

CITIZEN PETITION

January 31, 2022

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852
Submitted electronically via Docket No. FDA 2013-S-0610

Re: Citizen Petition Seeking FDA Rulemaking to Update the Required Nutrition Information at Chain Restaurants to Include Added Sugars for Standard Menu Items

To Whom It May Concern:

The undersigned submit this petition pursuant to 5 U.S.C § 553(e), 21 U.S.C. §§ 331, 343, and 10 C.F.R. § 10.30, requesting that the Commissioner of Food and Drugs amend its regulations¹ to require chain restaurants to declare added sugars alongside other nutrition information they are already required to publish. These amendments are necessary to harmonize the nutrition information required by law for chain restaurants with the information required by the Food and Drug Administration (FDA) in the Nutrition Facts label,² and to enable consumers to make informed choices and maintain healthy dietary practices when ordering from restaurants.

This action is one of several updates to FDA rules needed to reflect the latest science on added sugars. In 2016, the FDA issued a final rule updating Nutrition Facts to require, among other changes, a declaration for added sugars, which are sugars added during the processing of foods, distinguishable from the naturally occurring sugars present in milk, fruits, and vegetables. The 2016 rule also established a Daily Reference Value (DRV) for added sugars of 50 grams for a 2,000 calorie per day diet, derived directly from the recommendations of the Scientific Report of the 2015 Dietary Guidelines Advisory Committee, which recommended limiting added sugars intakes to less than 10 percent of calories.³

However, some regulations promulgated before the issuance of the 2016 rule have not been updated to reflect the added sugars declaration and DRV.⁴ The action we are requesting in the

¹ *Specifically*, 21 C.F.R. § 101.11 (2021), *promulgated in*: Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, Final Rule, 79 Fed. Reg. 71155 (Dec.1, 2014). [Hereinafter: Food Labeling; Nutrition Labeling of Standard Menu Items, Final Rule].

² *See* Food Labeling: Revision of the Nutrition and Supplement Facts Labels, Final Rule, 81 Fed. Reg. 33741 (May 27, 2016) [Hereinafter: Food Labeling; Revision of the Nutrition and Supplement Facts Labels, Final Rule].

³ Food Labeling: Revision of the Nutrition and Supplemental Facts Labels; Supplemental Proposed Rule to Solicit Comment on Limited Additional Provisions, 40 Fed. Reg. 44303, 44303-4 (July 27, 2015).

⁴ For example, CSPI previously urged the FDA to move expeditiously to define “low added sugar” claims, which remain undefined. Letter from Center for Science in the Public Interest to United States Food and Drug

present petition is one such update, necessary to ensure Americans have access to added sugars information across FDA-regulated foods. Specifically, we are asking the agency to require added sugars to be reported within the nutrition information for standard menu items published by chain restaurants. This information is required under the Patient Protection and Affordable Care Act (ACA) to be available in written form on the premises of such restaurants and provided to the customer on request.

CSPI, America's Food and Health Watchdog, is a non-profit consumer education and advocacy organization that has worked since 1971 to improve the public's health through better nutrition and safer food. The organization does not accept government or corporate grants and is supported by subscribers to its *Nutrition Action* magazine, as well as grants from individuals and private foundations. CSPI provides nutrition and food safety information directly to consumers and regularly publishes articles, reports, and other resources that rely on nutrition information made available by restaurants. A recent such example was the report *Sweet Excess*, published in July 2021 comparing the sugar in fountain drinks offered by the leading chain restaurants.⁵ *Nutrition Action* also publishes articles utilizing restaurant nutrition information, including *Cheers? Counting calories in booze* (Jan/Feb 2020); *Breakfast on the Run: A quick guide to coffee shops* (Oct 2019); *Winners and Losers: What to order when you eat out* (Dec 2017); and *Savvy Swaps: How to cut calories in half* (Oct 2017).⁶

Founded in 1936, CR is an independent, nonprofit, and nonpartisan organization that works with consumers to create a fair and just marketplace. Known for its rigorous testing and ratings of products, CR advocates for laws and company practices that put consumers first. CR is dedicated to amplifying the voices of consumers to promote safety, digital rights, financial fairness, and sustainability. The organization surveys millions of Americans every year, reports extensively on the challenges and opportunities for today's consumers, and provides ad-free content and tools to 6 million members across the U.S. The Consumer Reports website and magazine also regularly publishes articles providing its readers with advice based on the nutrition information published by restaurants, including *Healthier Fast Food Breakfasts* (Dec 2021), and the cover story, *Fast Food Makeover Which Restaurants are Healthier* (May 2020).⁷

Jason Block is an Associate Professor and the Director of Research of the Department of Population Medicine at Harvard Medical School/Harvard Pilgrim Health Care Institute. Dr. Block's primary research interests are the evaluation of governmental and institutional policies intended to change dietary behaviors and use of large data systems for population health surveillance and to explore the clinical epidemiology of chronic disease. He is also a practicing primary care physician at Brigham and Women's Hospital, co-directs a clinical epidemiology course at Harvard Medical School, and served as a Senior Advisor to the Acting Assistant Secretary for Health at the US Department of Health and Human Services from 2016 to 2017. Dr. Block has co-authored several studies using Menustat, a free, interactive nutrition database used

Administration (Jan. 9, 2020). https://cspinet.org/sites/default/files/attachment/Low_Sugar_Letter-1.9.20.pdf. Accessed January 31, 2022.

⁵ Center for Science in the Public Interest. *Sweet Excess*. 2021. <https://cspinet.org/resource/sweet-excess>. Accessed January 31, 2022.

⁶ Appendix A.

⁷ *Ibid.*

by researchers as a source of chain restaurant menu nutrition information.^{8,9,10} He and colleagues are currently exploring several new studies that would evaluate the effect of labeling on added sugars.

I. REQUESTED ACTION

The petitioners request that the FDA amend 21 C.F.R. § 101.11(ii) to include added sugars among the nutrients for which information is required to be available in written form on the premises of covered establishments and provided to the customer on request.

II. STATEMENT OF GROUNDS

A. Legal Authority to Require a Declaration for Added Sugars on Chain Restaurant Menus

As noted above, the FDA has authority under the ACA of 2010 to require restaurant or similar retail establishments that are part of a chain of 20 or more to make nutrition information for standard menu items available to consumers upon request.¹¹ The ACA specifically requires that restaurants maintain, at minimum, information about specific nutrients: total fat, saturated fat, cholesterol, sodium, total carbohydrates, sugars, dietary fiber, and total protein.¹² While added sugars are not required to be made available under the ACA, the statute authorizes the FDA to require, by regulation, disclosure of additional nutrients if it determines that the nutrient “should be disclosed for the purpose of providing information to assist consumers in maintaining healthy dietary practices.”¹³

These requirements in the ACA mirror the language authorizing the Nutrition Facts label under the Nutrition Labeling and Education Act of 1990 (NLEA). The NLEA also begins with a specific list of nutrients required to be published, and grants the FDA the discretion to require the disclosure of additional nutrients if such disclosure “will assist consumers in maintaining healthy dietary practices.”¹⁴ The agency exercised this discretionary authority under the NLEA when it required an added sugars declaration in the updated Nutrition Facts panel in 2016.¹⁵

⁸ Bleich SN, Wolfson JA, Jarlenski MP, Block JP. Restaurants with calories displayed on menus had lower calorie counts compared to restaurants without such labels. *Health Affairs*. 2015; 43 (11): 1877-1884.

⁹ Bleich SN, Soto MJ, Dunn CG, Moran AJ, Block JP. Calorie and nutrient trends in large U.S. chain restaurants, 2012-2018. *PLoS One*. 2020; 15(2): e0228891.

¹⁰ Grummon AH, Petimar J, Soto MJ, Bleich SN, Simon D, Cleveland LP, Rao A, Block JP. Changes in calorie content of menu items at large chain restaurants after implementation of calorie labels. *JAMA Netw Open*. 2021; in press.

¹¹ Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 STAT. 119 § 4205, *codified as* 21 U.S.C. § 343(q)(5)(H)(ii)(III).

¹² 21 U.S.C. §§ 343(q)(1)(D) & (5)(H)(ii)(III) The statute also requires reporting of “complex carbohydrates,” but the FDA has through rulemaking opted not to enforce this requirement. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Proposed Rule, 76 Fed. Reg. 19192, 19211 (Apr. 6, 2011) [Hereinafter: Food Labeling; Nutrition Labeling of Standard Menu Items, Proposed Rule].

¹³ 21 U.S.C. § 343(5)(H)(vi).

¹⁴ 21 U.S.C. § 343(q)(2)(A). The NLEA also grants the FDA the authority to remove a statutory nutrient from the requirements if the information is “not necessary to assist consumers in maintaining healthy dietary practices.” 21 U.S.C. § 343(q)(2)(B).

¹⁵ Food Labeling; Revision of the Nutrition and Supplement Facts Labels, Final Rule, 81 Fed. Reg. at 33745.

The FDA has previously worked to ensure that the nutrition information maintained by restaurants is harmonized with the information the FDA has required to be published in Nutrition Facts. For example, when the FDA issued its proposed rule for menu labeling in 2011, it required that restaurants disclose *trans* fat, a nutrient not expressly required under the ACA, “for the same public health reasons that supported the requirement that the amount of *trans* fat be declared on the label or labeling of [packaged] foods.”¹⁶

However, the menu labeling rule was finalized in 2014, two years before the agency updated the Nutrition Facts panel to include an added sugars declaration and establish a DRV for this nutrient. Accordingly, to harmonize the two rules with respect to added sugars, the agency now must update the menu labeling requirements through additional rulemaking.

B. Disclosure of Added Sugars in Restaurant Menu Items Would Assist Consumers in Maintaining Healthy Dietary Patterns

The food choices Americans make away from home shape our overall diet. Food prepared outside the home is a significant source of American’s calories, nutrients, and food expenses.¹⁷ According to a 2018 report by the Economic Research Service, Americans eat out between 4.2 and 5.5 occasions per week.¹⁸ In recent years, food prepared away from home has accounted for a third of the average person’s calories¹⁹ and nearly 40 percent of total food expenditures.²⁰ Household purchases of food away from home have increased over the last 40 years in the United States, with the share of calories obtained away from home nearly doubling from 17 percent in 1977-78 to a third of all calories in 2017-18.²¹

¹⁶ Food Labeling; Nutrition Labeling of Standard Menu Items, Proposed Rule, 76 Fed. Reg. at 19212.

The FDA also declined to require that restaurants report complex carbohydrates, as this nutrient, while required under the statute, had been removed by the agency from Nutrition Facts regulations. *Ibid* at 19211.

¹⁷ USDA Economic Research Service. Limited-service and full-service restaurants accounted for 73 percent of food-away-from-home spending in 2019. Last updated July 24, 2020. <https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=98897>, Accessed January 31, 2022 [Hereinafter: USDA ERS Food-away-from-home spending 2019].

¹⁸ Households with incomes at or below the Federal poverty line ate out about 4.2 times per week, whereas households above the poverty line ate out about 5.2 times per week. Saksena et al. America’s Eating Habits: Food Away from Home, USDA Economic Research Service. September 2018. <https://www.ers.usda.gov/publications/pub-details/?pubid=90227>. Accessed January 31, 2022.

¹⁹ USDA Agricultural Research Service. What We Eat in America, NHANES 2017-2018. Table 9. Away from Home. https://www.ars.usda.gov/ARSUserFiles/80400530/pdf/1718/Table_9_AWY_GEN_17.pdf. Accessed January 31, 2022 (Reporting that food and beverages consumed away from home account for 32 percent of energy for males and females age 2 and over in 2017-18).

²⁰ USDA Economic Research Service. Food Dollar Series Nominal Data [data file]. Retrieved from: <https://www.ers.usda.gov/data-products/food-dollar-series/download-the-data/>. Accessed January 31, 2022. (Reporting that 38.5 cents of every dollar spent by U.S. consumers on domestically produced food in 2019 went to food service establishments, such as restaurants and other eating places).

²¹ Saksena, 2018.

Prior to the COVID-19 pandemic, over a third of US adults consumed fast food on any given day.²² And while restaurant sales slumped in 2020 due to social distancing measures implemented to address the pandemic, sales have rebounded significantly since then, hitting a new all-time high of \$67.3 billion in revenue in May 2021.²³

Consumers are often presented with extremely unhealthy options when eating out, including meals that are high in added sugars. The average nutrient profile of a default combination meal served by fast food chains in the U.S. includes 68 grams of total sugar, much of it from beverages sweetened with added sugars.²⁴ *Sweet Excess*, a report published in 2021 by CSPI, compared added sugars in fountain drinks at the largest fast food chains and found that even most “small” drinks exceed the 50-gram DRV for added sugars.²⁵

Information about added sugars could help support consumers in making healthy dietary choices. The 2020–2025 Dietary Guidelines for Americans advises individuals to limit intake of added sugars to no more than 10 percent of calories per day starting at age 2.²⁶ (The DGA recommends children under two years of age completely avoid added sugars.²⁷)

Yet in order to follow this advice to limit added sugars consumption, consumers must be armed with the information to distinguish between added sugars and naturally occurring sugars, which do not have a daily limit.

Today, consumers lack access to this information on restaurant menus. An extraordinarily savvy consumer might be able to estimate the added sugar for some items based on total sugar and any ingredients the restaurant chooses to report voluntarily.²⁸ For example, the full-calorie sodas assessed in CSPI’s *Sweet Excess* report contain no natural sugars, so all of the sugar in the products was added sugars. Yet even the most nutritionally savvy customer could not figure out the added sugar in items that contain milk, fruit juice, or other naturally occurring sources of sugar, unless the chain chooses to disclose it voluntarily.

²² Fryar C, et al., Fast Food Consumption Among Adults in the United States, 2013–2016. *Caloric Intake From Fast Food Among Adults: United States, 2007–2010*. NCHS Data Brief No. 322, October 2018.

<https://www.cdc.gov/nchs/products/databriefs/db322.htm>. Accessed January 31, 2022.

²³ Bartash J. Restaurants Come Back from Brink as Americans Spend More Than Ever Eating Out. *Market Watch*. June 15, 2021. <https://www.marketwatch.com/story/restaurants-come-back-from-brink-as-americans-spend-more-than-ever-eating-out-11623784825>.

²⁴ Vercammen K, et al. Calorie and Nutrient Profile of Combination Meals at U.S. Fast Food and Fast Casual Restaurants. *American Journal of Preventive Medicine*. 2019; 57(3), e77–e85. <https://doi.org/10.1016/j.amepre.2019.04.008>.

²⁵ As described *infra*, CSPI assumed all of the sugars in fountain drinks were from added sugars in order to create this report. Center for Science in the Public Interest, 2021.

²⁶ United States Department of Health and Human Services, United States Department of Agriculture. *Dietary Guidelines for Americans, 2020 – 2025*. 9th Ed. Dec. 2020. https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary_Guidelines_for_Americans_2020-2025.pdf. Accessed January 31, 2022.

²⁷ *Ibid.*

²⁸ The FDA does not require restaurants to publish ingredients for menu items, as the ACA required publication of calories and nutrition information only.

For example, a customer at Smoothie King can learn that nearly half the 86 grams of sugar in its 20 oz. “Pineapple Surf” smoothie are added sugars, because that restaurant chose to disclose the information voluntarily.²⁹ But if that same customer were to buy a 20 oz. “Aloha Pineapple” smoothie from Jamba Juice, they would have no way to learn what percent of the 77 grams of sugar in that beverage were added sugars, as opposed to naturally occurring sugars from juice.³⁰

Similarly, a customer at Dunkin’ can see from its nutrition information that there are 46 grams of added sugar out of 69 grams of total sugar in the chain’s “Caramel Swirl Hot Latte with Skim Milk – Large.”³¹ But a customer ordering a “Caramel Brulée Latte – Venti” at Starbucks would not be able to learn how many of the 60 grams of total sugar in that beverage³² were from added sugar, as opposed to the naturally occurring sugars from milk.

Requiring chain restaurants to publish added sugars information also creates opportunities for consumers to obtain the information without making in-store requests. Diet-tracking applications allow consumers to make use of added sugars information aggregated from restaurant chain websites,³³ nutrition databases, and user-entered information, allowing consumers to easily track and monitor their own nutrient intake over the course of the day. Yet these applications cannot be populated with added sugars information if the restaurants decline to disclose it, undermining the apps’ usefulness for consumers.

In addition, consumers may also benefit from product reviews and articles, such as those published by CSPI and CR, that utilize nutrition information to compare the offerings at different chains. But without added sugars information, the publication may be forced to rely on estimates of added sugars, or simply to not compare added sugars.³⁴

Finally, nutrition information published by restaurants is useful for public health research and policy. For example, MenuStat, as previously noted, is a database of chain restaurant menu

²⁹ Smoothie King. Pineapple Surf. 2022. <https://www.smoothieking.com/menu/smoothies/break-time-blends/pineapple-surf>. Accessed January 31, 2022.

³⁰ Jamba. Aloha Pineapple. 2022. <https://www.jamba.com/smoothies/classic/aloha-pineapple>. Accessed January 31, 2022.

³¹ Dunkin’. Nutrition Guide. Last updated 12-14-2021. www.dunkindonuts.com/content/dam/dd/pdf/nutrition.pdf. Accessed January 31, 2022.

³² Starbucks. Caramel Brulée Latte. 2022. www.starbucks.com/menu/product/517/hot. Accessed January 31, 2022.

³³ While the FDA does not require nutrition information, other than calories, be published on restaurant websites, many leading chains, publish the same information online that they make available in stores. For example, CSPI visited the website of 20 leading fast food chains for its *Sweet Excess* report, and found that 18 of the chains provided nutrition information online. The two chains that did not, Dairy Queen and Hardee’s, also did not provide nutrition information when we contacted multiple individual locations by telephone. Center for Science in the Public Interest, 2021, at Appendix: Methods.

³⁴ For example, in December 2021, Consumer Reports magazine published an article evaluating ‘healthful’ options at three chains – Dunkin’, Starbucks and Panera –but could not compare added sugars information across chains, because only Dunkin’ provided added sugars information on its website. Consumer Reports was able to contact Panera customer service to obtain the information, but Starbucks did not provide added sugars information even upon request. Similarly, CSPI published articles in 2017, 2019, and 2020 assessing the nutrition in restaurant foods and beverages. In these articles, CSPI staff either did not assess added sugars, or attempted to estimate using the ingredients and comparable products. And in its report *Sweet Excess*, CSPI could estimate the added sugars only in the fountain beverages offered by the leading chain restaurants, and could not assess added sugars in meals, which can include substantial amounts of added sugars from desserts and sauces. See Appendix A.

nutrition information.³⁵ Yet, because added sugars information is not published by most restaurants, researchers conducting analyses using data from MenuStat can study only the total sugar in restaurant meals, leaving critical gaps in the public’s knowledge of the industry.³⁶

Lack of information can also undermine policy initiatives. For example, the New York City Council recently passed “the Sweet Truth Act” (Int 1326), a bill to require warnings on prepackaged menu items that exceed the daily value for added sugars.³⁷ Yet the policy covers only prepackaged items, which are required to declare added sugars under the 2016 Nutrition Facts rule.³⁸ Requiring added sugars information to be reported for all restaurant items will make it easier for New York City and other jurisdictions to design and enforce public health policies by making added sugars information available across the menu.

III. CONCLUSION

Reconciling the nutrition labeling requirements for menu labeling with Nutrition Facts would provide consumers with consistent, transparent, and accessible nutrition information for the food they eat, regardless of whether it is purchased at the grocery store or a chain restaurant. Information about added sugars is critical for individual consumers to be able to follow the DGA guidance on added sugars and will support efforts to design resources, publications, and policies that improve the health of Americans.

IV. ENVIRONMENTAL IMPACT

Under 21 C.F.R § 10.30(3), petitioners must provide an environmental impact assessment or claim a categorical exclusion from such requirement. The action requested herein is subject to a categorical exclusion under 21 C.F.R. §§ 25.30 (h) and 25.30(k), and therefore does not require the preparation of an environmental assessment. Further, the undersigned believe that the actions requested in this petition would have no environmental impact.

V. ECONOMIC IMPACT

Under 21 C.F.R § 10.30(3), upon request by the Commissioner following review of the petition, petitioners must submit “a statement of the effect of requested action on: (1) Cost (and price) increases to industry, government, and consumers; (2) productivity of wage earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5) employment; and (6) energy supply or demand.”

³⁵ Menustat. 2022. <http://menustat.org/#/home>. Accessed January 31, 2022. The public version of this database was last updated with data from 2018, but petition signatory Dr. Jason Block is, with colleagues, in the process of compiling data to update the database for more recent years.

³⁶ Vercammen, 2019.

³⁷ Center for Science in the Public Interest. New York City Passes the Sweet Truth Act, Requiring Warnings on Chain Restaurants’ Prepackaged Foods and Drinks that are High in Added Sugars. December 15, 2021.

<https://www.cspinet.org/news/new-york-city-passes-sweet-truth-act>. Accessed January 31, 2022.

³⁸ *Ibid.*

The Commissioner has not requested a statement of the economic impact of the requested action in this instance. However, the petitioners believe this petition will have no impact on any of the factors identified in 21 C.F.R § 10.30(3).

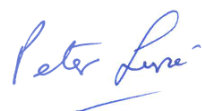
Unlike members of the public, chain restaurants have direct knowledge of the amount of added sugars used in their recipes. Moreover, chains have already developed methods for calculating and publishing nutrition information, including total sugars, to comply with the existing menu labeling requirements. Many, if not all, of these chain restaurants make use of nutrition analysis software with existing capacity to calculate added sugars, such as the ESHA food processor database.³⁹ The burden is sufficiently light that some restaurant chains, including Smoothie King,⁴⁰ Dunkin',⁴¹ and Domino's,⁴² have already begun voluntarily publishing grams of added sugars alongside total sugars as part of their nutrition information. Moreover, because chains need to maintain only a single copy of the nutrition information in each establishment, in cases where nutrition facts must be updated, printing expenses will be limited to one document per physical location. Any additional costs associated with a new requirement for added sugars are therefore likely to be negligible for the nation's leading restaurant chains, and would not be sufficient to impact price, employment, or the other factors identified in the economic impact statement.

VI. CERTIFICATION

The undersigned certify, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

Correspondence related to the petition should be directed to Sarah Sorscher, Deputy Director of Regulatory Affairs, Center for Science in the Public Interest, 202-777-8397, ssorscher@cspinet.org,

Signed,



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³⁹ Esha Research. *Our Customers*. n.d. <https://esha.com/about-us/customers/>. Accessed January 31, 2022.

⁴⁰ Smoothie King. Nutrition Information. <https://www.smoothieking.com/menu/smoothies/nutrition/fitness-blends>. Accessed January 31, 2022.

⁴¹ Dunkin'. Nutrition Guide. Last updated 12-14-2021. www.dunkindonuts.com/content/dam/dd/pdf/nutrition.pdf. Accessed January 31, 2022.


⁴² Domino's. Nutrition Guide. July 2021. https://cache.dominos.com/olo/6_72_2/assets/build/market/US/en/pdf/DominosNutritionGuide.pdf. Accessed January 31, 2022.



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