling of foods containing more than 10 % added polyols must include the advisory statement "excessive consumption may produce laxative effects" (Commission Directive 94/54/EC).

Reduction of post-prandial glycaemic responses (ID 617, 619, 669, 1590, 1762, 2903, 2908, 2920)

- The claimed effects are "low glycaemic properties", "reduced speed of digestion and absorption results in lower glycaemic response", and "post-prandial blood glucose". The target population is assumed to be individuals wishing to reduce their post-prandial glycaemic responses. In the context of the proposed wordings, it is assumed that the claimed effects refer to the reduction of post-prandial glycaemic responses. Reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) may be a beneficial physiological effect.

- A cause and effect relationship has been established between the consumption of foods/drinks containing xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose or polydextrose instead of sugar and reduction in post-prandial blood glucose responses (without disproportionally increasing post-prandial insulinaemic responses) as compared to sugar-containing foods/drinks.

- The following wording reflects the scientific evidence: "Consumption of foods/drinks containing <name of sugar replacer> instead of sugar induces a lower blood glucose rise after meals compared to sugar-containing foods/drinks".

- In order to bear the claim, sugars should be replaced in foods or drinks by xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose or polydextrose, or a combination of them, so that foods or drinks contain reduced amounts of sugars as per Annex of Regulation (EC) No 1924/2006 and in accordance with the Guidance on the implementation of Regulation (EC) No 1924/2006 of the Standing Committee on the Food Chain and Animal Health for comparative nutrition claims made on foods[8] (section 2.2.3).

- If excessive amounts of bulk sweeteners (polyols) are consumed, laxative effects may occur. In order to ensure that consumers receive adequate information, the labelling of foods containing more than 10 % added polyols must include the advisory statement "excessive consumption may produce laxative effects" (Commission Directive 94/54/EC).

[8] Guidance on the implementation of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods – Conclusions of the Standing Committee on the Food Chain and Animal Health, 14 December 2007.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1250, EFSA-Q-2008-1251, EFSA-Q-2008-1350, EFSA-Q-2008-1404, EFSA-Q-2008-1405, EFSA-Q-2008-1406, EFSA-Q-2008-1434, EFSA-Q-2008-1456, EFSA-Q-2008-1921, EFSA-Q-2008-2327, EFSA-Q-2008-2328, EFSA-Q-2008-2495, EFSA-Q-2008-3636, EFSA-Q-2008-3640, EFSA-Q-2008-3641, EFSA-Q-2008-3653, EFSA-Q-2008-3654, EFSA-Q-2010-00253). 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

Achten J, Jentjens RL, Brouns F and Jeukendrup AE, 2007. Exogenous oxidation of isomaltulose is lower than that of sucrose during exercise in men. Journal of Nutrition, 137, 1143-1148.

Anderson CA, Curzon ME, Van Loveren C, Tatsi C and Duggal MS, 2009. Sucrose and dental caries: a review of the evidence. Obesity Reviews, 10 Suppl 1, 41-54.

Arai H, Mizuno A, Sakuma M, Fukaya M, Matsuo K, Muto K, Sasaki H, Matsuura M, Okumura H, Yamamoto H, Taketani Y, Doi T and Takeda E, 2007. Effects of a palatinose-based liquid diet (Inslow) on glycemic control and the second-meal effect in healthy men. Metabolism: Clinical and Experimental, 56, 115-121.

DoH (Department of Health), 1991. Dietary Reference Values for Food Energy and Nutrients for the United Kingdom. HMSO, London.

Edgar WM, 1998. Sugar substitutes, chewing gum and dental caries--a review. British Dental Journal, 184, 29-32.

EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010. Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre. EFSA Journal, 8(3):1462, 40 pp.

FDA (Food and Drug Administration), 1996. Food Labeling: Health Claims; Sugar Alcohols and Dental Caries. Federal Register 61 FR 43433, August 23.

FDA (Food and Drug Administration), 2010. Code of Federal Regulations, Title 21 - Food and Drugs, Volume 2, Chapter 1, Subchapter B - Food for Human Consumption - Part 101 - Food Labelling, Subpart E - Specific Requirements for Health Claims Sec. 101.80 Health claims: dietary noncariogenic carbohydrate sweeteners and dental caries (21CFR101.80).

Imfeld T, 1999. Chewing gum--facts and fiction: a review of gum-chewing and oral health. Critical Reviews in Oral Biology and Medicine, 10, 405-419.

IoM (Institute of Medicine), 2005. Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty acids, Cholesterol, Protein, and Amino Acids. National Academies Press, Washington DC.

Kawai K, Okuda Y and Yamashita K, 1985. Changes in blood glucose and insulin after an oral palatinose administration in normal subjects. Endocrinologia Japonica, 32, 933-936.

Livesey G, 2003. Health potential of polyols as sugar replacers, with emphasis on low glycaemic properties. Nutrition Research Reviews, 16, 163-191.

MacDonald I and Daniel JW, 1983. The Bio-Availability of Isomaltulose in Man and Rat. Nutrition Reports International, 28, 1083-1090.

Moynihan P and Petersen PE, 2004. Diet, nutrition and the prevention of dental diseases. Public Health Nutrition, 7, 201-226.

SUGiRS (Sydney University's Glycaemic Index Research Service), 2004. A study to measure the glycaemic index and insulin index value of tagatose sugar.Glycaemic Index Research Report for Arla Foods (unpublished study).

Touger-Decker R and van Loveren C, 2003. Sugars and dental caries. American Journal of Clinical Nutrition, 78, 881S-892S.

Venn BJ and Green TJ, 2007. Glycemic index and glycemic load: measurement issues and their effect on diet-disease relationships. European Journal of Clinical Nutrition, 61 Suppl 1, S122-131.

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[9] (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 FOOD[10]

Foods are commonly involved in many different functions[11] 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.

[9] OJ L12, 18/01/2007
[10] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[11] 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 the sugar replacers xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose and polydextrose, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
463	Carbohydrates - non-cariogenic e.g. isomaltulose; tagatose, polyols, polydextrose. Absence of, or low , fermentable carbohydrates	Dental health	-food X is kind to teeth; -food/drink X is safe for teeth; -X food helps keep teeth healthy when used between meals in place of [food] made with fermentable sugars; -helps keep teeth healthy; -use of graphic device such as toothfriendly logo.
	Conditions of use - According to US 21CFR§101.80: the food shall not lower plaque pH below 5,7 by bacterial fermentation during consumption and up to 30 min after consumption, as determined by plaque pH telemetry, and other comparable methods. - According to US 21CFR§101.80: When fermentable carbohydrates are present in the food, the food shall not lower plaque pH below 5,7 by bacterial fermentation during consumption and up to 30 min after consumption, as determined by plaque pH telemetry. Σύμφωνα με το US 21CFR§101.80: Εάν υπάρχουν στα τρόφιμα ζυμούμενοι υδατάνθρακες, τότε τα τρόφιμα δεν πρέπει να μειώνουν την τιμή pH της πλάκας κάτω από το 5,7 μέσω βακτηριακής ζύμωσης, κατά τη διάρκεια της κατανάλωσης του τροφίμου και έως και 30' μετά από αυτήν. Ο υπολογισμός γίνεται με τηλεμετρική μέθοδο προσδιορισμού του pH της πλάκας.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
464	Polydextrose	Dental health	-food X is kind to teeth; -food/drink X is safe for teeth; -X food helps keep teeth healthy when used between meals in place of [food] made with fermentable sugars; -helps keep teeth healthy; -use of graphic device such as toothfriendly logo.
	Conditions of use - According to US 21CFR§101.80: the food shall not lower plaque pH below 5,7 by bacterial fermentation during consumption and up to 30 min after consumption, as determined by plaque pH telemetry, and other comparable methods.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
563	Xylitol in candy and bakery industry products and in dairy products.	Mouth, teeth	Tooth-friendliness
	Conditions of use		

	- Candy and bakery industry products and dairy products with a xylitol content of 0.5 g/kg of body weight recommendation. As with other sugar alcohols, the use of xylitol is not permitted in drinks.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
617	Isomaltulose	Reduced speed of digestion and absorption results in lower glycemic and insulinemic response	-isomaltulose is fully yet slowly digested and absorbed; -isomaltulose is slowly released; -isomaltulose is a slow release form of energy; -isomaltulose has a low glycemic response; -isomaltulose provides energy in form of blood glucose over a longer period of time.
	Conditions of use - A reasonable portion of this food provides at least 10g isomaltulose In cases where the claims wording refers the slow release to a longer lasting glucose supply: A reasonable portion of this food provides at least 20g isomaltulose - gem. US 21CFR§101.80: Bei Anwesenheit vergärbarer Kohlen- hydrate in der Nahrung darf der Plaque -pH infolge der bakteriellen Säurebildung während des Verzehrs und bis zu 30 min. nach der Mahlzeit nicht unter pH 5,7 absinken (Mess-methode: Plaque pH-Telem)		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
618	Polyols	Remineralisation of teeth	-promotes remineralisation of teeth when used after meals.
	Conditions of use - The food shall fulfil the conditions of a dental health claim [according to US 21CFR §101.80: the food shall not lower plaque pH below 5.7 by bacterial fermentation during consumption and up to 30 min after consumption, as determined by plaque pH telemetrie, and other comparable methods] and be consumed 3-5 times per day. - Use as a replacement of sugar; - Use as a replacement of sugar after meal;		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
619	Polyols	Low glycemic properties	- polyols induce a low glycemic response - polyols induce a low blood sugar rise (+ explanation + simplified figure of blood glucose response curves) - polyols help to regulate blood sugar levels - polyols help to maintain blood sugar levels - poyols have a lower impact on blood sugar levels than traditional product; -suitable for those following a low

			glycemic diet
	Conditions of use - Use as a replacement of sugar; - The glycemic response is not more than half that of glucose, assessed from blood glucose response curves (e.g. test food vs glucose) wither based on a portion of the food providing 50g (minimum 10g) of total carbohydrates (incl available carbohydrates and their replacements by polyols) or based on the amount of carbohydrates in one serving of the food vs the equivalent amount of glucose.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
647	ISOMALTULOSE (PALATINOSE™)	Dental health	Isomaltulose is kind to teeth; Isomaltulose inhibits glucan synthesis; Isomaltulose helps to keep teeth healthy; The isomaltulose in [name of food] helps keep teeth healthy when used between meals in place of fermentable sugars; Graphic and pictorial representations e.g. in form of pH telemetry curves.
	Conditions of use - Use instead of sugar; According to US 21CFR§101.80: ;When fermentable carbohydrates are present in the food, the food shall not lower plaque pH below 5,7 by bacterial fermentation during consumption and up to 30 min after consumption, as determined by plaque pH telemetry. - According to US 21CFR§101.80: When fermentable carbohydrates are present in the food, the food shall not lower plaque pH below 5,7 by bacterial fermentation during consumption and up to 30 min after consumption, as determined by plaque pH telemetry.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
669	ISOMALTULOSE ;(PALA-TINOSE™)	The considerably slow digestion (but total digestion), and absorption of isomaltulose (disaccharide) in comparison to that of sacharose result a lower glycaemic index and insulinemic response;	Isomaltulose is fully but slowly digested and absorbed. Isomaltulose is slowly released / Isomaltulose is a slow release form of energy / longer lasting energy. Low effect on blood glucose levels / may support fat oxidation.;
	Conditions of use - Use instead of sugar		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1182	Xylitol in candy and bakery industry products and in dairy products.	Mouth, teeth	Tooth-friendliness
	Conditions of use - Candy and bakery industry products and dairy products with a xylitol content of 0.5 g/kg of body weight recommendation. As with other sugar alcohols, the use of xylitol is not permitted in		

	drinks.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1590	Isomalt	Low glycemic properties	Isomalt induces a low glycemic and low insulinemic response Low glycemic and low insulinemic response / effect Low glycemic Isomalt induces a low blood sugar rise (+ explanation + simplified figure of blood glucose response)
	Conditions of use - keine Einschränkung (Bevölkerung allgemein). Postprandiale physiologische Reaktion auf den Verzehr eines LM; daher nicht relevant. Eintritt einer Blutglukosewirkung innerhalb der ersten Minuten für die Dauer von 1-2 Stunden. Die glykämische Wirkung des isomalthaltigen Produkts beträgt nicht mehr als die Hälfte der von Glukose, ermittelt anhand von Blutglukoseresponsekurven (z.B. Testlebensmittel vs Glukose) entweder auf Basis einer Portion, die 50g (mindestens 10g) Gesamtkohl - keine Einschränkung (Bevölkerung allgemein), Diabetiker. 30 Gramm (g). Während einer niedrig glykämischen Ernährung. Die glykämische Wirkung des isomalthaltigen Produkts beträgt nicht mehr als die Hälfte der von Glukose, ermittelt anhand von Blutglukoseresponsekurven (z.B. Testlebensmittel vs Glukose) entweder auf Basis einer Portion, die 50g (mindestens 10g) Gesamtkohl		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1591	Isomalt	Dental health - General	Used as an alternative to sugars between meals can promote dental health. Does not cause acid production and thus is kind to teeth. Safe for teeth / kind to teeth. Tooth friendly / good for teeth. Promotes dental health.
	Conditions of use - Gemäß US 21CFR§101.80: Wenn fermentierbare Kohlenhydrate in dem Lebensmittel vorhanden sind, dann soll das Lebensmittel den Plaque pH Wert nicht unter 5,7 absenken durch bakterielle Fermentation während des Verzehrs und bis zu 30 Min nach dem Verzehr, be - keine Einschränkung (Bevölkerung allgemein); mehrmals tägliches Lutschen/Kauen eines zuckerfreien (isomalthaltigen) Bonbons oder Kaugummis nach oder zwsichen den Mahlzeiten; Eintritt einer zugrundeliegenden Speicheflußstimulierung innerhalb der ersten Minuten und i.d.R. für die Dauer des Verzehrs; Höchstmenge: passives Wirkprinzip, daher nicht relevant; Das isomalthaltige Produkt sollte den Bedingungen einer Zahngesundheitsbezogenen Angabe entsprechen und nach einer Mahlzeit bzw zwischen Mahlzeiten verzehrt werden. - keine Einschränkung (Bevölkerung allgemein); Lutschen/Kauen eines zuckerfreien (isomalthaltigen) Bonbons oder Kaugummis nach oder zwsichen den Mahlzeiten; Eintritt einer Speicheflußstimulierung innerhalb der ersten Minuten und i.d.R. für die Dauer des Verzehrs; Höchstmenge: passives Wirkprinzip, daher nicht relevant; Das isomalthaltige Produkt sollte den Bedingungen einer Zahngesundheitsbezogenen Angabe entsprechen und nach einer Mahlzeit		

	bzw zwischen Mahlzeiten verzehrt werden.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1762	D- Tagatose (ingredient not found in the Spanish food laws)	Postprandial blood glucose	Helps to balance blood glucose levels (to be evaluated by EFSA)
	Conditions of use - ≤7.5 g/meal.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2903	Isomaltulose (or trademark Palatinose)	Reduced speed of digestion and absorption results in lower glycemic response	-isomaltulose is fully yet slowly digested and absorbed; -isomaltulose is slowly released; -isomaltulose is a slow release form of energy/ Longer lasting energy -Isomaltulose has a low effect on blood glucose and insulin response; low glycemic Isomaltulose provides energy in form of blood glucose over a longer period of time Low effect on blood glucose levels / supports fat oxidation This food [name of food] containing the carbohydrate Isomaltulose is low glycemic and can be part of a low glycemic diet Figures of blood glucose response curves
	Conditions of use - at least 10g per portion		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2907	Polyols	Remineralisation of teeth	- promotes remineralisation of teeth when used after meals
	Conditions of use - (US 21CFR §101.80) food shall not lower plaque pH below 5.7 by bacterial fermentation during and up to 30 minutes after consumption as determined by plaque pH telemetrie and other comparable methods and be consumed 3-5 times per day.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2908	Polyols	Low glycemic properties	- uitable for those following a low glycemic diet. -polyols induce a low glycemic and low insulinaemic response - polyols induce a low blood sugar rise (+ explanation + simplified figure of

			blood glucose response curves) - polyols help controling blood sugar and insulin levels - polyols help to maintain blood sugar levels - polyols improve blood glucose control - poyols have a lower impact on blood sugar levels than traditional product;
	Conditions of use - glycemic response is not more than half that of glucose, assessed from blood glucose response curves (e.g. test food vs glucose) eitherbased on a portion of food providing 50g (min 10g) of total carbs (available + polyols) or based on the amount of carbs in one serving of food vs equivalent amount of glucose		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2920	Isomalt	Low glycemic properties	Isomalt induces a low glycemic and low insulinemic response Low glycemic and low insulinemic response / effect Low glycemic Isomalt induces a low blood sugar rise (+ explanation + simplified figure of blood glucose response) Isomalt helps controlling blood sugar and insulin levels Isomalt can improve blood glucose control Isomalt has a lower impact on blood sugar levels than traditional products; suitable for those following a low glycemic diet. Graphic representations of blood glucose curves
	Conditions of use - Total or partial replacement of high and/or medium glycemic carbohydrates by isomalt alone or in combination with other low glycemic carbohydrates		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2921	Isomalt	Dental health - General	Used as an alternative to sugars between meals can promote dental health. Does not cause acid production and thus is kind to teeth. Safe for teeth / kind to teeth. Tooth friendly / good for teeth.

			Promotes dental health. Isomalt in [name of the food] helps keep teeth healthy when used between meals in place of sugars / fermentable carbohydrates. Graphical and pictorial representations e.g. in form of pH telemetry curves
	Conditions of use - According to US 21CFR§101.80: When fermentable carbohydrates are present in the polyol-containing food, the food shall not lower plaque pH below 5,7 by bacterial fermentation during consumption and up to 30 min after consumption, as determined by plaque pH telemetry		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4300	Name of Food product: Low Calorie Sweetener / Table-top Sweetener (Granular & tablets - sucralose based). Description of food in terms of food legislation categories: food not covered by specific food legislation. Was food on Irish market before 1st July 2007: Yes.	Health benefits of food: "intense sweeteners are not cariogenic. Intense sweeteners do not promote tooth decay. This table top sweetener is safe for teeth". Do benefits relate to a disease risk factor: No. Target group: All of the general population including children and adults.	Exact wording of claim as it appears on product: "intense sweeteners are not cariogenic". Examples of any alternative wording that may be used in relation to claim: "This low calorie sweetener does not promote tooth decay". "This table top sweetener is tooth friendly". "Splenda is tooth friendly". Is claim a picture: No.
	Conditions of use - Names of nutrient/other substances and Quantity in Average daily serving: 0.1g sucralose. Weight of average daily food serving: 1 gram. Daily amount to be consumed to produce claimed effect:1 gram. Number of food portions this equates to in everyday food portions: 2.00. Are there factors that could interfere with bioavailability: No. Length of time after consumption for claimed effect to become apparent: It is apparent immediately. Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: Yes. State the maximum limit in mg/kg body weight/day: 15.00. Potential adverse health effects: n/a - it is extremely unlikely that the consumer will exceed the ADI. (See FSAI report on intake). Describe subgroups this limit applies to: all sub-groups. Where applicable outline nutritional composition (g per 100g) of food: Total Fat: .00, Saturated Fat: .00, Trans Fat: .00, Sugar: 6.90, Salt: .00, Sodium: .00. Other conditions for use: Requires food or beverage not lower plaque pH below 5.7 by bacterial fermentation during and up to 30min after consumption as determined by pH telemetry or other similar method.		