Ingredients Declared as Evaporated Cane Juice: Guidance for Industry

Additional copies are available from:
Office of Nutrition and Food Labeling
Food Labeling and Standards Staff, HFS-820
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
(Tel) 240-402-2371
http://www.fda.gov/FoodGuidances

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to http://www.regulations.gov. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2009-D-0430 listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services Food and Drug Administration Center for Food Safety and Applied Nutrition

May 2016

Table of Contents

- I. Introduction
- II. Background
- III. Discussion
- IV. References

Ingredients Declared as Evaporated Cane Juice: Guidance for Industry¹

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

The purpose of this guidance is to enhance consumers' ability to make informed choices among sweeteners by promoting accurate and consistent labeling. More specifically, this guidance is intended to advise the regulated industry of our view that the term "evaporated cane juice" is not the common or usual name of any type of sweetener and to assist manufacturers in appropriately labeling products that contain sweeteners derived from the fluid extract of sugar cane.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Background

In recent years the term "evaporated cane juice" has appeared as an ingredient on food labels, most commonly to declare the presence of sweeteners derived from the fluid extract of sugar cane. However, as discussed in detail in section III of this guidance document, FDA's view is that such sweeteners should not be declared on food labels as "evaporated cane juice" because that term does not accurately describe the basic nature of the food and its characterizing properties (i.e., that the ingredients are sugars or syrups) (Refs. 1, 2, 3). Moreover, the use of "juice" in the name of a product that is essentially sugar is confusingly similar to the more common use of the term "juice" -- "the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree" (21 CFR 120.1(a)). Thus, the term "evaporated cane juice" is false or misleading because it suggests that the sweetener is "juice" or is made from "juice" and does not reveal that its basic nature and characterizing properties are those of a sugar.

As provided in 21 CFR 101.4(a)(1), "Ingredients required to be declared on the label or labeling of a food . . . shall be listed by common or usual name" The common or usual name for an

¹ This guidance has been prepared by the Food Labeling and Standards Staff in the Office of Nutrition and Food Labeling in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

ingredient is the name established by common usage or by regulation (21 CFR 102.5(d)). Each class or subclass of food is to be given a common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods. The common or usual name, which may be a coined term, must accurately describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients; must be uniform among all identical or similar products; and may not be "confusingly similar to the name of any other food that is not reasonably encompassed within the same name" (21 CFR 102.5(a)).

Sugar cane products exist in many different forms, ranging from raw sugars and syrups to refined sugar and molasses. These products are differentiated by their moisture, molasses, and sucrose content as well as by crystal size and any special treatments (e.g., treatment with sulfur). Sugar cane products with common or usual names established by regulation are sugar (21 CFR 101.4(b)(20)) and cane sirup (alternatively spelled "syrup") (21 CFR 168.130). Several other sugar cane products have common or usual names established by common usage (e.g., molasses, brown sugar, turbinado sugar, muscovado sugar, and demerara sugar). For purposes of ingredient labeling, "sugar" is defined to mean sucrose obtained from sugar cane or sugar beets in accordance with 21 CFR 184.1854, the regulation affirming that sucrose is generally recognized as safe (GRAS) for use in food when used under specified conditions. The GRAS regulation describes sucrose as the substance "obtained by crystallization from sugar cane or sugar beet juice that has been extracted by pressing or diffusion, then clarified and evaporated" (21 CFR 184.1854(a)). To be GRAS for use in food, sucrose must be of a purity suitable for its intended use (21 CFR 184.1854(b)).

On October 7, 2009, FDA published a draft guidance entitled "Guidance for Industry: Ingredients Declared as Evaporated Cane Juice" in the Federal Register (74 FR 51610) to advise industry of FDA's view that the common or usual name for the solid or dried form of sugar cane syrup is "dried cane syrup," and that sweeteners derived from sugar cane syrup should not be declared on food labels as "evaporated cane juice" because that term falsely suggests the sweeteners are juice. On March 5, 2014, we reopened the comment period (79 FR 12507) for the draft guidance seeking further comments, data, and information about how the ingredient sometimes declared as "evaporated cane juice" is produced, what its basic nature and characterizing properties are, and how it compares with other sweeteners made from sugar cane. We received numerous comments on the draft guidance. The majority of comments objected to the term "dried cane syrup." Several comments from sugar producers asserted that this term does not accurately describe the ingredient they produce, mostly because the standardized food "cane syrup" is not the starting material or an intermediate step for the ingredient they refer to as "evaporated cane juice." Based on comments stating that the ingredient sometimes declared as evaporated cane juice is not made from cane syrup as defined in 21 CFR 168.130, FDA is no longer recommending that this ingredient be labeled as "dried cane syrup."

Many comments described the process used to manufacture the ingredient described as "evaporated cane juice," and some comments also described the manufacturing process for other products derived from sugar cane. The initial processing steps are generally the same for all products produced from sugar cane. After sugar cane is harvested, it is cut or shredded and then crushed to extract the fluid. The extracted fluid is clarified and then evaporated to concentrate

-

² Honig, P. Principles of Sugar Technology. Elsevier Publishing Company. 1953.

the solids. To make the product "evaporated cane juice," the concentrated cane extract is filtered and undergoes a single crystallization process. The crystals are then separated from the molasses using centrifugation. From the comments, the method of filtering the "evaporated cane juice" fluid varies from producer to producer, as does the method used for single crystallization.

Most other common types of cane sugar (e.g., white sugar, brown sugar) are not filtered prior to the first crystallization. After the crystals are separated from the molasses using centrifugation, as part of the refining process, the sugar is melted and re-crystallized. Most cane-based sweeteners, including white sugar, undergo multiple crystallization steps.

Some comments stated that "evaporated cane juice" has essentially the same composition as white sugar and other sweeteners derived from sugar cane. As support for this point, one comment provided a specification sheet for "evaporated cane juice" indicating that the ingredient contains between 99.0 and 99.8% sucrose. The comment also included a specification sheet for another product identified as "certified organic sugar" and pointed out that the composition of the two products was identical except that the organic ingredient was made with organic sugar cane. Other comments focused on the differences between "evaporated cane juice" and other cane-based sweeteners. For example, some of these comments stated that "evaporated cane juice" has a different composition from white sugar because it retains traces of molasses and minerals. A few comments said that "evaporated cane juice" is different than other less refined, "alternative" sugars because it contains less molasses and can be substituted for white sugar in processed foods without affecting the taste or appearance of the finished product.

III. Discussion

This guidance is intended to help consumers make informed choices among sweeteners by promoting accurate and consistent labeling. To that end, we are advising the regulated industry of our view that the term "evaporated cane juice" is not the common or usual name of any type of sweetener and that this ingredient should instead be declared on food labels as "sugar," preceded by one or more truthful, non-misleading descriptors if the manufacturer so chooses (e.g., "cane sugar").

In developing this guidance, FDA reviewed the Codex Alimentarius Commission's (Codex's) Standard for Sugars, Codex Stan. 212-1999 (Ref. 4), which provides standards for certain sugars intended for human consumption without further processing, to determine whether Codex had established a standard for a product similar to that described on some U.S. food labels as "evaporated cane juice." The Codex Standard for Sugars contains no product identified as "evaporated cane juice." However, the Codex standard does define "raw cane sugar" as "[p]artially purified sucrose, which is crystallised from partially purified cane juice, without further purification, but which does not preclude centrifugation or drying, and which is

_

http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074439.htm

³ The Codex's definition of "raw cane sugar" refers to a different product than "raw sugar" as FDA uses that term. As used in FDA's Compliance Policy Guide (CPG) entitled "Raw Sugar," that term refers to "the intermediate food product as it leaves the sugar factory mill for further refinement in sugar refineries before use as food. In general, raw sugar is unsuitable for human food use because it contains extraneous impurities which are removed in the refining process." CPG 515.400; revised March 1995.

characterised by sucrose crystals covered with a film of cane molasses." This standard appears to describe the same sweetener referred to in many of the comments as "evaporated cane juice." We agree that the common or usual name used to describe this ingredient on food labels should include the term "sugar" because that term describes the basic nature and characterizing properties of the food.

In contrast, the term "evaporated cane juice" describes neither the basic nature of the food nor its characterizing properties, and therefore does not comply with 21 CFR 102.5(a). "Juice" is defined by 21 CFR 120.1(a) as "the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree." This relatively narrow definition is the one used for purposes of the juice hazard analysis and critical control point (HACCP) regulations (21 CFR Part 120) and the juice labeling regulation in 21 CFR 101.30. There are broader definitions of "juice" that are used in other contexts. For example, in the context of botany and food technology, "juice" is a general term referring to the fluid extract of any plant. However, in the context of diet and nutrition, "juice" has the narrower meaning reflected in the definition of "juice" in 21 CFR 120.1(a), which covers only liquid obtained from fruits or vegetables. Although we do not dispute that sugar cane is a member of the vegetable kingdom in the broad sense of classifying an article as "animal," "vegetable," or "mineral," FDA considers the term "vegetable" in the context of the juice definition to refer more narrowly to edible plant parts that consumers are accustomed to eating as vegetables in their diet. Sugar cane is not a vegetable in this sense. While consumers can purchase pieces of sugar cane, consumers do not eat sugar cane as a "vegetable" but instead use it as a source of sugar by chewing on the cane or its fibers or by placing the cane in a beverage to sweeten it. There are other plant juices used for human food that similarly are not "vegetable juice" or "fruit juice" for purposes of the juice definition; e.g., maple syrup and sorghum syrup. In summary, our view is that the fluid extract of sugar cane is not the juice of a plant that consumers are accustomed to eating as a vegetable in their diet and is not, therefore, "juice" as contemplated by the regulation defining that term (Refs. 1, 3).

Sugar cane is clearly not considered a fruit or vegetable by experts in nutrition and health, nor do those experts consider the fluid extract of sugar cane to be a type of fruit or vegetable juice. Rather, they consider it to be a source of sugar. For example, the Department of Agriculture's Center for Food Policy and Promotion lists "cane juice" and "sugar cane juice" among the many names for added sugars on its dietary guidance Web site for consumers (Ref. 5). A newsletter posted on the Department of Health and Human Services Web site warns that "cane juice" is one of the ingredient names used to hide added sugar in beverages and recommends for health reasons that any fruit juice given to children be 100 percent fruit juice without any form of added sugar, including "cane juice." Dietary advice on health organization Web sites is similar. For

_

⁴ For example, Dictionary.com Unabridged defines "juice" in relevant part as "the natural fluid, fluid content, or liquid part that can be extracted from a plant or one of its parts" http://www.dictionary.com/browse/juice. Retrieved April 25, 2016.

⁵ U.S. Department of Agriculture, Center for Nutrition Policy and Promotion. "Added Sugars." http://www.choosemyplate.gov/added-sugars. Retrieved April 20, 2016.

⁶ U.S. Department of Health and Human Services, Office of Head Start, National Center on Health. "Health Services Newsletter: The Role of Drinks with Sugar in Children's Oral Health." February 2015. http://eclkc.ohs.acf.hhs.gov/hslc/tta-system/health/docs/health-services-newsletter-201502.pdf. Retrieved April 20, 2016.

example, the Mayo Clinic Web site lists "cane juice" and "cane syrup" as forms of added sugar that consumers should cut back on for better health and nutrition. None of these Web sites defines sugar cane as a vegetable or classifies the fluid extract of the sugar cane plant as "juice" that counts toward the recommended number of daily fruit and vegetable servings.

In FDA's view, the common or usual name for the ingredient currently labeled as "evaporated cane juice" includes the term "sugar" and does not include the term "juice." The basic nature of the ingredient is that it is a sugar and its characterizing property is that of a sweetener. FDA's food labeling regulations provide that sucrose obtained from sugar cane or sugar beets in accordance with 21 CFR 184.1854 shall be referred to as "sugar" in ingredient labeling (21 CFR 101.4(b)(2)). Section 184.1854(a) describes sucrose as the substance "obtained by crystallization from sugar cane or sugar beet juice that has been extracted by pressing or diffusion, then clarified and evaporated." Based on the numerous comments indicating that the ingredient declared as "evaporated cane juice" is produced in this manner, it follows that the common or usual name for the product should be or include "sugar." As discussed in the Background section, current names that are used for several other sweeteners made from sugar cane (e.g., turbinado sugar, demerara sugar, and muscovado sugar) are names that have been established by common usage. In each instance, the basic nature of the food is described by use of the term "sugar." FDA would not object to the addition of one or more truthful, non-misleading descriptors before the common or usual name "sugar." Such a descriptor, which could be a coined term, could be used to distinguish the ingredient from white sugar and other sugars on the market by describing characteristics such as source, color, flavor, or crystal size.

Sweeteners derived from sugar cane should not be listed in the ingredient declaration by names such as "evaporated cane juice," which suggest that the ingredients are made from or contain fruit or vegetable "juice" as defined in 21 CFR 120.1. We consider such representations to be false and misleading under section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 343(a)(1)) because they do not accurately describe the basic nature of the food and its characterizing properties (i.e., that the ingredients are sugars or syrups), as required by 21 CFR 102.5.

Because sweeteners derived from sugar cane are not "juice" as defined in 21 CFR 120.1, they should not be included in the percentage juice declaration on the labels of beverages that are represented to contain fruit or vegetable juice (see 21 CFR 101.30). Section 101.30 requires the percentage of fruit or vegetable juice in beverages purporting to contain such ingredients to be declared on the label of the beverage. FDA would consider a juice product sweetened with an ingredient derived from sugar cane and labeled as 100% fruit juice to be misbranded under section 403(a)(1) of the Act (21 U.S.C. 343(a)(1)) because the "100% fruit juice" claim is false and misleading in that the product contains a non-juice sweetener in addition to the juice. FDA would also consider such a product adulterated under section 402(b) of the Act (21 U.S.C. 342(b)) because the sweetener has been substituted for part of the juice.

7

⁷ Mayo Clinic Staff. "Added sugars: Don't get sabotaged by sweeteners." http://www.mayoclinic.org/healthy-lifestyle/nutrition-and-healthy-eating/in-depth/added-sugar/art-20045328. Retrieved April 25, 2016.

IV. References

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of May 12, 2016, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after May 12, 2016.

- 1. Intergovernmental Ad Hoc Codex Task Force on Fruit and Vegetable Juices, Government Comments, p. 16, September 2000.
- 2. FDA letter from Martin Stutsman to Dr. Eric Wilhelmsen (Wilhelmsen Consulting), May 8, 2000.
- 3. FDA letter from Martin Stutsman to Martin Hahn, Esq., March 9, 2001.
- 4. Codex Standard for Sugars. Codex Standard 212-1999. http://www.fao.org/input/download/standards/338/CXS_212e_u.pdf. Adopted 1999. Amendment 2001. Retrieved April 26, 2016.
- 5. U.S. Department of Agriculture, Center for Nutrition Policy and Promotion. "MyPlate." http://www.choosemyplate.gov. Retrieved April 25, 2016.