INFORMATIONAL HEARING
October 3, 2008
State Capitol, Room 126

The Health Effects of Artificial Sweeteners

Artificial sweeteners, also referred to as sugar substitutes or low-calorie sweeteners, are non-nutritive, high-intensity sweeteners. Artificial sweeteners may be in so many foods, drinks, drugs, and hygiene products that some argue that every citizen of Western countries probably uses them. Because they are so sweet, less is needed to sweeten foods and fewer calories are added. As Americans battle epidemic overweight and obesity and related diseases, including diabetes, high blood pressure, and heart disease, consumers seek ways to control weight and reduce caloric intake. Consumers use artificial sweeteners as part of weight-loss plans, to reduce sugar or carbohydrate consumption to manage diabetes, or simply to improve general health. Although artificial sweeteners are widely available and may be beneficial in addressing important health problems, there is still considerable confusion and controversy surrounding their safety.

I. Regulation of Artificial Sweeteners

Artificial sweeteners are considered food additives. According to the California Department of Public Health (CDPH), regulatory authority of artificial sweeteners and other food additives rests with the federal Food and Drug Administration (FDA) and, if the additives are to be used in meat and poultry products, the U.S. Department of Agriculture (USDA). In addition, the National Toxicology Program (NTP), a scientific advisory unit within the United States (U.S.) Department of Health and Human Services, provides recommendations on "agents of public health concern." The five artificial sweeteners approved by FDA are sucralose, aspartame, saccharin, acesulfame potassium, and neotame.

The FDA approval process. When a company develops a new food additive, it must go through a petition process with FDA to establish that the additive is safe and performs as it is intended. The company must submit studies of the product, often including animal studies using large doses of the additive for long periods and showing that the substance would not cause harmful effects at expected levels of human consumption. Studies of the additive in humans may also be submitted. The scientific evidence FDA uses is generally based on published studies, which may be corroborated by unpublished studies and other data and information. FDA is tasked with considering the additive's composition and properties, the amount likely to be consumed, probable long-term effects, and various safety factors. A successful petition will lead to a regulation establishing the specifications for the additive, including any limitations for its use and how it should be identified on food labels. FDA states that it then monitors Americans' consumption of the new additive and subsequent safety research to assure the additive's use is safe.

FDA also operates an Adverse Reaction Monitoring System (ARMS), which is intended to monitor and investigate all complaints by individuals or their physicians that are

believed to be related to specific foods, food and color additives, or vitamin and mineral supplements. According to FDA, the ARMS database helps officials decide whether adverse reactions represent a public health hazard associated with food, so appropriate action can be taken.

California Statutes and Regulations. Pursuant to the Sherman Food, Drug, and Cosmetic Law, California adopts FDA's food additive regulations as its own regulations. CDPH has additional statutory authority to regulate foods in a manner different from the federal regulations, but according to CDPH, the state has no compelling need to reexamine issues FDA has already studied. CDPH's food safety actions are generally in response to complaints raised about food additive companies that violate statutes or regulations.

Under the Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as Proposition 65, the governor is required to annually revise and publish a list of chemicals that have been scientifically proven to cause cancer or reproductive toxicity. As the lead agency for the implementation of Proposition 65, the California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (OEHHA) lists chemicals known to the state to cause cancer or reproductive toxicity when a body considered to be authoritative has formally identified the chemical as causing cancer or reproductive toxicity. Alternatively, OEHHA reviews scientific studies that examine whether a chemical causes cancer or reproductive toxicity in humans and animals. If the studies show that a chemical causes cancer or reproductive toxicity, and Californians are exposed to the chemical, OEHHA lists the chemical. OEHHA had placed sodium saccharin on the Proposition 65 list in 1988 as a chemical that causes cancer, but removed it from the list in 2003. OEHHA also listed saccharin in 1989 but removed it from the list in 2001. OEHHA is currently examining studies on aspartame due to concern that it might cause cancer.

II. Potential Benefits of Artificial Sweeteners

The American Diabetes Association recommends reducing the number of carbohydrates people consume and approves the use of artificial sweeteners, considering artificial sweeteners as “free foods” which contain no calories and do not raise blood glucose levels. The American Dietetic Association, a national organization of food and nutrition professionals, recently completed a comprehensive evidence analysis on nonnutritive sweeteners and concluded that meals are lower in calories when nonnutritive sweeteners are substituted for higher calorie food or beverages, but also that more research is needed to determine the effect of artificial sweeteners on diabetes, glycemic response, and cholesterol levels.

III. Safety of Artificial Sweeteners

The National Cancer Institute, one of the National Institutes of Health, U.S. Department of Health and Human Services, states there is no clear evidence of an association between artificial sweeteners and cancer in people. The American Diabetes Association also accepts FDA’s conclusions that artificial sweeteners are safe and can be part of a healthy diet. However, questions concerning the safety of some artificial sweeteners continue to

surface. The Center for Science in the Public Interest (CSPI), a nutrition and health policy advocacy organization, reviews research and provides consumers with independent recommendations on food additives. CSPI's recommendations often diverge from those of FDA.

IV. FDA-approved Artificial Sweeteners and Safety Questions

This section briefly describes each of the artificial sweeteners approved by FDA, including when it was approved, how it is used, and major safety concerns.

Sucralose, marketed under the trade name Splenda, is 600 times sweeter than sugar by weight. Sucralose starts as pure cane sugar but is chemically altered to create a compound that contains no calories and no sugar, according to McNeil Nutritionals, the manufacturer of Splenda. According to an article in the *FDA Consumer* in November/December 1999, FDA reviewed more than 110 animal and human safety studies conducted over 20 years, and in 1998, approved sucralose as a tabletop sweetener and for use in products such as baked goods, nonalcoholic beverages, chewing gum, frozen dairy desserts, fruit juices, and gelatins, and in 1999 as a general-purpose sweetener for all foods. Sucralose is currently in over 4,000 products.

Sucralose has been the subject of considerable controversy over potential toxicity and marketing. A recent study by scientists at Duke University, funded by the Sugar Association (a trade association representing sugar beet and sugar cane farmers), and published in the *Journal of Toxicology and Environmental Health,* asserts that Splenda (which contains sucralose and the fillers maltodextrin and glucose) contributed to increased body weight, destroyed beneficial intestinal bacteria, and possibly reduced bioavailability of drugs and chemicals, at doses of sucralose that are approved by FDA for the food supply. The study authors state the Sugar Association had no input on the study's findings and conclusions. According to the Sugar Association's website, www.truthaboutsplenda.com, many consumers have also complained of a variety of gastrointestinal symptoms, migraines, seizures, dizziness and blurred vision, allergic reactions, blood sugar increases and weight gain, and numerous other problems associated with consumption of Splenda. CSPI considers sucralose safe, though it notes that a small number of people may be allergic to any additive.

As of this writing, the Sugar Association and Merisant, the maker of Equal, had filed lawsuits against McNeil Nutritionals alleging misleading advertising. McNeil Nutritionals and Merisant reached an undisclosed settlement in May 2007. McNeil Nutritionals had also filed a lawsuit against the Sugar Association, alleging false and misleading claims about Splenda.

Aspartame, commonly marketed as Nutrasweet or Equal, is approximately 200 times sweeter than sugar. Aspartame was first approved by FDA in 1981, with additional product use approvals through 1996, when FDA approved it for general use. According to the Calorie Control Council (Council), a nonprofit trade association of companies that use or make low calorie ingredients, aspartame is unique among low-calorie sweeteners

in that it is completely broken down by the body. Aspartame cannot be consumed by individuals with phenylketonuria because they are unable to metabolize phenylalanine, a byproduct of aspartame metabolism. Aspartame is an ingredient in more than 6,000 products, including soft drinks, drink mixes, gelatin desserts, frozen desserts, and is used as a tabletop sweetener.

According to the Council, aspartame is one of the most thoroughly studied food ingredients ever, with more than 200 studies confirming its safety. Observational studies have not demonstrated a relationship between aspartame and cancer in humans. However, animal studies, including a large controlled trial published in 2006, suggest a link between aspartame and leukemia, lymphoma, and other tumors in rats fed aspartame over their lifetime, even at doses in the range of consumption by humans. FDA has reviewed the 2006 study and maintains that the data do not support a link between aspartame and cancers. A follow-up study published in 2007 linked in utero aspartame exposure to leukemia, lymphoma, and mammary cancer. CSPI points to the recent rat studies and asserts that a recent study showing no link between aspartame and human cancer had important flaws. CSPI asserts that lifelong consumption of aspartame probably causes cancer, and recommends avoidance of aspartame. OEHHA is currently reviewing aspartame as a possible carcinogen. According to the website www.sweetpoison.com, which was created by a woman who states she nearly died from a thyroid disorder caused by aspartame, consumers of aspartame have complained of a variety of side effects, including seizures, blindness, multiple sclerosis, lupus, severe headaches, depression, and fatigue. FDA and many other health organizations do not consider such claims to be credible.

Saccharin, commonly available as a tabletop sweetener such as Sweet-N-Low, was discovered in 1879 and is 300 times sweeter than sugar. Studies in the 1970s raised concern that saccharin caused bladder cancer in rats; consequently, Congress required products containing saccharin to bear a warning that saccharin causes cancer in laboratory animals and might be hazardous, until the law was repealed in 2000. In the late 1970s, the federal NTP and FDA examined saccharin's role in causing bladder cancer in humans, and found "suggestive evidence" that those who use six or more servings of saccharin per day may be at increased risk. However, in 2000 NTP removed saccharin from the list of potential carcinogens, after considering that humans would not be likely to have an exposure as high as the levels consumed by the rats that developed bladder cancer, and the mechanism by which saccharin caused bladder cancer in rats was not relevant to humans. Similarly, OEHHA had listed saccharin and sodium saccharin as likely Proposition 65 carcinogens but removed them from the list in 2001 and 2003, respectively.

Acesulfame potassium, marketed as Sunett, is about 200 times sweeter than sugar and was first approved by FDA in 1988 as a tabletop sweetener and is now approved for a wide variety of products, including baked goods, candies, and beverages. Acesulfame potassium is used in more than 4,000 products, often combined with other sweeteners. and, according to an article in the *FDA Consumer* in November/December 1999, more than 90 studies verify its safety. According to the International Food Information

Council, an organization supported by food, beverage and agricultural industries to communicate information on food safety and nutrition, no human health problems associated with consumption of acesulfame potassium have been reported in the literature. However, CSPI asserts that safety tests of acesulfame potassium were of mediocre quality.

Neotame is 7,000 to 13,000 times sweeter than sugar, depending on how it is used. FDA approved neotame in 2002 as a general-purpose sweetener for use in a wide variety of products, including baked goods, soft drinks, chewing gum, processed fruit and juices, and other foods, although it is not yet widely used. According to CSPI, neotame is chemically related to aspartame but has more chemical stability and therefore versatility, and appears to be safe.

For additional information related to this Assembly Health Committee Hearing, please contact Allegra Kim at (916) 319-2097.