SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to sugar-free chewing gum sweetened with xylitol and plaque acid neutralisation (ID 485), maintenance of tooth mineralisation (ID 486, 562, 1181), reduction of dental plaque (ID 485, 3085), and defence against pathogens in the middle ear (ID 561, 1180) 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 sugar-free chewing gum sweetened with xylitol and plaque acid neutralisation, maintenance of tooth mineralisation, reduction of dental plaque, and defence against pathogens in the middle ear. 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 claims is sugar-free chewing gum sweetened with xylitol. The Panel considers that sugar-free chewing gum sweetened with xylitol is sufficiently characterised in relation to the claimed effects.

Plaque acid neutralisation

The claimed effect is "plaque reduction". The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effect refers

[1] On request from the European Commission, Question No EFSA-Q-2008-1272, EFSA-Q-2008-1273, EFSA-Q-2008-1348, EFSA-Q-2008-1349, EFSA-Q-2008-1919, EFSA-Q-2008-1920, EFSA-Q-2008-3817, adopted on 25 March 2011.

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[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.

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to plaque acid neutralisation. The Panel considers that plaque acid neutralisation is a beneficial physiological effect.

A claim on sugar-free chewing gum and plaque acid neutralisation has already been assessed with a favourable outcome. The Panel considers that the scientific substantiation and proposed conditions of use also apply to sugar-free chewing gum sweetened with xylitol.

Maintenance of tooth mineralisation

The claimed effects are "mouth, teeth" and "tooth remineralisation". The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the promotion of a beneficial balance between de- and remineralisation of tooth enamel and dentin. Maintenance of tooth mineralisation is a beneficial physiological effect.

A claim on sugar-free chewing gum and maintenance of tooth mineralisation has already been assessed with a favourable outcome. The Panel considers that the scientific substantiation and proposed conditions of use also apply to sugar-free chewing gum sweetened with xylitol.

Reduction of dental plaque

The claimed effects are "plaque reduction" and "plaque formation". The target population is assumed to be the general population. Reduction of dental plaque may be a beneficial physiological effect.

A claim on sugar-free chewing gum and reduction of dental plaque has already been assessed with an unfavourable outcome. The Panel considers that the scientific substantiation of the claimed effect also applies to sugar-free chewing gum sweetened with xylitol. The references cited for this claim did not provide any additional scientific data which could be used to substantiate the claim.

Defence against pathogens in the middle ear

The claimed effect is "ears". The target population is assumed to be the general population. In the context of the proposed wordings, clarifications from Member States and references provided, the Panel assumes that the claimed effect refers to defence against pathogens (i.e. *Streptococcus pneumoniae*) in the middle ear. The Panel considers that defence against pathogens (i.e. *Streptococcus pneumoniae*) in the middle ear is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that two intervention studies in healthy children showed an effect of xylitol-sweetened chewing gum chewed five times a day on acute otitis media in healthy children, that two additional studies did not show an effect of xylitol-sweetened chewing gum on acute otitis media in children with acute respiratory infections, or when consumed three times daily, and that the evidence provided did not show an effect of xylitol-sweetened chewing gum on *Streptococcus pneumoniae* carrier rate. The Panel notes that the results from the intervention studies are inconsistent, and that no evidence of a mechanism by which xylitol-sweetened chewing gum could exert the claimed effect has been provided.

On the basis of the data presented, the Panel concludes that the evidence provided is insufficient to establish a cause and effect relationship between the use of sugar-free chewing gum sweetened with xylitol and defence against pathogens (i.e. *Streptococcus pneumoniae*) in the middle ear.

KEY WORDS

Xylitol, chewing gum, plaque acid, tooth mineralisation, dental plaque, pathogens, ear, health claims.

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006[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 foods/food constituents that are the subject of the health claims are "xylitol-sweetened chewing gum", "sugar-free chewing gum with xylitol" and "xylitol". From the information provided, including the conditions of use and the references submitted for the scientific substantiation of the claims, the Panel assumes that the food, which is the subject of the health claim, is sugar-free chewing gum sweetened with xylitol, either alone or in combination with other polyols.

The composition of the gum, i.e. the gum base, 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, together with sweetening and flavouring agents (Imfeld, 1999; Rassing, 1996). 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 (Rassing, 1996). Many of the ingredients in the gum base, and most of the sweetening agents used in sugar-free chewing gums, occur naturally in foods.

Xylitol is a well characterised sugar alcohol which occurs naturally in foods. It can be measured by established methods and its manufacturing processes are also well established.

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

2. Relevance of the claimed effect to human health

2.1. Plaque acid neutralisation (ID 485)

The claimed effect is "plaque reduction". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to plaque acid neutralisation.

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

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

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 a beneficial physiological effect.

2.2. Maintenance of tooth mineralisation (ID 486, 562, 1181)

The claimed effects are "mouth, teeth" and "tooth remineralisation". The Panel assumes that the target population is the general population.

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

The Panel considers that maintenance of tooth mineralisation is a beneficial physiological effect.

2.3. Reduction of dental plaque (ID 485, 3085)

The claimed effects are "plaque reduction" and "plaque formation". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the reduction of dental plaque.

Dental plaque is found on the tooth surface, and consists of a biofilm of microorganisms embedded in a matrix of polymers of host and bacterial origin. Plaque can also become mineralised and form calculus (tartar), a form of hardened dental plaque which provides an ideal medium for further plaque formation. Fermentation of carbohydrates in the mouth by oral bacteria increases the formation of a type of dental plaque that may contribute to dental caries, as well as increase the proportion of cariogenic bacteria in the plaque (Marsh and Nyvad, 2008). Dental plaque can exert adverse effects on dental health (e.g. in relation to approximal caries, gingivitis and periodontitis) when it occurs at sites such as the cervical third, interdentally below the approximal contact point between teeth, along the gingival margin, and in the fissures and pits of the teeth. "Plaque formation" is usually not measured in clinical or *in situ* studies, but rather the amount of plaque (or "net" plaque formation).

The Panel considers that reduction of dental plaque may be a beneficial physiological effect.

2.4. Defence against pathogens in the middle ear (ID 561, 1180)

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

In the context of the proposed wordings, clarifications from Member States and references provided, the Panel assumes that the claimed effect refers to defence against pathogens (i.e. *Streptococcus pneumoniae*) in the middle ear.

The Panel considers that defence against pathogens (i.e. *S. pneumoniae*) in the middle ear is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

3.1. Plaque acid neutralisation (ID 485)

A claim on sugar-free chewing gum and plaque acid neutralisation has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009). The

Panel considers that the scientific substantiation and proposed conditions of use also apply to sugar-free chewing gum sweetened with xylitol.

3.2. Maintenance of tooth mineralisation (ID 486, 562, 1181)

A claim on sugar-free chewing gum and maintenance of tooth mineralisation has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009). The Panel considers that the scientific substantiation and proposed conditions of use, also apply to sugar-free chewing gum sweetened with xylitol.

3.3. Reduction of dental plaque (ID 485, 3085)

A claim on sugar-free chewing gum and reduction of dental plaque has already been assessed with an unfavourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010). The Panel considers that the scientific substantiation of the claim also applies to sugar-free chewing gum sweetened with xylitol. The references cited for this claim did not provide any additional scientific data which could be used to substantiate the claim.

3.4. Defence against pathogens in the middle ear (ID 561, 1180)

In one randomised, double-blind, placebo-controlled intervention study the effect of xylitol administered in chewing gum on otitis media and carrier rate of *S. pneumoniae* was studied in 336 children (mean age 4.9 years) with recurrent acute otitis media (Uhari et al., 1996). Children were randomised to chew two pieces of xylitol chewing gum (8.4 g per day) or sucrose chewing gum (control), five times a day, after meals for two months. The chewing lasted until there was no taste left or for at least five minutes. Nasopharyngeal samples were taken at baseline, at two weeks and at the end of the intervention. Parents were asked to complete a symptom sheet to record the time and reasons for being absent from school, additional xylitol products consumed and medications taken. At any physician's appointment, physicians were asked to record diagnosis and medications prescribed. The criteria for diagnosis of acute otitis media (AOM) were symptoms and signs of acute respiratory infection, and simultaneous signs of middle ear effusion, cloudy tympanic membrane or impaired tympanic membrane motility in pneumatic otoscopy. As the sample size required to observe a clinically significant effect on *S. pneumoniae* carrier rate was greater than that required for occurrence of AOM, sample size calculations were based on carrier rates. Considering a carrier rate of 30 % in the study population, 152 subjects per group were needed to reduce the carrier rate to 15 %, with a power of 90 % and a two-tailed p value of 0.05. A total of 30 children dropped out from the study. No reasons for withdrawal were reported. Statistical analyses were performed in the sample of completers (157 in the xylitol chewing gum group and 149 in the control group). No significant differences were observed between groups with respect to the number of upper respiratory tract infections without complications, the duration of any symptom of infection or the pneumococcal carrier rate during the study. The total number of AOM in the xylitol group was 22/157 compared to 43/149 in the control group (relative risk (RR)=0.49, 95 % CI 0.31-0.77). The number of children with at least one episode of AOM was 19/157 (12.1 %) in the xylitol group compared to 31/149 (20.8 %) in the control group (8.7 % difference; 95 % CI 0.4-17 %, p=0.040, relative risk=0.58, 95 % CI 0.34-0.98). The Panel notes that this study shows an effect of xylitol chewing gum use on the incidence of AOM compared to sugar-sweetened chewing gum.

In the randomised, double-blind, placebo-controlled intervention study by Uhari et al. (1998), 857 healthy children were recruited from day care centres, and randomised to one of five intervention groups: control syrup (n=165), xylitol syrup (n=159), control (sugar-sweetened) chewing gum (n=178), xylitol sweetened-chewing gum (n=179) or xylitol lozenges (n=176). The intervention lasted three months and the trial was blinded within the chewing gum and syrup groups. The design, the

protocol for administration of the chewing gums, the daily doses of xylitol, and the diagnosis of AOM were the same as those reported in the study by Uhari et al. (1996). The primary outcome of the study was occurrence of AOM. It was calculated that a total of 150 subjects per group were needed to observe a decrease of 30 % in the occurrence of AOM, with a power of 80 % and a p value of 0.05. A total of 46 children dropped out from the lozenge and the chewing gum groups, twice as many in the lozenge group, but the exact number of drop-outs per group is not reported. Statistical analyses were performed in the sample of completers. The total number of AOM in the xylitol group was 44 (incidence rate 1.04) compared to 72 (incidence rate 1.69) in the control group (difference=0.65, 95 % CI 0.14-1.16, p=0.012). The Panel notes that the RR for the intention-to-treat analysis was 0.61 (95 % CI 0.45-0.84). At least one episode of AOM occurred in 29 children in the xylitol chewing gum group (16 %) and in 39 children receiving the control gum (28 %). The difference was statistically significant (95 % CI 10-71 %; p=0.025). The Panel notes that the RR of having at least one AOM in an intention-to-treat analysis is 0.60 (95 % CI 0.40-0.90). The Panel notes that this study showed an effect of xylitol chewing gum use on the incidence of AOM compared to sugar-sweetened chewing gum.

A recently published systematic review of randomised controlled trials on the use of xylitol in the prevention of AOM in children (Danhauer et al., 2010) identified four publications which met the inclusion criteria (Hautalahti et al., 2007; Tapiainen et al., 2002; Uhari et al., 1996; 1998). All the studies were carried out by the same research group in Oulu (Finland). The authors considered that only the studies by Uhari et al. (1996; 1998) were sufficiently homogeneous to be combined in a meta-analysis. The reasons for not including the studies by Hautalahti et al. (2007) and Tapiainen et al. (2002) in the meta-analysis were that xylitol-sweetened chewing gum was administered at the same doses but only three times daily (Hautalahti et al., 2007), and that xylitol-sweetened chewing gum was administered to children at the onset of an acute respiratory infection (ARI) only (Tapiainen et al., 2002). The Panel considers that the meta-analysis of only two studies, already considered separately in this opinion, does not provide additional information on which further conclusions can be drawn for the scientific substantiation of the claim.

In the randomised, double-blind, placebo-controlled intervention study by Tapiainen et al. (2002), 1,277 healthy children were recruited and randomised to receive either control mixture (n=212), xylitol mixture (n=212), control chewing gum (n=280), xylitol chewing gum (n=286) or xylitol lozenges (n=287) at the onset and during an ARI. The trial was randomised and double blinded within the chewing gum and mixture groups. The design, the protocol for administration of the chewing gums, the daily doses of xylitol, and the diagnosis of AOM were the same as in the study by Uhari et al. (1996). The follow-up lasted until resolution of the infection, or up to three weeks. Sample size calculations were based on the occurrence of ARI and AOM in previous trials. A total of 274 subjects in each group which received the chewing gum were needed to observe a 45 % reduction in AOM, with a power of 80 % and a p value of 0.05. Statistical analyses were performed in the sample of completers (277 in the xylitol chewing gum group and 277 in the control group). A total of 980 subjects (78 %) experienced ARI and visited the study clinic. The proportion of children with ARI was not different between groups. AOM was diagnosed in 24 (8.7 %) of the children in the control chewing gum group and in 31 (11.2 %) of the children in the xylitol chewing gum group (i.e. in 24 (11.0 %) of 218 children and in 31 (14.1 %) of 220 children who had an ARI, in the control and xylitol chewing gum groups, respectively). None of the differences were statistically significant. The Panel notes that this study does not show an effect of xylitol chewing gum use on AOM in children with an ARI compared to sugar-sweetened chewing gum.

In the randomised, double-blind, placebo-controlled intervention study by Hautalahti et al. (2007), 663 healthy children aged 7 months to 7 years were recruited and randomised to receive either control product (n=331), as a sugar sweetened control chewing gum (n=274) or as a control mixture (n=57), or xylitol (n=332), as xylitol chewing gum (n=272) given three times a day after meals (daily dose 9.6 g) or as a xylitol mixture (n=60), for three months. The trial was randomised and double blinded

within the chewing gum and mixture groups, but results are provided only for control and xylitol groups combined. The primary outcome of the study was occurrence of AOM. It was calculated that a total of 244 subjects per group were needed to observe a decrease of 30 % in the occurrence of AOM, with a power of 80 % and a p value of 0.05, assuming that 40 % of children would have at least one episode of AOM in the three months. A total of 38 children (11 %) dropped out in the control group and 58 (17 %) in the intervention group. The most important reason for dropping out was refusal to take the mixture or the gum. At least one episode of AOM occurred in 94 children taking a xylitol product (28 %) and in 98 (30 %) taking a control product, the total number of episodes being 156 and 142, respectively. The incidence rate of AOM per ARI was 2.1 in the xylitol group and 1.8 in the control group. Differences between groups were not statistically significant for any of these variables. The Panel notes that this study does not show an effect of xylitol chewing gum use on the occurrence of AOM in children compared to sugar-sweetened chewing gum.

In weighing the evidence, the Panel took into account that two intervention studies in healthy children showed an effect of xylitol-sweetened chewing gum chewed five times a day on AOM in healthy children (Uhari et al., 1996; 1998), that two additional studies did not show an effect of xylitol-sweetened chewing gum on AOM in children with ARI (Tapiainen et al., 2002), or when consumed three times daily (Hautalahti et al., 2007), and that the evidence provided did not show an effect of xylitol-sweetened chewing gum on *S. pneumoniae* carrier rate (Uhari et al., 1996). The Panel notes that the results from the intervention studies are inconsistent, and that no evidence of a mechanism by which xylitol-sweetened chewing gum could exert the claimed effect has been provided.

The Panel concludes that the evidence provided is insufficient to establish a cause and effect relationship between the use of sugar-free chewing gum sweetened with xylitol and defence against pathogens (i.e. *S. pneumoniae*) in the middle ear.

CONCLUSIONS

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

- The food, sugar-free chewing gum sweetened with xylitol, which is the subject of the health claims, is sufficiently characterised in relation to the claimed effects.

Plaque acid neutralisation (ID 485)

- The claimed effect is "plaque reduction". The target population is assumed to be the general population. Plaque acid neutralisation is a beneficial physiological effect.

- A claim on sugar-free chewing gum and plaque acid neutralisation has already been assessed with a favourable outcome. The scientific substantiation and proposed conditions of use also apply to sugar-free chewing gum sweetened with xylitol.

Maintenance of tooth mineralisation (ID 486, 562, 1181)

- The claimed effects are "mouth, teeth" and "tooth remineralisation". The target population is assumed to be the general population. Maintenance of tooth mineralisation is a beneficial physiological effect.

- A claim on sugar-free chewing gum and maintenance of tooth mineralisation has already been assessed with a favourable outcome. The scientific substantiation and proposed conditions of use also apply to sugar-free chewing gum sweetened with xylitol.

Reduction of dental plaque (ID 485, 3085)

- The claimed effects are "plaque reduction" and "plaque formation". The target population is assumed to be the general population. Reduction of dental plaque may be a beneficial physiological effect.

- A claim on sugar-free chewing gum and reduction of dental plaque has already been assessed with an unfavourable outcome. The scientific substantiation of the claim also applies to sugar-free chewing gum sweetened with xylitol. The references cited for this claim did not provide any additional scientific data which could be used to substantiate the claim.

Defence against pathogens in the middle ear (ID 561, 1180)

- The claimed effect is "ears". The target population is assumed to be the general population. In the context of the proposed wordings, clarifications from Member States and references provided, it is assumed that the claimed effect refers to defence against pathogens (i.e. *Streptococcus pneumoniae*) in the middle ear. Defence against pathogens (i.e. *Streptococcus pneumoniae*) in the middle ear is a beneficial physiological effect.

- The evidence provided is insufficient to establish a cause and effect relationship between the use of sugar-free chewing gum sweetened with xylitol and defence against pathogens (i.e. *Streptococcus pneumoniae*) in the middle ear.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1272, EFSA-Q-2008-1273, EFSA-Q-2008-1348, EFSA-Q-2008-1349, EFSA-Q-2008-1919, EFSA-Q-2008-1920, EFSA-Q-2008-3817). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

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

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods[6] (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[7]

Foods are commonly involved in many different functions[8] of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

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

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

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

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

(a) the claimed effect of the food is beneficial for human health,

(b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),

(c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,

(d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

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

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

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

WORDING OF HEALTH CLAIMS

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

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

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

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

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

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

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

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

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

TERMS OF REFERENCE

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

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

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

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

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity

consumed.

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

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

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

APPENDIX B

EFSA DISCLAIMER

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

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

APPENDIX C

Table 1. Main entry health claims related to sugar-free chewing gum sweetened with xylitol, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
485	Xylitol	Plaque reduction	Xylitol helps reduce plaque formation Xylitol helps neutralize plaque acids Xylitol helps protect teeth against the formation of plaque
	Conditions of use - Chewing gum with 46-77g/100g, 500-600mg/piece or 500-860mg/piece or 1020mg/piece of xylitol. Lozenges with 90-96g/100g, 540-580mg/piece of xylitol. Analysis of the end product shows that xylitol is well-retained. - 1-2g/3-5 times/day - Chewing gum with 35-45% xylitol, 2 pieces 3-5 times per day. The product may not contain sugars capable of fermentation and other Finnish Dental Association recommendations must be fulfilled."		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
486	Xylitol	Tooth remineralisation	Xylitol enhances tooth remineralisation
	Conditions of use - 1-2g/3-5 times/day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
561	Xylitol-sweetened chewing gum	Ears Clarification provided Ears Clarification: Inhibits the absorption of cholesterol. Heart Health and artery health	Xylitol is good for the health of ears. Maintains good health of the ears.
	Conditions of use - Chewing gums with 65% xylitol. 2 pieces3-5 times per day. The product may not contain sugars capable of fermentation and the requirements for other Finnish Dental Association recommendations must be fulfilled.		
	Comments from Member States Sub claim ref.nr 60939 has been wrongly placed under the claim ID 561. There is a separate claim ID 1180 for Xylitol sweetened chewing gum, where the subclaim ref.nr 60939 is already mentioned. Clarification related to claim ID 1180 has already been sent from Finland at the end of May. The other claims under ID 561 relate to plant stanol esters or phytosterols. The Finnish economical operator is of the opinion that subclaim ref.no 60848 shall be considered as a main claim. Ii should NOT be placed as a subclaim to any other proposed plant stanol ester claim.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
562	Xylitol-sweetened chewing gum	Mouth, teeth	Repairs initial enamel damage (demineralisation)

	Conditions of use - Chewing gum with 35-45% xylitol, 2 pieces 3-5 times per day. The product may not contain sugars capable of fermentation and other Finnish Dental Association recommendations must be fulfilled. - Chewing gum with 65% xylitol, 2 pieces 3-5 times per day. The claim is linked to regular use. The product may not contain sugars capable of fermentation and other Finnish Dental Association recommendations must be fulfilled.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1180	Xylitol-sweetened chewing gum	Ears Clarification provided Xylitol promotes ear health by helping to limit the adherance of Steptococcus pneumoniae / ear infection bacteria Xylitol promotes ear health by helping to limit the growth of *Steptococcus pneumoniae* / ear infection bacteria Xylitol helps to limit the amount of ear infection bacteria Comment of the operator: The original claim was too vague but in this case it´s difficult to change it more precise, but in the same time not making it medical.	Xylitol is good for the health of ears. Maintains good health of the ears.
	Conditions of use - Chewing gums with 65% xylitol. 2 pieces3-5 times per day. The product may not contain sugars capable of fermentation and the requirements for other Finnish Dental Association recommendations must be fulfilled.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1181	Xylitol-sweetened chewing gum	Mouth, teeth	Repairs initial enamel damage (demineralisation)
	Conditions of use - Chewing gum with 46-77g/100g, 500-600mg/piece or 500-860mg/piece or 1020mg/piece of xylitol. Lozenges with 90-96g/100g, 540-580mg/piece of xylitol. Analysis of the end product shows that xylitol is well-retained. - Chewing gum with 35-45% xylitol, 2 pieces 3-5 times per day. The product may not contain sugars capable of fermentation and other Finnish Dental Association recommendations must be fulfilled. - Chewing gum with 65% xylitol, 2 pieces 3-5 times per day. The claim is linked to regular use. The product may not contain sugars capable of fermentation and other Finnish Dental Association recommendations must be fulfilled.		

ID	Food or Food constituent	Health Relationship	Proposed wording
3085	Sugar-free chewing gum with Xylitol	Plaque formation (Xylitol is not metabolised by bacteria that can lead to plaque growth)	- works against the formation of plaque and tartar; - keep plaque at bay; - helps counter the plaque formation thereby keeping teeth and gums in normal healthy conditions; - works against plaque
	Conditions of use - Use after eating or drinking		

GLOSSARY AND ABBREVIATIONS

AOM	Acute otitis media
ARI	Acute respiratory infection
CI	Confidence interval
RR	Relative risk