

Four animal studies confirmed that maltitol was significantly less cariogenic than sucrose. FDA tentatively concludes that the overall results from both human and animal studies support the claim that maltitol does not promote dental caries.

#### *E. Isomalt*

The agency reviewed two plaque pH studies evaluating the acidogenic potential of isomalt. Results with 10 percent isomalt showed a minimum in vitro plaque pH of 5.7. An intraoral test with a 20 percent solution of isomalt reported a minimum pH of about 6.0. Results of five animal studies consistently showed that isomalt was significantly less cariogenic than sucrose. FDA tentatively concludes that the overall results show that isomalt does not lower plaque pH below 5.5 and does not promote dental caries.

#### *F. Lactitol*

Two in vitro plaque pH studies showed that lactitol produced little acid and only slight changes in plaque pH from resting baseline values. Results of two animal studies are consistent with these results and showed lactitol to be significantly less cariogenic than sucrose. The cariogenicity of lactitol was not significantly different than xylitol. FDA tentatively concludes that the overall results support the claim that lactitol does not promote dental caries.

#### *G. Hydrogenated Starch Hydrolysates and Hydrogenated Glucose Syrups*

In an ICT, a solution of HSH resulted in significantly less demineralization than sucrose. The investigators attributed the observed demineralization with HSH to an effect of other dietary components. The effects of sucrose on enamel demineralization, however, were noted to be over and above the effect of other dietary components.

Seven studies evaluating the effect of HSH on plaque pH showed inconsistent results in final pH values reported. The differences in results are attributed to the source of the HSH. HSH is manufactured by hydrolyzing a source of food grade starch (usually potato or corn starch) with acid or an enzyme to a mixture of sugars and dextrins of various glucose lengths (i.e., glucose syrups). The hydrogenated mixture contains sorbitol, maltitol, maltitriol, maltotrititol, and hydrogenated dextrins of various molecular weights (Ref. 79). The percentage of each component sugar alcohol in the final substance depends on the manufacturing process and controls. The two major forms of HSH (i.e., one manufactured in Sweden

and the other in France) used in the studies reviewed gave dramatically different results in plaque pH and acid production tests. The Swedish version, which has a higher percentage of higher molecular weight, fermentable polysaccharides than the French version, produced plaque pH values of 5.5 to 6.0 and an acid production of 50 to 70 percent compared to sucrose. The French version produced final plaque pH values above 6.0 and an acid production rate of 20 to 40 percent of sucrose. Results with HGS of unidentified composition showed minimum plaque pH values all above 6.0. Results of 4 rat studies support the observations that HSH (source not identified) is significantly less cariogenic than sucrose. FDA tentatively concludes that the overall results support the claim that HSH and HGS do not promote dental caries.

Based on its review of the scientific evidence, the agency noted that the HSH and HGS sugar alcohol mixtures may vary in their acidogenic response in dental plaque. For example, HSH manufactured in Sweden usually gave a lower plaque pH response than the French version of HSH. This variation in acidogenic response has been attributed to the differences in the chemical composition of these substances. HSH and HGS are not well defined chemical substances as are xylitol and sorbitol. Instead, the sugar alcohol compositions of these substances will vary depending on the manufacturing process. Therefore, the agency is asking for comments on how to determine whether sugar alcohol mixtures, such as HSH, when used in a food whose label bears a dental caries health claim, are in compliance with any final rule resulting from this proposal.

#### **V. Decision To Propose An Exemption From § 101.14(E)(6) For Chewing Gum and Confectioneries**

Section 101.14(e)(6) provides, as stated above, that except for dietary supplements or where provided for in other regulations in part 101, subpart E, to be eligible to bear a health claim, a food must contain 10 percent or more of the reference daily intake or the daily reference value for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed before there is any nutrient addition.

The petition states that products containing sugar alcohols often will not be able to satisfy the requirement of § 101.14(e)(6) because the products utilizing sugar alcohols are largely chewing gum and confectioneries, none

of which are a significant source of any nutrients. The petition states that the use of these products in lieu of traditional sugar-based confectionery would be consistent with public health recommendations, and that the health claim statement, "useful only in not promoting tooth decay," is an important and useful message for consumers in making decisions on which foods to purchase.

FDA has tentatively determined that there is significant public health evidence to support providing an exemption to § 101.14(e)(6) for sugar alcohol-containing foods, e.g., chewing gums, hard candies, and mints. In the Surgeon General's Report (Ref. 7), dental caries is recognized as an important and widespread public health problem in the United States. Although dental caries among children are declining, the overall prevalence of the condition imposes a substantial economic burden on American health care costs. The Surgeon General's report states that of the 13 leading health problems in the United States, dental disorders rank second in direct costs (Ref. 7).

The role of sugars, and of sucrose in particular, in the etiology of dental caries is well established. Caries-producing bacteria can readily metabolize a range of simple sugars (e.g., sucrose, glucose, fructose) to acids that can demineralize teeth. The unique role of sucrose, however, is related to its ability to be used by *S. mutans*, the primary etiologic agent in coronal caries, and other oral bacteria to form extracellular polymers of glucose or fructose that adhere firmly to tooth surfaces (Ref. 7).

The Surgeon General's report recommends several types of intervention to help reduce the risk of dental caries. The diet-related factors include the use of fluoridated drinking water and control of sugars consumption. In this regard, the Surgeon General's report recommends that those who are particularly vulnerable to dental caries, especially children, should limit their consumption and frequency of use of foods containing relatively high levels of sugars.

FDA agrees that limiting the amount of sugars in the diet is one important approach to help reduce the risk of dental caries. Sugar alcohols can be used to replace dietary sugars in food by providing sweetness and usefulness as bulking agents. Sugar alcohol-containing chewing gum and confectioneries, such as hard candies and mints, are specifically formulated without dietary sugars. Although these foods have little or no nutritional value,