Nonnutritive Sweeteners: Where Are We Today?

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Controversy continues to surround use of nonnutritive sweeteners among consumers, despite extensive premarket safety studies used in the rigorous approval process of the U.S. Food and Drug Administration (FDA). The American Diabetes Association and the National Cancer Institute hold positions that FDA-approved nonnutritive sweeteners may be safely used by consumers.[1] However, people with diabetes also continue to question the use of nonnutritive sweeteners in a diabetes eating plan even with this assurance. Misinformation regarding nonnutritive sweeteners is shared routinely through multiple sources such as the Internet, print media, and electronic communications. As a result, diabetes educators and other health care professionals need to become more familiar with the safety and usage of these products to help people with diabetes discern fact from fiction.

The potential benefits of nonnutritive sweeteners for people with diabetes are reductions in calories and carbohydrates for weight management and glycemic control, respectively, as well as reductions in the risk of tooth decay.[2] This article reviews the history of nonnutritive sweeteners, explains FDA safety standards and definitions, and provides an overview of nonnutritive sweeteners available in the United States and practical teaching tips for counseling consumers about their use.

Sweetening agents are broadly classified as nutritive sweeteners, which provide energy, and nonnutritive sweeteners, which provide little to no energy. Nonnutritive sweeteners are several hundred to several thousand times sweeter than sucrose. Although some actually provide calories, their intense sweetness means that they are used in such small amounts that they are generally considered noncaloric. Familiar nutritive sweeteners include sucrose, fructose, agave nectar, fruit juice, and honey. Each provides ~ 4 kcal/g. Nonnutritive sweeteners are different from sugar alcohols (also known as polyols) such as xylitol and sorbitol, which are considered nutritive sweeteners, providing an average of 2 kcal/g because of their incomplete digestion and absorption.[3] Foods labeled "sugar free" may contain sugar alcohols, nonnutritive sweeteners, or both.

Overview of Regulations

Most nonnutritive sweeteners in the United States are regulated by the FDA as food additives. A food additive is "any substance the intended use of which results . . . in its becoming a component of . . . or affecting the characteristics of any food."[4] In 1906, Congress passed a law regulating all food additives, and in 1958, it passed a food additives safety amendment requiring safety to be proven on the basis of scientific evidence.

Food additives may be granted the status of Generally Recognized As Safe (GRAS). GRAS status includes "any substance that is intentionally added to food . . . and generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use . . . ."[5]

Five nonnutritive sweeteners have been approved by the FDA as food additives: aspartame, saccharin, acesulfame K, neotame, and sucralose.

The highly purified stevia extract rebaudioside A (reb A) has been granted GRAS status by the FDA but has not undergone the same rigorous approval process as the nonnutritive sweeteners approved as food additives.

Safety Research and Standards for Nonnutritive Sweeteners

The FDA review process for nonnutritive sweeteners that are food additives considers short- and long-term toxicity, carcinogenicity, and reproductive toxicity studies. The FDA must determine, based on the available scientific evidence, that there is "reasonable certainty of no harm" before granting approval.[6]

Clinical studies examining nonnutritive sweeteners review the nutritional consequences and physiological responses of their use and determine potential toxicity levels. Toxicity is examined closely because nonnutritive sweeteners may be ingested in larger quantities than traditional additives. Studies of nonnutritive sweeteners evaluate the potential of a product or its metabolites to alter or interfere with normal absorption, metabolism, or excretion of any nutrient or metabolic intermediates, as well as any toxicological consequences.[5] Clinical studies also consider potential allergic reactions, accumulation in tissue, levels in the stomach, effects on normal gut flora, blood glucose homeostasis, and potential drug interactions.[7]

The key determinant in the safety evaluation of a food additive is the relationship between its probable human intake from use in food to the level at which adverse effects are observed in toxicological studies. Safety standards called acceptable daily intakes (ADIs) and estimated daily intakes (EDIs) guide decisions about safe consumption levels.

Scientists analyze results from animal feeding studies and observations in humans to determine the ADI of a substance.[8] The ADI is an estimated, conservative amount of nonnutritive sweetener that can be safely consumed by any person in the population on a daily basis over a lifetime without risk from the exposure. See Table 1 for information on ADIs and EDIs for nonnutritive sweeteners. ADIs, expressed in mg/kg body weight/day, ensure that human intake of a given substance is well below toxic levels. They are based on 100 times lower intake than the maximum level at which there is "no observable effect level" for a given additive. For example, if the daily dose that shows no effect is 1,000 mg/kg, then the ADI = 1,000/100 = 10 mg/kg.[5]

The EDI represents a conservative estimate based on probable daily intake over a lifetime and the concentration of the food additive in each food.[9] Daily intake is estimated from three factors: *1*) the amount of additive in a product, 2) the frequency with which the product may be consumed, and *3*) the amount of probable intake by 100% of the market across all subpopulations by age-groups, including children, older adults, and pregnant or lactating women. EDIs are based on the 90th percentile estimates of the population that will consume the food with the given additive.[10] The FDA also monitors consumer complaints and conducts eating pattern surveys to determine ongoing consumption.

FDA-Approved Nonnutritive Sweeteners

Aspartame. Brand names for aspartame include NutraSweet and Equal. Aspartame was first discovered in 1965 and received initial FDA approval in 1981.[11] Aspartame contains the same number of calories as sucrose (4 kcal/g). Because of the minimal amount of aspartame needed to impart sweetness in a product, its energy content is negligible.[4]

Aspartame continues to be controversial among consumers, and myths abound regarding this nonnutritive sweetener. The primary safety concerns relate to the breakdown products of aspartame (methanol and formaldehyde), which sound frightening to consumers.

Aspartame does not enter the bloodstream intact because of rapid breakdown into its constituent components.[12] Therefore, safety studies in which aspartame was directly injected into the body or directly exposed to cells grown in a Petri dish do not accurately reflect safety in humans.[12]

When aspartame is eaten, it is completely broken down into two amino acids and methanol, but in much smaller quantities than are found naturally in foods. For example, in comparing equal volumes of tomato juice and an aspartame-sweetened beverage, the tomato juice provides approximately four to six times more methanol.

Methanol is converted to formaldehyde in the liver, which the body rapidly converts to formic acid, which is either excreted unchanged in the urine or broken down to carbon dioxide and water. Formaldehyde is naturally present in the body in amounts thousands of times greater than one could get from aspartame.[12]

The FDA reaffirmed the safe use of aspartame in 2007, after claims suggested an association with cancer.[13] Additionally, the FDA determined that there is no scientific evidence supporting anecdotal adverse event claims associating aspartame with seizures, hyperactivity, multiple sclerosis, and other ailments.[14]

Because aspartame contains the amino acid phenylalanine, a warning label is required on any product containing aspartame for people with the rare genetic disorder phenylketonuria (PKU). People with PKU are unable to metabolize the amino acid phenylalanine found in aspartame and other foods and beverages.[15]

Saccharin. Brand names for saccharin include Sweet'N Low, Necta Sweet, Sweet Twin, and Sugar Twin. First discovered in 1878, saccharin has the longest history of use of all the nonnutritive sweeteners. Because it is not metabolized by humans and is excreted unchanged, it is considered calorie-free.[4]

From 1970 to 1981, saccharin was the only nonnutritive sweetener available in the United States. In 1972, after almost 100 years of use, it was removed from the GRAS list based on findings from a Canadian study linking it to bladder cancer in rats. In 1977, the FDA proposed a ban on saccharin, based on the animal study findings. Because of the

Table 1. ADIs and EDIs for Nonnutritive Sweeteners

Nonnutritive Sweetener	Sweetening Power Compared to Sucrose	ADI (mg/kg body weight/day)*†	EDI‡ as a Percentage of ADI in Adults (%)	ADI Equivalents in 12-oz Cans of No-Calorie Diet Soda Each Day Over a Lifetime§,‖ (Based on a 150-lb Body Weight)	ADI Equivalents in Packets of Tabletop Sweetener Each Day Over a Lifetime§ (Based on a 150-lb Body Weight)
Ace-K	200 ×	15	20	25	20
Aspartame	200 ×	50	6	17	97
Saccharin	300 ×	5¶	12	2	9
Sucralose	600 ×	5	32 (includes children > 2 years of age)	5	68
Stevia (expressed as steviol)	200–300 ×	0–4	20–30#	Sodas containing stevia are not widely available	30**

**ADI calculation is determined by dividing X mg/kg by 100 = ADI mg/kg, where X = daily dose that showed no effect and ADI = 1/100 maximum level at which no adverse effects are observed. For example, if the daily dose is 1,500 mg/kg, the calculation would be 1,500 ÷ 100 = an ADI of 15 mg/kg.*
†From ref. 8.
‡EDI calculations can be found at www.caloriecontrol.org.
§An acceptable daily intake calculator of noncaloric sweeteners is available from http://www.nafwa.org/sweetener.php.
‖From the European Food Safety Authority Panel on Food Additives and Nutrient Sources Added to Food scientific opinion on the safety of steviol glycosides for the proposed uses as a food additive. Available from http://www.efsa.europa.eu/fr/scdocs/doc/1537.pdf.
¶From the International Programme on Chemical Safety evaluation of the Joint FAO/WHO Expert Committee on Food Additives for Sodium Saccharin. Available from http://apps.who.int/ipsc/database/evaluations/chemical.aspx?chemID=4003.
#From Institute of Food Technologists: Ensuring the safety of sweeteners from stevia [article online]. Available from http://www.ift.org/food-technology/past-issues/2011/april/features/ensuring-the-safety-of-sweeteners-from-stevia.aspx?page=viewall.
***Tabletop equivalents can be found at http://www.beverageinstitute.org/en_US/pages/article-understanding-low-and-no-calorie-sweeteners.html.*

public outcry in response, Congress put a moratorium on the ban but mandated that further research be conducted and required a warning label on all products containing saccharin.[1] Additional studies determined that the mechanism leading to bladder tumors in rats was not relevant to humans, and human epidemiology studies have shown no consistent evidence that saccharin use has increased the incidence of bladder cancer. As a result of these findings, in 2000, the U.S. National Toxicology Program's Report on Carcinogens removed saccharin from the list of substances "reasonably anticipated to be a human carcinogen." In December 2000, legislation was passed repealing the warning label requirement for saccharin-containing products.[1]

Sucralose. Brand names for sucralose include Splenda and Nevella. Sucralose gained FDA approval in 1998 for use in 15 food and beverage categories, the broadest initial approval of any food additive.

Sucralose is made from a sucrose molecule with three of the hydrogen oxygen groups replaced by three chlorine atoms. The body does not recognize sucralose as a carbohydrate, its absorption is poor, and it is excreted unchanged in the urine or feces. As a result, sucralose provides no calories.[11]

In a 2000 opinion report, the Scientific Committee on Food concluded that, "There is adequate evidence, both for sucralose and its hydrolysis products, that there are no concerns about mutagenicity, carcinogenicity, or developmental or reproductive toxicity."[16] Since the allocation of an ADI by the Joint U.N. Food and Agriculture Organization/World Health Organization Expert Group on Food Additives (JECFA) in 1990, sucralose has been approved for consumption in more than 80 countries.[11]

Stevia. Stevia is a plant native to South America and is used around the world to sweeten foods and beverages. Some stevia sweeteners have an added bulking agent for palatable flavor and reduced aftertaste. Brand names with bulking agents include SweetLeaf (inulin), PureVia (dextrose

Table 2. Teaching Tips About Nonnutritive Sweeteners

Teaching Points	Related Information for Clients	
1. Nonnutritive sweeteners can help clients achieve a consistent carbohydrate intake and reduce calories.		
• Compare the differences in the Nutrition Facts labels of regular products and ones containing nonnutritive sweeteners, including the calorie and fat content as well as the carbohydrate content.	Regular fruit-flavored yogurt (6 oz): • 170 calories • 33 g total fat • 33 g total carbohydrate	Light/fat-free fruit-flavored yogurt (6 oz): • 100 calories • 0 g total fat • 19 g total carbohydrate
	Regular soda (12 oz): • 145 calories • 0 g total fat • 40 g total carbohydrate	Diet soda (12 oz): 1 calorie 0 g total fat 0 g total carbohydrate
• Help reduce clients' confusion about label claims.	• "Sugar-free" or "no sugar added" on a food label does not mean the food is carbohydrate- or calorie-free. These products may have as many carbohydrates and calories as the regularly sweetened product, if not more. • Products may be labeled either "low calorie" or "reduced calorie" if they in fact are lower in calories than the original product. "Reduced" or "less" sugar indicates a sugar reduction of 25% compared to the original product. • If a food is not lower in calories, the label must state that it is "not a low-calorie food," "not a reduced-calorie food," or "not for weight control."	
• Explain that all calories count; weight loss requires eating fewer calories than are used.	• Total calorie intake should be the focus for weight management. This includes calories from fat and protein.	
• Teach clients how to read Nutrition Facts labels on packaged foods. • *Note that total carbohydrate is the same for whole milk and nonfat milk. "Sugars" on the Nutrition Facts label include naturally occurring sugars including lactose (milk sugar). Total carbohydrate is the focus. Whole milk has significantly more calories because of its fat content.	Whole milk (8 oz): • 150 calories • 70 calories from fat • 8 g total fat • 5 g saturated fat • 0 g trans fat • 0 g polyunsaturated fat • 2.5 g monounsaturated fat • 35 mg cholesterol • 120 mg sodium • 380 mg potassium • 12 g total carbohydrate* • 0 g dietary fiber • 11 g sugars • 8 g protein	Skim (nonfat) milk (8 oz): • 90 calories • 0 calories from fat • 0 g total fat • 0 g saturated fat • 0 g trans fat • 0 g polyunsaturated fat • 0 g monounsaturated fat • 35 mg cholesterol • 120 mg sodium • 380 mg potassium • 12 g total carbohydrate* • 0 g dietary fiber • 11 g sugars • 8 g protein
1. Nonnutritive sweeteners are found in the ingredient list on packaged foods. They are included in the total calories and total grams of carbohydrate per serving as well as on the label claims.		
• Teach clients the names of nonnutritive sweeteners.	Look for nonnutritive sweeteners in the ingredient list on packaged foods: • Aspartame • Sucralose • Acesulfame-K (or Ace-K) • Saccharin • Reb A (highly purified stevia extract)	
• Help dispel myths about nonnutritive sweeteners and provide resources for clients to learn more about the safety of nonnutritive sweeteners.	Resources to learn about the safety of nonnutritive sweeteners: International Food Information Council: http://www.ific.org Academy of Nutrition and Dietetics: http://www.eatright.org "The Truth About Artificial Sweeteners or Sugar Substitutes": http://www.adaevidencelibrary.com/files/Docs/nonnutritive sweetenersResourceDraft3.pdf	

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Table 2. Teaching Tips About Nonnutritive Sweeteners, *continued from p. 107*

Teaching Points	Related Information for Clients
• Nonnutritive sweeteners can be used in place of nutritive sweeteners in some recipes.	
• Teach patients the equivalents of nonnutritive sweeteners compared to sugar.	The following provide equivalent sweetness to 1 cup of sugar: • 8 tsp. saccharin • 1 cup or 24 packets aspartame • 1 cup sucralose • 24 packets Ace-K
• Explain that patients can modify recipes by using nonnutritive sweeteners to reduce calories and sugar but that, in some cases, nonnutritive sweeteners can affect flavor, texture, browning, or cooking time.	Cooking tips for nonnutritive sweeteners: • Using nonnutritive sweeteners in place of 1 cup sugar in a recipe saves 774 calories and 200 g carbohydrate. • Nonnutritive sweeteners can completely replace sugar in recipes for sweet sauces, fruit pie fillings, cheesecakes, glazes, and beverages. • Some recipes work better if you only partially replace sugar with nonnutritive sweeteners. Recipes that call for baking or browning require some sugar. • Aspartame should be added to recipes after heating the ingredients to avoid a bitter taste. Although it is not harmful, aspartame is not recommended for use in baking because it is not heat stable and loses sweetness when heated. • Saccharin and sucralose are heat stable and work well in baked products, but the lack of sugar may affect the structure, texture, and volume of the cooked item. • You can replace sugar with an equal amount of sucralose, but the baking time will be quicker with the sucralose. • Adding 1/2 tsp. baking soda to a recipe helps the product rise in a short baking period. • A blend of sugar and sucralose or stevia extract (for example, Truvia) is recommended for use in baking to maintain structure. This can reduce calories and carbohydrate from sugar by 50%. • Using stevia will require a replacement of "filler" (for example, fiber fill) because its sweetness potency causes a loss of volume of the baked good. • Flatten cookies with a fork before baking because cookies made with nonnutritive sweeteners will not spread like the full-sugar versions. • Activate yeast with 2 tsp. sugar before using nonnutritive sweeteners to replace sugar in bread products. • To maintain browning on bread products, brush them with an egg wash (1 egg mixed with 1 Tbsp. water) before baking. • Sprinkling cinnamon or nutmeg can help replace the color of normal browning in baked goods.
• Provide patients with sources for recipes incorporating nonnutritive sweeteners.	Recipes using nonnutritive sweeteners can be found: On the Internet: American Diabetes Association: www.diabetes.org Diabetes Care and Education Practice Group of the Academy of Nutrition and Dietetics: www.dce.org. The Food Network Web site (search term "sugar substitute"): http://www.foodnetwork.com In magazines: *Diabetes Forecast*: www.forecast.diabetes.org *Diabetes Self-Management*: www.diabetesselfmanagment.com *Diabetic Cooking*: www.diabeticcooking.com *Diabetic Living*: www.diabeticlivingonline.com

Source for nutrition information: www.calorieking.com. Accessed 24 January 2012.

and cellulose), SunCrystals (cane sugar), and Truvia (erythritol).[17]

There are four major steviol glycosides found in the stevia plant, including rebaudioside A, also known as reb A.[11] Steviol glycosides have been referred to as stevia, stevioside, and stevia glycoside in the scientific literature.

In 2008, reb A was placed on the GRAS list with no objection by the FDA.[18] In June 2008, JECFA completed a multiyear review of scientific data related to high-purity steviol glycosides and concluded that they are safe for use as general purpose sweeteners.[11] Reb A is the only stevia derivative currently on the FDA GRAS list.[19] Unpurified stevia is not on the GRAS list, although it continues to be sold as a dietary supplement in the United States.

Acesulfame-potassium (Ace-K). Brand names for Ace-K sweeteners include Sunett, Sweet & Safe, and Sweet One. Ace-K was approved in 1988 for use in food products and as a tabletop sweetener. The FDA expanded its approval for use in beverages in 1998 and as a general sweetener in 2003.[11]

Ace-K is often blended with other sweeteners as an ingredient in low-calorie foods and beverages. It has no glycemic effect, although it may be blended with other sweeteners that do. Ace-K is not metabolized or stored in the body, but rather is rapidly absorbed and excreted unchanged by the kidneys.

Neotame. Currently neotame is only used in food manufacturing and is not available for direct purchase by consumers. Like aspartame, it is a derivative of the amino acids aspartic acid and phenylalanine. It was approved by the FDA as a general sweetener in 2002.

Neotame is intensely sweet, with 7,000–8,000 times the sweetening power of sucrose. Because such a small amount is needed to sweeten foods, exposure to phenylalanine from neotame is insignificant. As a result, the FDA does not require a label warning for people with PKU on products containing neotame.

Nonnutritive Sweeteners: Appetite, Weight, and Glycemic Control

The Evidence Analysis Library (EAL) of the Academy of Nutrition and Dietetics recently examined the evidence related to the use of nonnutritive sweeteners and potential effects on weight, appetite, food intake, glycemic control, and other health issues. The conclusion of the EAL workgroup was that sucralose, aspartame, and saccharin have no effect on appetite in adults.[20]

Although there are concerns that consumption of nonnutritive sweeteners contributes to obesity, a critical review of the literature by Mattes and Popkin[21] found no supportive evidence for mechanisms that would produce weight gain. In fact, the majority of studies examining the use and effect of nonnutritive sweeteners on weight in adults have indicated that nonnutritive sweeteners may help reduce caloric intake, yield a few pounds of weight loss, and help prevent unwanted weight gain.[21]

Using nonnutritive sweeteners does not appear to affect blood glucose or lipids in adults with diabetes; no studies were found examining this issue in children. Individuals with diabetes must consider total carbohydrate consumed. People with diabetes may improve their glycemic control and better manage their weight with the use of nonnutritive sweeteners when foods with sugar, starch, and fat are also reduced.22,23 Table 2 offers teaching tips about use of nonnutritive sweeteners.

The EAL workgroup mentioned above also concluded that there is acceptable safety evidence for using FDA-approved nonnutritive sweeteners in pregnancy, although moderation is prudent. It is important to note the nonnutritive sweetener stevia is not FDA-approved for general use. The American Medical Association suggests avoiding saccharin during pregnancy because of possible slow fetal clearance.[24]

Summary

Individuals with diabetes and diabetes health care professionals can benefit from learning more about nonnutritive sweeteners to make informed decisions about their use based on available evidence, rather than on myths and misinformation shared on the Internet and in the print and electronic media. Research on five approved nonnutritive sweeteners supports safety when used under FDA recommendations. Potential benefits include calorie and carbohydrate reduction for weight management, glycemic control, and reduction in the risk of tooth decay.

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