SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to sugar-free chewing gum and dental and oral health, including gum and tooth protection and strength (ID 1149), plaque acid neutralisation (ID 1150), maintenance of tooth mineralisation (ID 1151), reduction of oral dryness (ID 1240), and maintenance of the normal body weight (ID 1152) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2]

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 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to sugar-free chewing gum and the following claimed effects: dental and oral health including gum and tooth protection and strength, plaque acid neutralisation, maintenance of tooth mineralisation, reduction of oral dryness, and maintenance or achievement of a normal body weight. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food that is the subject of the health claim is sugar-free chewing gum. The common characteristic of sugar-free chewing gums is the absence of fermentable carbohydrates. Although the composition of the gum base and sweetening agents is unspecified, the ingredients and the principles of the manufacturing process have been described. The Panel considers that sugar-free chewing gum is sufficiently characterised in relation to the claimed effects.

Dental and oral health including gum and tooth protection and strength

The Panel considers that the claimed effects "dental and oral health including gum and tooth protection and strength" is too general and non-specific and do not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

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1 On request from the European Commission, Question No EFSA-Q-2008-1890, EFSA-Q-2008-1978, EFSA-Q-2008-1888, EFSA-Q-2008-1889, EFSA-Q-2008-1891 adopted on 02 July 2009.

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For citation purposes: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to sugar-free chewing gum and dental and oral health, including gum and tooth protection and strength (ID 1149), plaque acid neutralisation (ID 1150), maintenance of tooth mineralisation (ID 1151), reduction of oral dryness (ID 1240), and maintenance of the normal body weight (ID 1152) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 on request from the European Commission. EFSA Journal 2009; 7(9):1271. [20 pp.]. doi:10.2903/j.efsa.2009.1271. Available online: www.efsa.europa.eu

Plaque acid neutralisation
The claimed effect is "to support plaque acid neutralisation". The Panel considers that plaque acid neutralisation is beneficial to human health.

On the basis of the data available, the Panel concludes that a cause and effect relationship has been established between the consumption of sugar-free chewing gum and plaque acid neutralisation. The following wording reflects the scientific evidence: "Sugar-free chewing gum helps neutralise plaque acids". In order to obtain the claimed effect, sugar-free chewing gum should be used for at least 20 minutes after eating or drinking. The target population is the general population. The use of chewing gum should be avoided in children less than three years of age due to a high choking hazard.

Maintenance of tooth mineralisation
The claimed effect is "supporting localised tooth mineralisation". In the context of the proposed wordings, the Panel notes that the claimed effect refers to the promotion of a beneficial balance between de- and remineralisation of tooth enamel and dentin. The Panel considers that maintaining tooth mineralisation is beneficial to human health.

On the basis of the data available, the Panel concludes that a cause and effect relationship has been established between the consumption of sugar-free chewing gum and maintenance of tooth mineralisation. The following wording reflects the scientific evidence: "Sugar-free chewing gum helps maintain tooth mineralization". In order to obtain the claimed effect, sugar-free chewing gum should be used for at least 20 minutes after eating or drinking. The target population is the general population. The use of chewing gum should be avoided in children less than three years of age due to a high choking hazard.

Reduction of oral dryness
The claimed effect is "reduces/improves dry mouth". In the context of the proposed wordings, the Panel notes that the claimed effect relates to the relief of symptoms owing to a lowered saliva secretion or inadequate moistening or lubrication of oral tissues. The Panel considers that reducing oral dryness is beneficial to human health.

On the basis of the data available, the Panel concludes that a cause and effect relationship has been established between the consumption of sugar-free chewing gum and reduction of oral dryness. The following wording reflects the scientific evidence: "Sugar-free chewing gum may reduce oral dryness". In order to obtain the claimed effect, sugar-free chewing gum should be used whenever mouth feels dry. The target population is the general population. The use of chewing gum should be avoided in children less than three years of age due to a high choking hazard.

Maintenance or achievement of a normal body weight
The claimed effect is "weight management". Weight management can be interpreted as the contribution to the maintenance of a normal body weight. In this context even a moderate weight loss in overweight subjects without achieving a normal body weight is considered beneficial to health. The Panel considers that the maintenance or achievement of a normal body weight is beneficial to human health.

On the basis of the data available, the Panel concludes that a cause and effect relationship has not been established between the consumption of sugar-free chewing gum and the maintenance or achievement of a normal body weight.

KEY WORDS

Sugar-free chewing gum, chewing gum, saliva, dental health, oral health, plaque acid neutralisation, dental plaque, tooth mineralisation, oral dryness, body weight, health claims.

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ACKNOWLEDGEMENTS

The European Food Safety Authority wishes to thank for the preparation of this opinion:

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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.

INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006[3] submitted by Member States contains main entry claims with corresponding conditions of use and literature from similar health claims. The information provided in the consolidated list for the health claims subject to this opinion is tabulated in appendix C.

ASSESSMENT

1. Characterisation of the food/constituent

The food that is the subject of the health claim is sugar-free chewing gum. The composition of the gum, i.e. gum base and sweetening agent, is unspecified. The characteristic components of chewing gums are the gum base, which may comprise a complex mixture of elastomers, natural and synthetic resins, fats, emulsifiers, waxes, antioxidants, and filler, and the sweetening and flavouring agents (Rømer Rassing, 1996; Imfeld, 1999). The common characteristic of sugar-free chewing gums is the absence of fermentable carbohydrates (Edgar, 1998; Ly et al., 2008). The ingredients are well characterised, can be measured by established methods, and the principles of the manufacturing process have been described (Rømer Rassing, 1996). Many ingredients in the gum base and most sweetening agents used in sugar-free chewing gums occur naturally in foods.

Gums with specific active ingredients, such as urea, carbamide or fluoride, are not included in this evaluation.

The Panel considers that the food, sugar-free chewing gum, which is the subject of the health claims, is sufficiently characterised in relation to the claimed effects.

2. Relevance of the claimed effect to human health

2.1. Dental and oral health, including gum and tooth protection and strength (ID 1149)

The claimed effects are "dental health", "oral health" and "gum and tooth protection and strength". The Panel assumes that the target population is the general population.

The claimed effects are general and non-specific and the proposed wordings ("beneficial to dental health", "safe for teeth", "promotes healthy teeth and gums", "helps protect teeth and gums", "helps to strengthen teeth and gums") do not identify any specific health claim as required by Regulation (EC) No 1924/2006.

The Panel considers that the claimed effects are general and non-specific and do not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

2.2. Plaque acid neutralisation (ID 1150)

The claimed effect is "to support plaque acid neutralisation". The Panel assumes that the target population is the general population.

Acid is produced in plaque through the fermentation of carbohydrates by acid-producing bacteria. Lowering plaque pH contributes to demineralisation of tooth tissues.

The Panel considers that plaque acid neutralisation is beneficial to human health.

[3] 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.

2.3. Maintenance of tooth mineralisation (ID 1151)

The claimed effect is "supporting localised tooth mineralisation". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel notes that the claimed effect refers to the promotion of a beneficial balance between de- and remineralisation of tooth enamel and dentin.

The Panel considers that maintaining tooth mineralisation is beneficial to human health.

2.4. Reduction of oral dryness (ID 1240)

The claimed effect is "reduces/improves dry mouth". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel notes that the claimed effect relates to the relief of symptoms owing to a lowered saliva secretion or inadequate moistening or lubrication of oral tissues. A dry mouth may lead to oral discomfort and to difficulties in swallowing and speaking.

The Panel considers that reducing oral dryness is beneficial to human health.

2.5. Maintenance or achievement of a normal body weight (ID 1152)

The claimed effect is "weight management". The Panel assumes that the target population is the general population.

Weight management can be interpreted as the contribution to the maintenance of a normal body weight. In this context even a moderate weight loss in overweight subjects without achieving a normal body weight is considered beneficial to health.

The Panel considers that the maintenance or achievement of a normal body weight is beneficial to human health.

3. Scientific substantiation of the claimed effect

Chewing and taste confer physiologic stimulation to the secretory cells of the salivary glands via autonomic nerve signalling (Anderson et al., 1998; Wong, 2008). At rest, low amounts of saliva are secreted (mean 0.2 ml/min), but chewing and taste stimulation may increase saliva flow more than 10 fold. Elevated secretion is maintained even after extended stimulation. The main component of saliva is water, with rinsing and dilution effects. Saliva also contains an array of other components (e.g. minerals, mucins and other proteins and peptides) with relevant biological functions, such as buffering of acids, bacteria regulatory effects, lubrication, or crystal formation (Screebny, 2000; Wong, 2008). The relationship between flow rate and concentrations of various saliva components varies. As flow rate increases, the concentration of calcium and bicarbonate in saliva increases, whereas the concentration of many proteins decreases significantly (Anderson et al., 1998; Wong, 2008).

Salivary factors of possible relevance for "oral health" differ between tissues. For the hard tissues (i.e., enamel, dentin), rinsing of debris, dilution, de- and remineralisation, pH neutralisation, and regulation of the bacterial community on the teeth are relevant, whereas flushing and innate immunity proteins and peptides, among others, are relevant for soft tissues (Screebny, 2000; Wong, 2008).

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 and for dentin 6.2. Buffering of acids (i.e. pH normalisation) and limiting the duration of periods of pH drop resulting from metabolic acid production by saccharolytic bacteria at carbohydrate exposure may

prevent demineralisation and promote remineralisation of the hydroxyapatite crystals. Calcium, phosphate, and fluoride in saliva, plaque fluid, and the inter-crystal water are key components for maintaining intact hydroxyapatite crystals. If appropriate concentrations of these ions are available (ionic equilibrium), demineralised crystals may re-mineralise when pH rises. Thus, any actions contributing to the ionic equilibrium may prevent demineralisation and promote remineralisation of the hydroxyapatite crystals (ten Cate et al., 2008).

In the absence of fermentable carbohydrates, no clinically relevant reduction on plaque pH may be expected by the consumption of sugar-free chewing gum (FDA, 1996; Edgar, 1998; Imfeld, 1999; Touger-Decker and van Loveren, 2003).

3.1. Plaque acid neutralisation (ID 1150)

The pH in dental plaque can be measured by established methods (Lingström et al., 1993). Saliva contains bicarbonate, phosphates and peptides, which contribute to buffering of acids (Wong, 2008). Secretion of bicarbonate increases markedly as saliva flow rate increases (Anderson et al., 1998; Wong, 2008).

The evidence provided by consensus opinions/reports from authoritative bodies, reviews and scientific original papers shows that there is good consensus on the role of chewing (e.g., a gum) in the stimulation of saliva flow and the secretion of buffering components (Edgar, 1990; Edgar, 1998; Manning and Edgar, 1993; Edgar et al., 2004; Imfeld, 1999; Anderson et al., 1998; Wong, 2008). A large number of studies confirm that chewing a sugar-free chewing gum enhances saliva flow and counteracts pH drops upon sugar-induced acid production by oral bacteria in the plaque (Nyvad, 1995; Gopinath et al., 1997; Imfeld et al., 1995; Sjögren et al., 2002; Smith et al., 2004). However, plaque pH normalisation may revert (fall again) if chewing is terminated earlier than 20 minutes after the sugar challenge (Dawes and Dibdin, 2001). Therefore, chewing for at least 20 minutes after meals may be needed to obtain the benefit of plaque pH neutralisation (Edgar and Geddes, 1990). The effect of chewing on plaque pH neutralisation will depend on the integrity of the salivary gland parenchyma and on the individual´s secretory capacity (Screebny, 2000).

The Panel concludes that a cause and effect relationship has been established between the consumption of sugar-free chewing gum and plaque acid neutralisation.

3.2. Maintenance of tooth mineralisation (ID 1151)

De- and remineralisation cannot be studied directly in animals or humans (Manning and Edgar, 1992). However, extrapolations can be made from clinical signs of net demineralisation, and from experimental studies using microradiography and/or measuring calcium release (ten Cate et al., 2008). Such studies provide a sufficient body of evidence to support that saliva stimulation by gum chewing is beneficial for tooth crystal de- and remineralisation balance (Manning et al., 1992; Manning and Edgar, 1998).

Studies in children from six years through school ages consistently show that children chewing sugar-free gums 3-5 times a day for 5-20 minutes after meals have significantly less persistent demineralisation of the tooth tissues, i.e. dental caries, than control children not chewing a gum (Mäkinen et al., 1995a, 1995b, 1996; Kandelman and Gagnon, 1990; Szöke et al., 2001; Beiswanger et al., 1998; Machiulskiene et al., 2001). These studies have been conducted in different parts of the world, including the European Union. Such studies are not available for adults or the elderly. However, *in situ* studies in adults strongly support that chewing a sugar-free gum prevents progression of demineralisation upon exposure to 10% sucrose (Kashket et al., 1989), and promotes remineralisation of artificial caries on enamel blocks worn in the mouth (Leach et al., 1989; Manning et al., 1992). One study did not find any additional remineralisation of artificial caries when sugar-free gum was chewed compared to no gum (Creanor et al., 1992) The Panel notes that, although the

vast majority of the studies presented on the effects of chewing a sugar-free gum on tooth mineralisation have been conducted in children populations, the biological plausibility for the effect applies to adult populations as well.

A further indirect support of an important role for saliva flow in the de- and remineralisation processes is that conditions where saliva is lacking or severely reduced are associated with rampant persistent tooth demineralisation (Imfeld, 1999; Screebny, 2000).

In weighing the evidence, the Panel took into account the consistent, positive results obtained in numerous clinical trials investigating the effects of sugar-free chewing gum consumption on net tooth mineralisation and the biological plausibility for the effect.

The Panel concludes that a cause and effect relationship has been established between the consumption of sugar-free chewing gum and the maintenance of tooth mineralisation.

3.3. Reduction of oral dryness (ID 1240)

The evidence provided by consensus opinions/reports from authoritative bodies, reviews, and scientific original papers shows that there is good consensus on the role of chewing (e.g., a gum) in the stimulation of saliva flow and associated secretion of salivary components (Edgar, 1990; Edgar et al., 2004; Imfeld, 1999; Anderson et al., 1998; Wong, 2008). The net effect, however, depends on the individual's secretory capacity of the salivary glands (Screebny, 2000). Increased saliva flow leads to the reduction of oral dryness.

The Panel concludes that a cause and effect relationship has been established between the consumption of sugar-free chewing gum and reduction of oral dryness.

3.4. Maintenance or achievement of a normal body weight (ID 1152)

The orosensory stimulation associated with eating is key to the development of satiation. Foods that require a greater amount of chewing, and hence are present in the mouth for longer, appear to enhance the orosensory stimulation, resulting in a greater suppression of appetite (Lavin et al., 2002) and food intake (Hetherington and Boyland, 2007). However, it is not clear whether these short term effects on food intake are maintained over time.

Copies of a petition to the United States Food and Drug Administration (FDA) by the Calorie Control Council and an acknowledgement of receipt from the FDA to the petition were provided as supporting evidence for this claim. However, this document does not appear to contain a response from FDA (Citizen Petition, 2003; FDA, 2004).

Studies cited in the petition from The Calorie Control Council evaluated effects of polyols and synthetic sweetening agents used in sugar-free products on weight maintenance as part of a complete diet-and-exercise programme (Berryman et al., 1968; Kanders et al., 1988, 1996; Blackburn et al., 1997; Morris et al., 1989; Tordoff and Alleva, 1990; Raben et al., 2002). However, sugar-free chewing gum was not directly tested in any of the cited studies. The remaining human studies contained within the petition report data on food intake and/or appetite but did not address the influence of sugar-free chewing gum on body weight and were thus not considered pertinent to the claimed effect.

Of the three papers provided in support of the claim, two related to sugar-free chewing gum and one to sugar-free pastilles. However, none of these studies considered the influence of these products on body weight and were thus not considered pertinent to support the claimed effect (Hetherington and Boyland, 2007; Levine et al., 1999, Lavin et al., 2002).

In weighing the evidence, the Panel took into account that no studies were presented on the effects of sugar-free chewing gum consumption on either body weight loss or body weight maintenance.

The Panel considers that a cause and effect relationship has not been established between the consumption of sugar-free chewing gum and the maintenance or achievement of a normal body weight.

4. Panel's comments on the proposed wordings

4.1. Plaque acid neutralisation (ID 1150)

The Panel considers that the following wording reflects the scientific evidence: "Sugar-free chewing gum helps neutralise plaque acids".

4.2. Maintenance of tooth mineralisation (ID 1151)

The Panel considers that the following wording reflects the scientific evidence: "Sugar-free chewing gum helps maintain tooth mineralization".

4.3. Reduction of oral dryness (ID 1240)

The Panel considers that the following wording reflects the scientific evidence: "Sugar-free chewing gum may reduce oral dryness".

5. Conditions and possible restrictions of use

5.1. Plaque acid neutralisation (ID 1150)

The Panel considers that, in order to obtain the claimed effect, sugar-free chewing gum should be used for at least 20 minutes after eating or drinking. The target population is the general population.

The use of chewing gum should be avoided in children less than three years of age owing to a high choking hazard.

5.2. Maintenance of tooth mineralisation (ID 1151)

The Panel considers that, in order to obtain the claimed effect, sugar-free chewing gum should be used for at least 20 minutes after eating or drinking. The target population is the general population.

The use of chewing gum should be avoided in children less than three years of age owing to a high choking hazard.

5.3. Reduction of oral dryness (ID 1240)

The Panel considers that, in order to obtain the claimed effect, sugar-free chewing gum should be used whenever mouth feels dry.

The use of chewing gum should be avoided in children less than three years of age owing to a high choking hazard.

CONCLUSIONS

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

- The food, sugar-free chewing gum, which is the subject of the health claims, is sufficiently characterised.

Dental and oral health, including gum and tooth protection and strength (ID 1149)

- The claimed effects are "dental health", "oral health", "gum and tooth protection and strength". The target population is assumed to be the general population. These claimed effects are too imprecise for a scientific evaluation.
- The Panel considers that the claimed effects are general and non-specific and do not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

Plaque acid neutralisation (ID 1150)

- The claimed effect is "to support plaque acid neutralisation". The target population is assumed to be the general population. Plaque acid neutralisation is beneficial to human health.
- A cause and effect relationship has been established between the consumption of sugar-free chewing gum and plaque acid neutralisation.
- The following wording reflects the scientific evidence: "Sugar-free chewing gum helps neutralise plaque acids".
- In order to obtain the claimed effect sugar-free chewing gum should be used for at least 20 minutes after eating or drinking.

Maintenance of tooth mineralisation (ID 1151)

- The claimed effect is "supporting localised tooth mineralisation". The target population is assumed to be the general population. Maintaining tooth mineralisation is beneficial to human health.
- A cause and effect relationship has been established between the consumption of sugar-free chewing gum and the maintenance of tooth mineralisation.
- The following wording reflects the scientific evidence: "Sugar-free chewing gum helps maintain tooth mineralization".
- In order to obtain the claimed effect sugar-free chewing gum should be used for at least 20 minutes after eating or drinking.

Reduction of oral dryness (ID 1240)

- The claimed effect is "reduces/improves dry mouth". The target population is assumed to be the general population. Reducing oral dryness is beneficial to human health.
- A cause and effect relationship has been established between the consumption of sugar-free chewing gum and reduction of oral dryness.
- The following wording reflects the scientific evidence: "Sugar-free chewing gum may reduce oral dryness".
- In order to obtain the claimed effect, sugar-free chewing gum should be used whenever the mouth feels dry.

Maintenance or achievement of a normal body weight (ID 1152)

- The claimed effect is "weight management". The target population is assumed to be the general population. Maintenance or achievement of a normal body weight is beneficial to human health.

- A cause and effect relationship has not been established between the consumption of sugar-free chewing gum and the maintenance or achievement of a normal body weight.

Conditions and possible restrictions of use

- The use of chewing gum should be avoided in children less than three years of age owing to a high choking hazard.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1890, EFSA-Q-2008-1978, EFSA-Q-2008-1888, EFSA-Q-2008-1889, EFSA-Q-2008-1891). The scientific substantiation is based on the information provided by the Members States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

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

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods[4] (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[5]

Foods are commonly involved in many different functions[6] 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.

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

[4] OJ L12, 18/01/2007
[5] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[6] The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

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 DISCAIMER

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 sugar-free chewing gum, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
1149	Sugar-free chewing gum	Dental health/ oral health, gum and tooth protection/ strength	- Beneficial to dental health; - safe for teeth; -promotes healthy teeth and gums; -helps protect teeth and gums; -helps to strengthen teeth and gums.
	Conditions of use - Use after eating or drinking.		
1150	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
	Sugar-free chewing gum	Plaque acid neutralisation	- Helps stop plaque acid attacks; - neutralises plaque acids; - restores optimum pH levels in the mouth.
	Conditions of use - Use after eating or drinking. - Zuckerfrei, Kauen nach dem Essen oder zwischen den Mahlzeiten.		
1151	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
	Sugar-free chewing gum	Localised tooth mineralisation (non-systemic)	- Helps increase tooth surface hardness; - helps rebuild the enamel; - helps protect against early damage to tooth enamel; - increases saliva flow to help remineralise tooth enamel.
	Conditions of use - Use after eating or drinking.		
1152	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
	Sugar-free chewing gum containing polyols	Beneficial for weight management	- Sugar-free chewing gum may be useful in weight management; - sugar-free chewing gum helps maintain your body weight (as part of a calorie controlled diet); - chewing gum helps to reduce appetite or hunger.
	Conditions of use - Use after eating or between meals. - Use in place of snacking. - Use before eating.		

	Food or Food constituent	Health Relationship	Proposed wording
1240	Sugar-free chewing gum	Dry Mouth (Reduces/ Improves Dry Mouth)	- Reduces dry mouth; - moistens the mouth; - reduces oral dryness.
	Conditions of use - Chew one portion for 20 minutes when mouth feels dry.		