European Food Safety Authority

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SCIENTIFIC OPINION

Xylitol chewing gum/pastilles and reduction of the risk of tooth decay

Scientific substantiation of a health claim related to xylitol chewing gum/pastilles and reduction the risk of tooth decay pursuant to Article 14 of Regulation (EC) No 1924/2006[1]

Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies

(Question No EFSA-Q-2008-321)

Adopted on 30 October 2008 by written procedure

PANEL MEMBERS

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SUMMARY

Following an application from LEAF Int, Leaf Holland and Leaf Suomi Oy submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of Finland, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to xylitol chewing gum/pastilles and reduction of the risk of tooth decay.

The scope of the application was proposed to fall under a health claim referring to disease risk reduction.

The present health claim refers to chewing gum sweetened with 100% xylitol and pastilles sweetened with at least 56% xylitol, for which full description of the manufacturing process and stability information are provided. The Panel considers that chewing gum sweetened with 100% xylitol and pastilles sweetened with at least 56% xylitol are sufficiently characterised.

The claimed effect 'reduces the risk of tooth decay' relates to reduction of dental caries development. The target population is the general population. The Panel considers that reducing the risk of tooth decay is beneficial to health.

[1] For citation purposes: Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies on a request from LEAF Int, Leaf Holland and Leaf Suomi Oy on the scientific substantiation of a health claim related to xylitol chewing gum/pastilles and reduce the risk of tooth decay. *The EFSA Journal* (2008) 852, 1-16

The applicant has identified 31 publications reporting human intervention studies, two reporting human observational studies, one systematic review and 16 other review publications as being pertinent to the health claim under evaluation. The Panel considers that the health claim under evaluation, i.e 'xylitol chewing gum/pastilles might reduce the risk of development of caries', implies that habitual intake of chewing gum/pastilles with xylitol may reduce the risk of developing dental caries when added to the usual diet. This evaluation considers only the effects of chewing gums sweetened with 100% xylitol and of pastilles/candies sweetened with at least 56% xylitol as compared to no treatment.

Five studies have been presented investigating the effects of chewing gums sweetened with 100% xylitol as compared to no treatment in children. Most studies consistently report significantly less caries increment from baseline measured as decayed, missing and filled surfaces (DMFS) in the intervention group than in controls. The Panel notes some limitations in the studies presented: the studies were not fully randomised for practical reasons (concealed allocation was used in most cases), nor were sufficiently controlled for confounders that could potentially have affected the outcome (e.g., background diet and standard caries preventive measures were not fully assessed and reported). For one study only the per protocol analysis was presented and direct comparison between the chewing gum sweetened with 100% xylitol and the control groups was not reported. Nevertheless, considering the high number of studies, subjects and observation years presented, as well as the consistency of the results and the magnitude of the effect, the Panel considers that a cause and effect relationship has been established between the consumption of chewing gum sweetened with 100% xylitol and the reduction of the risk of tooth decay in children.

Three studies are presented on the effects of pastilles sweetened with at least 56% xylitol on caries incidence rate. Two of the studies report significantly less caries increment from baseline measured as DMFS in the intervention group than in controls. However, the Panel considers that the weaknesses of these studies (e.g., no direct comparison between the pastilles groups and controls in one study, lack of randomisation in the other, and insufficient control for confounders that could potentially have affected the outcome in both studies) greatly limit their value as a source of data to substantiate the claimed effect. In the third study, no differences between intervention and control groups in caries incidence rate were observed at the end of the intervention. The Panel considers that a cause and effect relationship between the consumption of pastilles sweetened with at least 56% xylitol and a reduction on the risk of tooth decay has not been established.

The following wording reflects the scientific evidence: "xylitol chewing gum reduces the risk of caries in children".

The scientific justification of the claim is related to the consumption of 2-3g of chewing gum sweetened with 100% xylitol at least three times per day after meals. This quantity of chewing gum sweetened with 100%xylitol can easily be consumed as part of a balanced diet.

There is a risk of osmotic diarrhoea at excessive intakes of xylitol. The use of chewing gum should be avoided in children less than three years of age owing to a high choking hazard of chewing gum in this age group.

Key words: Xylitol, chewing gum, pastilles, caries risk, tooth decay, adults, children

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BACKGROUND

Regulation (EC) No 1924/2006[2] harmonises the provisions that relate to nutrition and health claims and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of that Regulation and are authorised in accordance with this Regulation and included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Articles 14 to 17 of that Regulation lay down provisions for the authorisation and subsequent inclusion of reduction of disease risk claims and claims referring to children's development and health in a Community list of permitted claims.

According to Article 15 of that Regulation, an application for authorisation shall be submitted by the applicant to the national competent authority of a Member State, who will make the application and any supplementary information supplied by the applicant available to European Food Safety Authority (EFSA).

Steps taken by EFSA:

- The application was received on 05/05/2008.
- The scope of the application was proposed to fall under a health claim referring to disease risk reduction.
- During the check for completeness[3] of the application, the applicant was requested to provide missing information on 16/05/2008.
- The applicant provided the missing information on 05/06/2008.
- The application was considered valid by EFSA and the scientific evaluation procedure started on 15/06/2008.
- On 30/10/2008 the NDA Panel, after having evaluated the overall data submitted, adopted by written procedure an opinion on the scientific substantiation of a health claim related to xylitol chewing gum/pastilles and reduce the risk of tooth decay.

TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16 of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to: xylitol chewing gum/pastilles and reduce the risk of tooth decay.

EFSA DISCLAIMER

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

[2] European Parliament and Council (2006). 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. Official Journal of the European Union OJ L 404, 30.12.2006. Corrigendum OJ L 12, 18.1.2007, p. 3–18.

[3] In accordance with EFSA "Scientific and Technical guidance for the Preparation and Presentation of the Application for Authorisation of a Health Claim"

It should also be highlighted that the scope, the proposed wording of the claim and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 17 of Regulation (EC) No 1924/2006.

ACKNOWLEDGEMENTS

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1. Information provided by the applicant

Applicant's name and address: LEAF Int and Leaf Holland, Hoevestein 26, 4903 SC Oosterhout NB, The Netherlands; Leaf Suomi Oy, P.O. Box 25, FI-21381 Aura, Finland.

The application includes a request for the protection of proprietary data.

1.1. Food/constituent as stated by the applicant

The food products "chewing gum sweetened by 100% xylitol and pastilles sweetened with at least 56% xylitol" are claimed to reduce caries development.

The base of the applicant's chewing gum consists of gum, resin, emulsifier, other unspecified, ingredients, xylitol and flavourings. Gums are coated with sweeteners, flavourings and colouring agents. Pastilles are made of a body of syrup (origin unspecified), xylitol and other additives, a coating of fat, xylitol, and gum arabicum with lycasin, and a glazing of carnauba wax. Manufacturing of sweetened pastilles complies to ISO 9001:2000 management standards.

Xylitol is described as a five-carbon sugar alcohol (polyol) with a flavour similar to sucrose. It is a normal sugar in human metabolism (found in the pentose shunt of the Kreb's cycle) and of many plants, e.g. berries, fruits, vegetables, the woody fibres of birch tree bark and corn cobs. Xylitol is manufactured from natural xylan-rich sources of the birch tree bark. Briefly, xylan is extracted from birch wood pulp, and extracted liquid sugar is converted to crystalline xylitol.

1.2. Health relationship as claimed by the applicant

Chewing gum with 100% xylitol and pastilles sweetened with at least 56% xylitol are the foods claimed for and "dental caries" the human disease.

1.3. Wording of the health claim as proposed by the applicant

Xylitol chewing gum/pastilles reduces the risk of caries**.**

1.4. Specific conditions of use as proposed by the applicant

The applicant claims that systematic use of a chewing gum sweetened with 100% xylitol or pastilles sweetened with a minimum of 56% xylitol is associated with reduced risk to develop caries if targeted to the entire population. For children it is proposed that use of xylitol should be started at least 1 year before the permanent teeth erupt to maximize long-term caries prevention. To bring an additional reduction on caries development, the applicant proposes a daily intake of 5 to 10 g of xylitol divided into 5-6 pieces of 100% xylitol sweetened chewing gum or 8 pieces of 56% xylitol sweetened pastilles. The applicant emphasizes that a high proportion of xylitol, like in the proposed products, is crucial to achieve the efficient effect of lowered caries risk with feasible daily portions.

Xylitol is considered safe as a sweetener in any category of the population. In accordance with Directive 94/35/EC of European Parliament, where no maximum level of xylitol is specified (*"quantum satis"),* the applicant states that there are no risk groups for xylitol exposure even in a life time perspective. The applicant describes the known laxative effect at extensive intake of xylitol, but states that the proposed intake is not associated with osmotic diarrhoea.

2. Assessment

2.1. Characterisation of the food/constituent

The present health claim refers to chewing gum sweetened with 100% xylitol and pastilles sweetened with at least 56% xylitol. Xylitol is a well-defined component (5-carbon sugar alcohol) used for sugar substitution in sweet food products. It is measurable in foods by established methods. Xylitol is approved by Directive 94/35/EC for unrestricted use. The applicant manufactures chewing gum sweetened with 100% xylitol and pastilles sweetened with at least 56% xylitol for which complete specifications, full description of the manufacturing process and stability information are provided. Maltitol (approx. 38%) and sorbitol (approx. 6%) are the additional sweeteners contained in the pastilles. Even if the present evaluation will apply to all appropriate xylitol-containing chewing gums and pastilles in the specified amounts, it is noted that the majority of studies presented on xylitol-containing chewing gum (the Ylivieska study and the Belize study) and all the studies presented on xylitol-containing pastilles and considered as pertinent to the health claim have been conducted using the products supplied by the applicant.

The Panel considers that the foods subject of the health claim (i.e., chewing gum sweetened with 100% xylitol and pastilles sweetened with at least 56% xylitol) are sufficiently characterised.

2.2. Relevance of the claimed effect to human health

The claimed effect 'reduces the risk of tooth decay' relates to reduction of dental caries development. The target population is the general population. The applicant states that the application focuses on studies with dental caries as primary end point, and that although studies on the risk factors "number of mutans streptococci" and "amount of plaque" are also presented, these are not the primary outcome.

Dental caries is a disease with a high prevalence in the EU. Dietary factors may influence the development of dental caries.

The Panel considers that the claimed effect i.e., reducing the risk of tooth decay, is beneficial to health.

2.3. Scientific substantiation of the claimed effect

The applicant states to have performed a literature search on 2 November 2007 through PubMed (MEDLINE) using the key terms xylitol AND caries. Inclusion criteria were human clinical trials, randomised controlled trials, meta-analyses, reviews and practical guidelines. The goal of the literature search was to identify all clinical data concerning xylitol and dental decay. Exclusion criteria used in the selection of pertinent publications were another therapeutic area, another treatment of caries than xylitol, xylitol not as individual treatment, too general content or an article only replicating results from original articles. All publications reporting a follow-up of the initial studies were searched by hand. Besides caries studies, the applicant included all studies on *Streptococcus mutans* and dental plaque if there were follow-ups of the initial studies. The applicant has focused the scientific substantiation of the health claim to human intervention studies.

Following the above strategy, the applicant has identified 31 publications reporting human intervention studies, two reporting human observational studies, one systematic review and 16 other review publications as being pertinent to the health claim under evaluation. The Panel considers that the health claim under evaluation, i.e., 'xylitol chewing gum/pastilles might

reduce the risk of development of caries', implies that habitual intake of chewing gum/pastilles with xylitol may reduce the risk of developing dental caries when added to the usual diet, and therefore studies/intervention arms assessing: a) the effects of xylitol-containing food matrices other than chewing gum or pastilles/candies; b) the effects of either xylitol chewing gums or xylitol pastilles/candies as compared to sugars, to sugars-containing products (e.g., sucrose, fructose), to chewing gums containing other polyols than xylitol, to base gum (unsweetened), or to other caries-preventive measures (e.g., teeth brushing, sealants), or c) the effects of chewing gums containing other polyols than xylitol as compared to either sugars/sugars-containing products, control products or no treatment in relation to the development of dental caries are not considered pertinent to the health claim (Alanen *et al.*, 2000a; Gehring *et al.*, 1974 and 1976; Larmas *et al.*, 1975; Mäkinen and Scheinin, 1974; Mäkinen *et al.*, 1989; Mäkinen *et al.*, 1996a; Scheinin *et al.*, 1974, 1975, 1976, 1985a, and 1985b; Banoczy *et al.*, 1985; Kandelman *et al.*, 1988; Kovari *et al.*, 2003; Szöke *et al.*, 1985). This evaluation considers only the effects of chewing gums sweetened with 100% xylitol and of pastilles/candies sweetened with at least 56% xylitol as compared to no treatment.

Chewing gum sweetened with 100% xylitol

Five studies have been presented that investigated the effects of chewing gums sweetened with 100% xylitol as compared to no treatment in children.

The Ylivieska study (Isokangas *et al.*, 1988, 1989, and 1993) was conducted in Finland. The study population was children 11 to 12 years of age who had participated in a prevention program which included fluoride tables and teeth brushing with dentifrice containing fluoride in an environment with low fluoride concentrations in the water supply (< 0.1ppm). School classes were assigned to either the intervention group (212 subjects) or to the control group (154 subjects) to minimise the risk of chewing gum consumption by controls. The intervention consisted of consumption of one piece of 100% xylitol sweetened chewing gum during 5 minutes after each meal (three times per day, xylitol dose about 10g/day) for two years. Compliance was checked by nurses at school and by parents at home. The control group did not receive any gum. Nutrition counselling and background measures for caries prevention did not differ between groups. Intervention and control groups were comparable at baseline for all variables measured regarding teeth status. At the end of the 2-year intervention, the intervention group showed significantly less caries increment from baseline measured as decayed, missing and filled surfaces (DMFS) than controls (33% reduction). A post-hoc analysis showed that the effect was more pronounced in subjects regularly consuming three chewing gums per day than in subjects consuming either two or one. Caries incidence was assessed by 5 different dentists. Inter- and intra-examiner variation in caries recording, as well as baseline measures, were included in an intention-to-treat analysis. Unsupervised teeth brushing in both groups was reported as being about 90%, whereas consumption of fluoride tablets was less than 7.6%. Authors report that frequency of sweets consumption was not affected by chewing gum consumption, but how and how often consumption of sweets was assessed is not reported. The study was extended for an additional year (three years in total) in subjects at high risk of caries at baseline (intervention = 34, controls = 36). After the second year of the intervention, caries incidence decreased significantly in the intervention group as compared to controls (49%), but the highest benefit was observed at 3 years from baseline (69% caries reduction). Again, authors report that frequency of sweets consumption was not affected by chewing gum consumption, but how and how often consumption of sweets was assessed is not reported. About 85% of subjects in the intervention group (n =147) and 80% of subjects in the control group (n = 122) were re-examined two (high risk subjects) to three years (rest of subjects) after the end of the intervention study. Examiners were blinded to group assignment. Overall, there was a significant reduction in caries incidence between intervention

and control groups after five years from baseline in subjects using the xylitol gum for two years (31% reduction), but differences were not significant (neither after two years of intervention nor after three years of follow-up) when only subjects with no caries at baseline were taken into account. A greater reduction was observed after two years of follow-up in the high-risk group (39% reduction as compared to controls). The effect was more pronounced in the teeth erupting during the first year of chewing gum consumption. Overall, 10 subjects per group had regular consumption of commercially available xylitol chewing gum during the follow-up. Consumption of sweets and background diet are not reported. Two years later, about 65% of the initial sample was re-assessed (95 intervention and 70 controls). Nine subjects in the original xylitol group and 5 in the control group regularly consumed xylitol gums in this period. Caries incidence in this period did not differ between groups when teeth erupted during the intervention period were not considered. Caries reduction in these teeth was significant in the xylitol group as compared to controls (about 77% reduction). Background diet and consumption of sweets in this period are not reported.

The Belize study (Central America) consisted of two separate interventions. The first intervention (Mäkinen *et al.*, 1995) was conducted on 10 year old unselected subjects at high risk of caries (no fluoride in water supply, no fluoride tablets, inconsistent teeth brushing with fluoride dentifrice, mean consumption of sweets between 12 and 14 times per day, high caries incidence). Schools were allocated to receive either one chewing gum stick (2.70g/piece) or two pellets (1.35g/piece) sweetened with 100% xylitol either 3 or 5 times per day per 5 chewing minutes (four groups, sticks 3 times/d (xyl-s3, n=141, 5.4g xylitol/d), pellets 3 times/d (xyl-p3, n=126, 4.3g xylitol/d), sticks 5 times/d (xyl-s5, n=126, 9.0 g xylitol/d), pellets 5 times/d (xyl-p5, n=125, 8.5g xylitol/d) or no gum (control, n= 121) for 40 months. Sample size was decided based on investigators experience in other trials. Intention-to-treat analysis was performed. Groups appeared to be heterogeneous at baseline regarding sex distribution, caries incidence and visits to a dentist. Statistical analysis controlling for these characteristics at baseline are presented in the paper. Assessors of caries incidence were blinded to treatment. DMFS significantly decreased in all the xylitol groups at the end of the intervention as compared to controls (adjusted relative risk (95%CI) = 0.48 (0.37-0.61) for xyl-s3, 0.41 (0.31-0.54) for xyl-p3, 0.44 (0.34-0.56) for xyl-s5, and 0.27 (0.20-0.36) for xyl-p5, corresponding to a risk reduction of 52%, 59%, 56%, and 74%, respectively). The decrease in DMFS in the group consuming pellets administered 5 times/d was significantly higher than in the other three xylitol groups, which did not differ among them significantly. Sweets consumption occasions per day were assessed 3 times during the study, but data for each group are not presented, neither is the use of other caries preventive measures.

The second Belize study was conducted in 6 year old children with generally poor oral hygiene who did not receive systematic caries prevention (Mäkinen *et al.*, 1996b). Schools were allocated to receive either one stick of chewing gum (2.70g/piece) or two chewing gum pellets (1.35g/piece) sweetened with 100% xylitol 5 times per day per 5 chewing minutes (xyl-s5, n=126 and xyl-p5, n=126) at a daily dose of about 10g xylitol per day or no gum (control, n= 121) for 24 months. Daily frequency of consumption of sugar-containing items was 8-12, with no difference between groups at baseline. Examining dentists were blinded to treatment allocation. Sample size was decided based on investigators experience in other trials. Intention-to treat analysis was performed. Statistical analysis controlling for age, sex and baseline caries status are presented. DMFS significantly decreased in all the xylitol groups at the end of the intervention as compared to controls (adjusted relative risk (95%CI) = 0.53 (0.39-0.72) for xyl-s5, 0.35 (0.21-0.59) for xyl-p5, corresponding to a risk reduction of 0.47% and 0.65%, respectively). No significant differences were observed between the two xylitol groups. The children were re-examined 5 years after the intervention ended (xyl-s5 n=42, xyl-p5 n=22, and controls n= 70, Hujoel *et al.*, 1999). Both xylitol groups were analysed together on this

occasion because of the low sample size. Caries rate did not differ between intervention and control groups for teeth erupting either before or in the first year of the intervention, but was significantly lower in the intervention group for teeth erupting either in the second year of the intervention or after (relative risk (95%CI) = 0.07 (0.01-0.45), 93% reduction, and relative risk (95%CI) = 0.12 (0.04-0.39), 88% reduction, respectively). The overall effect (considering all teeth together) on caries rate of the intervention was statistically significant (60% reduction).

A fourth study conducted in Montreal (Canada) recruited elementary school children (8-9 years) from low socio-economic background, with high frequency of consumption of sugar-containing products and high caries rate, who were also participating in an ongoing preventive dental school program, including teeth brushing, cleansing, fluoride supplementation and visits to the dental clinic (Kandelman and Gagnon, 1987 and 1990). Subjects (schools) were allocated to receive either one piece of 100% xylitol sweetened chewing gum (65% xylitol by weight, XYL65, 3.3g/d, n=157) three times per day per 5 minutes, one piece of 23% xylitol and 72% sorbitol sweetened chewing gum (15% xylitol by weight, XYL15, 0.9g/d, n=138) three times per day per 5 minutes, or no intervention (controls, n=138) for 24 months. At the end of the intervention, results were available for 87 subjects in the XYL65 group, 95 in the XYL15 and 97 in the control group. Only per protocol (not intention-to-treat) analyses are presented. Statistical analyses on progression of tooth decay were adjusted by relevant characteristics of subjects at baseline (age, sex, plaque index, and DMFS) to account for differences observed on these variables between control and intervention groups. Only comparisons between both intervention groups together and controls, and between XYL65 and XYL15 intervention groups are presented, whereas no direct comparison has been made between the 100% xylitol sweetened chewing gum (XYL65) group and controls. After 24 months, adjusted net progression of decay was significantly lower in the intervention groups XYL65 and XYL15 considered together as compared to controls, but no differences between XYL65 and XYL15 were observed. Means (95%CI) for net progression of decay were 1.55 (1.16-1.94), 1.47 (1.08-1.86) and 4.60 (4.25-4.95), respectively, for the XYL65, XYL15 and control groups. The Panel considers that a significant decrease in net progression of decay in the XYL65 as compared to controls, even if not directly tested in this study, can be assumed.

A fifth study evaluating the effects of chewing gum sweetened with 100% xylitol versus no treatment was conducted in Kaunas, Lithuania, were fluoride concentration in drinking water is <0.2ppm (Machiulskine *et al.,* 2001). The study population was children 9-14 years. Subjects (by school) were allocated to intervention (n=126) or control (n=120) groups and re-evaluated after one, two (intervention = 107, controls = 102) and three years (intervention = 99, controls = 97) of intervention. The intervention consisted of chewing gum sweetened with 100% xylitol 5 times per day preferably after the meals. Significant differences between intervention and control groups were observed only after three years (and not after two years) in the intervention group as compared to controls. Differences in DMFS were only observed for clinically assessed cavitated stages, but not for all clinically assessed stages or those assessed by x-ray.

Several mechanisms have been proposed through which xylitol chewing gum could decrease the risk of tooth decay, including a decrease in the concentration of pathogenic bacteria in the oral cavity (e.g., mutans streptococci), an increase in saliva flow, or a reduction of plaque (Mäkinen *et al.,* 1989 and 1996c, Söderling *et al.,* 1991, Isokangas *et al.,* 1991). Also, and in addition to not being cariogenic, specific mechanisms of action have been attributed to xylitol alone regarding stimulation of saliva flow, reduction of oral pH, and regulation (in quantity and quality) of mutans streptococci strains in the oral cavity (Maguire and Rugg-Gunn, 2003).

The Panel notes some limitations in the studies presented: the studies were not fully randomised for practical reasons (concealed allocation was used in most cases), nor were sufficiently controlled for confounders that could potentially have affected the outcome (e.g.,

background diet and standard caries preventive measures were not fully assessed and reported). For one study (Kandelman and Gagnon, 1987 and 1990) only the per protocol analysis was presented and direct comparison between the chewing gum sweetened with 100% xylitol and the control groups was not reported. Nevertheless, considering the high number of studies, subjects and observation years presented, as well as the consistency of the results and the magnitude of the effect, the Panel considers that a cause and effect relationship has been established between the consumption of chewing gum sweetened with 100% xylitol and the reduction of the risk of tooth decay in children.

The Panel notes that all studies presented are in children with no or uncomplete permanent dentition, and that most of them (excluding the Ylivieska study) have been conducted outside Europe in populations at high risk of caries development either owing to high rate consumption of sugar-containing products, or to inconsistent and inadequate oral hygiene/caries preventive measures, or both. In addition, the long-lasting effect on caries incidence associated to xylitol gum use has been observed in teeth erupting either during the second year of xylitol gum consumption or later. Therefore, it is uncertain whether a reduction of the risk of tooth decay linked to xylitol gum use could be extrapolated to the adult European population, and whether the benefit to be obtained in the general population of European children could be as high as observed in the studies presented.

An additional consideration refers to the dose and pattern of consumption. About 2-3 g of chewing gum sweetened with 100% xylitol consumed on at least three occasions per day after the meals appears to be enough to achieve the claimed effect. This quantity of chewing gum sweetened with 100% xylitol can easily be consumed as part of a balanced diet.

Pastilles sweetened with at least 56% xylitol

Three studies are presented on the effects of pastilles sweetened with at least 56% xylitol on caries incidence rate.

The first study was conducted in Estonia (Alanen *et al.*, 2000b), where 10-year old children were allocated to consume either xylitol-maltitol candies (n=96 per 2 years, n=73 per 3 years), xylitol-polydextrose candies (n=71 per 2 years, n=66 per 3 years), xylitol chewing gum (n=115) or no treatment (n=146) for three years. The interventions consisted of consumption of two gums (10-minute chewing) or three (two in the morning) candies three times per day (5g xylitol/d) during school days (not on Saturdays, Sundays, or the three-month school vacation). Background caries preventive measures were uncontrolled during the study. The statistical analysis presented only addresses the effect of consuming xylitol-containing chewing gum or candies (all groups together) on caries incidence as compared to controls (DMFS increment was significantly lower in all xylitol groups combined as compared to controls), but not the specific effects of either xylitol candy or xylitol chewing gum alone as compared to controls. The authors state that differences between xylitol groups on caries incidence were not systematic, but these are not shown and no statistical analysis was carried out neither between xylitol groups, nor between individual xylitol groups and controls. The Panel also notes that the study was not sufficiently controlled for confounders that could potentially have affected the outcome (e.g., background diet and caries preventive measures during the study not reported). The Panel considers that the significant weaknesses of this study limit its value as a source of data to substantiate the claimed effect.

The second study was conducted in Kuwait on 10-27 year old physically disabled subjects with high caries incidence (Honkala *et al.*, 2006). Subjects were allocated to the intervention group (one xylitol candy three times per day after the meals, 5 days per week, n=126) if parents/caregivers had returned the consent form; if not, they were allocated to the control

group (no treatment, n=50). Both groups were comparable at baseline regarding demographic and clinical variables. After 18 months of intervention, subjects in the intervention group (n=105) showed a significant decrease in caries rate as compared to controls. No information on the background diet of either group is provided. The Panel notes a number of weaknesses in this study: subjects were not randomly allocated to the intervention or to the control group, the study population (i.e., physically disabled subjects) was not representative of the target population, the study was not sufficiently controlled for confounders that could potentially have affected the outcome (e.g., background diet and caries preventive measures during the study were not reported).

The Panel considers that the weaknesses of this study limit its value as a source of data to substantiate the claimed effect.

The third study (unpublished) is a randomised controlled trial investigating the effects of pastilles sweetened with at least 56% xylitol (n=151) as compared to no treatment (n=148) on caries incidence rate in an elderly (>60 years) population with history of root caries. The intervention consisted of consuming three pastilles (5.2 g xylitol/d) on three occasions (only two pastilles in the morning) daily, preferable after meals, for 24 months. At the end of the intervention, no differences between groups on caries incidence rate were observed. The applicant states that the negative results may have been due to the low caries incidence in the study population.

The Panel considers that a cause and effect relationship between the consumption of pastilles sweetened with at least 56% xylitol and a reduction of the risk of tooth decay has not been established.

2.4. Panel's comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence:

"Xylitol chewing gum reduces the risk of caries in children".

The specific risk factor(s) for tooth decay affected by xylitol chewing gum is unclear.

2.5. Conditions and restriction of use

The scientific justification of the claim is related to the consumption of 2-3g of chewing gum sweetened with 100% xylitol at least three times per day after the meals.

This quantity of chewing gum sweetened with 100% xylitol can easily be consumed as part of a balanced diet.

Xylitol has been approved for use in foods (Directive 94/35/EC) as *"quantum satis"*, and considered safe for the whole population in a life perspective. There is, however, a risk of osmotic diarrhoea at excessive intakes (Peldyak and Mäkinen, 2002). Also, the use of chewing gum should be avoided in children less than three years of age due to a high choking hazard.

CONCLUSIONS AND RECOMMENDATIONS

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

- The foods that are the subject of the health claim (i.e., chewing gum sweetened with 100% xylitol and pastilles sweetened with at least 56% xylitol) are sufficiently characterised.
- The claimed effect 'reduces the risk of tooth decay' relates to reduction of dental caries development. Reducing the risk of tooth decay is beneficial to health.

- A cause and effect relationship has been established between the consumption of chewing gum sweetened with 100% xylitol and a reduction of the risk of tooth decay in children.
- A cause and effect relationship has not been established between the consumption of pastilles sweetened with at least 56% xylitol and a reduction on the risk of tooth decay.
- The following wording reflects the scientific evidence: "xylitol chewing gum reduces the risk of caries in children".
- The scientific justification of the claim is related to the consumption of 2-3g of chewing gum sweetened with 100% xylitol at least three times per day after the meals.
- This quantity of chewing gum sweetened with 100% xylitol can easily be consumed as part of a balanced diet.
- There is a risk of osmotic diarrhoea at excessive intakes of xylitol.
- The use of chewing gum should be avoided in children less than three years of age due to a high choking hazard.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on xylitol chewing gum/pastilles and reduce the risk of tooth decay pursuant to Article 14 of the Regulation (EC) No 1924/2006 (Claim serial No: 0158-FI). June 2008. Submitted by LEAF Int, Leaf Holland and Leaf Suomi Oy.

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GLOSSARY / ABBREVIATIONS

DMFS	decayed missing filled surfaces