AMERICAN FROZEN FOOD INSTITUTE

Issue Brief: Sugars and Sweeteners (Sugars, Added Sugars, HFCS, and Artificial Sweeteners)

Sugar is the generalized name for a class of chemically-related substances. For the purpose of nutrition labeling, FDA defines the term "sugar" as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose). 1/ For the purpose of ingredient labeling, FDA defines the term "sugar" as sucrose. 2/ Sugar is mainly made by crystallizing sugar cane or beet juice. Sugar substitutes, which duplicate the taste of sugar, are generally non-nutritive, high-intensity sweeteners that are popular among consumers trying to reduce their caloric intake. Sugar alcohols can also impart sweetness and can be used as substitutes for sugar. The calorie content of sugar alcohols varies depending on the specific sugar alcohol. Regulatory authority of sugars and sweeteners largely rests with the U.S. Food and Drug Administration (FDA). There is considerable controversy concerning the safety and labeling of various sugars and sweeteners. Furthermore, the food industry is facing pressure from consumer groups to reduce the amount of sugars added to processed foods given their view that added sugar intake is linked to diet-related non-communicable diseases (NCD) such as obesity and diabetes.

Legal Framework

Under FDA's current regulatory scheme, sucrose and high fructose corn syrup (HFCS), as well as other sweeteners such as corn sugar, invert sugar, and corn syrup, are currently considered "generally recognized as safe" ("GRAS"), not as "food additives." 3/ In contrast, artificial sweeteners are generally classified as food additives and the five artificial sweeteners approved by FDA are sucralose, aspartame, saccharin, acesulfame potassium, and neotame. 4/ FDA also has issued "no objection letters" to industry determinations of the generally recognized as safe (GRAS) status of Rebaudioside A purified from stevia leaves when used as a

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1/ 21 CFR § 101.9(c)(6)(ii).
2/ 21 CFR § 104.4(b)(20).
3/ Specifically, sucrose is affirmed as GRAS under 21 CFR §184.1854 ("GRAS status for sucrose"), corn sugar is affirmed as GRAS under 21 CFR §184.1857 ("GRAS status for corn sugar"), invert sugar is affirmed as GRAS under 21 CFR §184.1859 ("GRAS status for invert sugar"), corn syrup is affirmed as GRAS under 21 CFR §184.1865 ("GRAS status for corn syrup"), and HFCS is affirmed as GRAS under 21 CFR §184.1866 ("GRAS status for HFCS").
4/ Specifically, sucralose is listed under 21 CFR §172.831 ("Sucralose."), aspartame is listed under 21 CFR §172.804 ("Aspartame"), saccharin is listed under 21 CFR §180.37 ("Saccharin, ammonium saccharin, calcium saccharin, and sodium saccharin."), acesulfame potassium is listed under 21 CFR §172.800 ("Acesulfame potassium."), neotame is listed under 21 CFR §172.829 ("Neotame"). Note that when aspartame is added to food the label must bear the warning statement "Phenylketonurics: Contains Phenylalanine" in bold type.

sweetener. 5/ While certain common sugar alcohols such as sorbitol are considered GRAS, other sugar alcohols such as xylitol are regulated as food additives. 6/

The Nutrition Labeling and Education Act (NLEA) gave FDA the authority to mandate nutrition labeling, including the mandatory declaration of "sugars." FDA's regulations require the declaration of "sugars" (the sum of all free mono- and disaccharides) as an absolute amount in grams per serving with no accompanying % DV (daily value). FDA also has approved nutrient content and health claims related to sugar. 7/

Because of recent consumer interest in "natural" products and those with simple or "plain language" ingredient statements, some food manufacturers have tried to declare sweeteners by other names in the ingredient statement. For example, some food products declare "evaporated cane juice" as an ingredient. FDA has issued draft guidance explaining that in the agency's view the term "evaporated cane juice" is not the common or usual name of any type of sweetener, including dried cane syrup. 8/ FDA considers such representations to be false and misleading because they fail to reveal the basic nature of the food and its characterizing properties (i.e., that the ingredients are sugars or syrups). Further, FDA has noted that sweeteners derived from sugar cane syrup are not juice. Although FDA has not yet finalized the guidance, the agency has recently issued Warning Letters objecting to the use of "evaporated cane juice." 9/ Similarly, FDA rejected a petition from the Corn Refiners Association (CRA) to use "corn sugar" as an alternate common or usual name for HFCS. FDA rejected the petition by characterizing sugar as "a solid, dried, and crystallized food" whereas syrup is "an aqueous solution or liquid food." 10/ Because HFCS is an aqueous solution sweetener derived from corn after enzymatic hydrolysis of cornstarch, FDA concluded the use of the term "corn sugar" would not accurately describe the nature of HFCS.

Recent Development

Despite the fact that FDA reviewed safety studies for all of the artificial sweeteners before they were introduced into the market, questions concerning their safety

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5/ *See, e.g.*, GRAS Notice No. 252 and 253.

6/ Specifically, sorbitol is affirmed as GRAS under 21 CFR §184.1835 ("Sorbitol.") and xylitol is listed under 21 CFR §172.395 ("Xylitol.").

7/ To bear a "sugar free" type of claim, a food must contain less than 0.5 g of sugars per reference amount customarily consumed or per labeled. In addition, such foods may not contain any ingredient that is a sugar or that is generally understood by consumers to contain sugars, unless the listing of the ingredient in the ingredient statement is followed by an asterisk that refers to statements such as "adds a trivial amount of sugar." The definition for "sugar free" also includes the requirement that any food that is not low or reduced in calorie disclose that fact.

8/ Food and Drug Administration, *Guidance for Industry: Ingredients Declared as Evaporated Cane Juice* (Oct. 2009), http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm181491.htm.

9/ *See, e.g.*, FDA Warning Letter to Bob's Red Mill Natural Foods, Inc. (07/31/12) http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm316268.htm

10/ Food and Drug Administration, *Response to Petition from Corn Refiners Association to Authorize "Corn Sugar" as an Alternate Common or Usual Name for High Fructose Corn Syrup (HFCS)* (May 30, 2012).

continue to surface. 11/ The Center for Science in the Public Interest (CSPI), a public health policy advocacy organization, is one of the most vocal groups that opposes the use of artificial sweeteners. In its "Chemical Cuisine" guide to food additives, CSPI has long given the artificial sweeteners saccharin, aspartame, and acesulfame potassium "avoid" ratings, the group's lowest. Relying on a 2005 European Aspartame study, CSPI claims the consumption of aspartame is associated with cancers in rodents. FDA reviewed the 2005 European Aspartame Study and concluded the data do not support a link between aspartame and cancer. 12/ In June 2013, CSPI's decision to downgrade the rating of sucralose from "safe" to "caution" generated significant media attention regarding the safety of artificial sweeteners.

Labeling of sweeteners also faces challenges from the plaintiff's bar. Processed foods that are marketed as natural have been challenged for containing sweeteners such as high fructose corn syrup and stevia. In September 2013, Cargill, Inc. agreed to settle a class action lawsuit alleging Cargill, Inc. misled consumers by marketing Rebaudioside A ("Truvia") product as "natural." 13/ Although Cargill, Inc. has not admitted any liability under the settlement, the company has nonetheless agreed to modify product labels and to pay $5 million as the settlement fund. Interestingly, the parties agreed that Cargill can continue the use of the tagline "Nature's Calorie-Free Sweetener," provided that the tagline is linked to a statement referring consumers to a website where they can obtain more detailed information on the product's manufacture process. As of yet, the court has not approved the settlement.

Last but not least, in June 2013, the USDA Food and Nutrition Service (FNS) issued a memorandum extending the provisions to serve frozen fruit with added sugar in the National School Lunch Program (NSLP) to School Year (SY) 2014-2015. 14/ Previously, FNS stated that schools may only serve frozen fruit with added sugar in the NSLP for SY 2012-2013 and SY 2013-2014. FNS recognized the importance of added sugar in frozen fruit products' flavor and texture as well as the long lead purchase time due to the growing season. The exemption applies to products acquired through USDA Food as well as those purchased commercially.

Issues to Watch

- Nutrition Facts Panel Updates. FDA is in the process of updating the Nutrition Facts panel and Reference Amounts Customarily Consumed. 15/ It published

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11/ Deborah Kotz, *Are no-calorie sweeteners safe to eat? (2014),* The Boston Globe, http://www.bostonglobe.com/lifestyle/health-wellness/2014/01/27/are-calorie-sweeteners-safe/B56kqUuKVJwcEfcWx2PmhO/story.html

12/ *FDA Statement on European Aspartame Study* (April 20, 2007), http://www.fda.gov/newsevents/newsroom/pressannouncements/2006/ucm108650.htm

13/ Martin, et.al v. Cargill, Inc., 86 Fed. R. Serv. 3d (West) 1593 (D. Minn. 2013).

14/ Food and Nutrition Service, *Frozen Fruit Products in the National School Lunch and School Breakfast Programs in School Year 2014-2015,* 2013, available at: http://www.fns.usda.gov/sites/default/files/SP49-2013os.pdf.

15/ *Food Labeling: Revision of the Nutrition and Supplement Facts Labels (https://www.federalregister.gov/articles/2014/03/03/2014-04387/food-labeling-revision-of-the-nutrition-and-supplement-facts-labels)* 79 Fed. Reg. 11879 -11987 (March 3, 2014); *Food Labeling: Serving Sizes of Foods That*

an advanced notice of proposed rulemaking in November 2007 and has submitted a proposed rule to the Office of Management and Budget for review. 16/ Suggested revisions include the addition of added sugars to the Nutrition Facts label. Furthermore, FDA intends to revise the way serving sizes are determined, thus affecting the declaration of the sugar content in a food.

- The 2015 Dietary Guidelines. The Dietary Guidelines for Americans 2010 recommends a maximal intake level of 25 percent or less of total calories from added sugars. We expect the Dietary Guidelines for Americans 2015, which is currently going through public hearings, will continue to recommend reducing intake of added sugar.

- Other Agency Initiatives. In 2013, CSPI submitted a petition which calls for the agency to determine what levels of added sugars would be safe for use in beverages and to require those limits to be phased in over several years. 17/ CSPI claims that the unsafe levels of sugars and HFCS in beverages cause obesity, diabetes, heart disease, and other health problems. The petition did not propose a specific safe level, but noted that several health agencies identified 2 ½ teaspoons (10 grams) as a reasonable limit. While FDA has not yet acted on the petition, emerging evidence that attempts to link sugar consumption with diabetes, obesity, and other health conditions could cause the agency to take a closer look at the petition. Indeed, it was the CSPI petition on partially hydrogenated oils (PHOs) that led to the FDA notice to explore withdrawing the GRAS status of PHOs. Our internal sources at FDA also have indicated that FDA may be exploring various options to decrease consumption of added sugars.

International Perspective

- European Union (EU): Sugar and syrup, including HFCS, are regulated in the EU under Council Directive 2001/111/EC (the "EU Sugar Directive"). 18/ Eleven sugar varieties are listed in the EU Sugar Directive with corresponding compositional characteristics and requirements related to packaging and labelling. Sweeteners, including artificial sweeteners, are considered to be food additives in the EU and are regulated under Regulation (EC) No 1333/2008 on food additives (the "EU Food Additives Regulation"). 19/ The labelling of sugars, fructose-glucose syrup and sweeteners used as food ingredients is regulated under the provisions of Directive 2000/13/EC on labelling, advertising and presentation of foodstuffs (the "EU Labelling

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Can Reasonably Be Consumed at One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments (https://www.federalregister.gov/articles/2014/03/03/2014-04385/food-labeling-serving-sizes-of-foods-that-can-reasonably-be-consumed-at-one-eating-occasion) 79 Fed. Reg. 11879 -11987 (March 3, 2014).

16/ *Food Labeling: Revision of Reference Values and Mandatory Nutrients*, 72 Fed. Reg. 62149-62175 (November 2, 2007).

17/ *Petition to Ensure the Safe Use of "Added Sugars."* Center for Science in the Public Interest. February 13, 2013. (http://cspinet.org/new/pdf/sugar_petition_2-12-13_final.pdf)

18/ http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2001L0111:20131118:EN:PDF

19/ http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2008R1333:20131014:EN:PDF

Directive"). 20/ Certain claims may be made regarding the content of sugar in foods, as long as that the requirements of Regulation (EC) 1924/2006 on nutrition and health claims made on foods (the "EU Claims Regulation") are met. 21/

Commission Regulation (EC) No 257/2010 sets up a program for the re-evaluation of food additives approved under the EU legislation. As part of the re-evaluation of sweeteners, EFSA completed a safety review of aspartame in December 2013. 22/ EFSA concluded that aspartame and its breakdown products are safe for the general population (including infants, children and pregnant women) under the current Acceptable Daily Intake (ADI) of 40mg/kg bw/day.

- Canada: Health Canada proposed changes to the nutrition information on food labels to include new guidelines to help make serving sizes – based on reference amounts - declared in the Nutrition Facts table more consistent among similar food products; changes to the list of nutrients and corresponding daily values (DV) to be declared in the Nutrition Facts table and the way sugar is labeled; and, formatting changes to the Nutrition Facts table and the list of ingredients, and the proposal to create an optional information box highlighting the presence of certain bioactive components, such as caffeine. Health Canada has published a series of fact sheets on the proposed changes to the NFP format, sugar labeling and serving size guidelines. Additionally, for more information on Canada's dietary guidelines about sugars, please visit Canada's Food Guide. 23/

- United Kingdom (UK): The same requirements for the sugars and sweeteners in the EU apply in the UK.

- Codex and World Health Organization (WHO): Recently, WHO issued draft guidance on "Sugars intake for adults and children" recommending that sugars contribute less than 10% of total energy intake per day. 24/ Further reductions below 5% of total daily energy intake may have additional health benefits. The WHO guideline is intended to provide recommendations on the consumption of free sugars to reduce the risk of NCDs in adults and children, with a particular focus on the prevention and control of weight gain and dental caries. Relative to non-nutritive sweeteners, the Joint FAO/WHO Expert Committee on Food Additives has evaluated the safety of sucralose, aspartame, saccharin, acesulfame potassium, neotame, steviol glycoside, and other sugar alcohols (e.g., xylitol).

20/ http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2000L0013:20110120:EN:PDF
21/ http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1924:20121129:EN:PDF
22/ http://www.efsa.europa.eu/en/search/doc/399e.pdf
23/ http://www.sugar.ca/Nutrition-Information-Service/Health-professionals/Dietary-Guidelines-About-Sugar.aspx
24/ *WHO opens public consultation on draft sugars guideline* (http://www.who.int/mediacentre/news/notes/2014/consultation-sugar-guideline/en/)

AFFI Action

AFFI is maintaining its leadership role in addressing the issue of sugars and sweeteners in food:

- AFFI will continue to work to ensure that frozen fruits with added sugars are treated fairly in the school meal program;

- The Nutrition Facts Panel Alliance - co-led by the American Frozen Food Institute and the American Bakers Association - will continue to meet with FDA on a regular basis to share industry views on issues of relevance;

- AFFI will monitor the status of pending citizen petitions and, if necessary, coordinate with other industry associations to provide comments; and

- AFFI will monitor FDA enforcement actions, class action lawsuits, and settlements, regarding the safety and labeling of sugars and sweeteners.

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