



Submission by Mail

January 6, 2020

Susan Mayne, Ph.D.
Director, Center for Food Safety and Applied Nutrition
c/o Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Horizontal Approaches to Food Standards of Identity Modernization (Docket No. FDA-2018-N-2381-0317)

Dear Dr. Mayne,

Center for Science in the Public Interest writes in response to recently completed proceedings of the Food and Drug Administration's Meeting on Horizontal Approaches to Food Standards of Identity Modernization (the Meeting on Horizontal Approaches).

CSPI 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 the roughly half million subscribers to its Nutrition Action Healthletter. CSPI provides nutrition and food safety information directly to consumers, and has long advocated for legislation, regulation, and judicial rulings to ensure that foods are safe and clearly labeled.

Throughout the past century, standards of identity have served as an important tool for transparency and promotion of public health. While the food marketplace has evolved over the years with the proliferation of many non-standardized products, food standards continue to play a key role in the American diet by defining the content of many of our commonly consumed staples, including bread, milk, and many cheeses.

Our comments below outline some of the public health benefits of food standards and describe the impact of prior horizontal changes, which were successful in fostering innovation but fell short on delivering promised transparency and public health benefits. We also review some of the changes that members of the food industry have proposed to the docket on the Meeting on Horizontal Approaches, and caution that while some of these changes undoubtedly offer potential public health benefits, others have the potential to do harm.

While CSPI supports the FDA's efforts to re-examine the standards of identity to promote public health, we are also concerned that making broadly conceived horizontal changes to the standards could introduce unintended negative consequences and/or confuse consumers about the quality

or nutritional value of foods. We therefore urge the agency to proceed cautiously and ensure that any amendments to the standards are targeted, clearly defined, and fully considered to support specific public health priorities.

In addition, we ask that the agency consider steps to strengthen the characterizing ingredients rule, which is intended to serve as a guardrail against consumer deception for foods that lack key ingredient requirements under a standard of identity.

We specifically recommend that the agency prioritize the following specific, clearly defined horizontal changes to the standards of identity and the related characterizing ingredients rule:

1. Issue regulations requiring the amount of key healthful ingredients to be declared
2. Allow salt substitutes to be used in standardized foods where necessary to achieve sodium reduction targets.
3. Maintain and expand key standards for enriched cereals.
4. Require dairy substitutes to disclose when the product contains less of a key nutrient than the reference dairy food.
5. Develop a streamlined process for reviewing other changes to standardized foods on a case-by-case basis.

A more detailed discussion of these points is included below.

I. Standards of Identity Help Ensure Transparency and Promote Public Health

The food standards of identity, now codified at 21 C.F.R. § 130-169, were important early tools for consumer protection, originating in an era when food fraud was rampant. In *The Poison Squad*, author Deborah Blum recounts how in the late 1800s and well into the 1900s, the American food supply was frequently adulterated. Spices could be filled with pulverized coconut shells or floor sweepings, coffee could include scorched sawdust, and foods were regularly dosed with formaldehyde, borax, and other dubious preservatives to disguise shoddy production practices.¹

When they were first created through the Food, Drug, and Cosmetic Act of 1938, food standards served to inform consumers of the nature of specific products and ensure that foods met consumer expectations for quality. As such, the standards not only “promot[ed] honesty and fair dealing in the interest of consumers,” they also provided a rudimentary framework for ensuring good manufacturing practices and reviewing the safety of new food additives.²

Since 1938, Congress has provided the FDA with additional tools to promote transparency in food labeling. Yet in some ways these tools still fall short of providing consumers with clear and actionable information about the quality and nutritional value of foods. For example, while the

¹ Blum D, *The Poison Squad: One Chemist's Single-minded Crusade for Food Safety at the Turn of the Twentieth Century*. New York, NY: Penguin Press; 2018.² Food and Drug Administration. Food Standards Under the 1938 Food, Drug, and Cosmetic Act: Bread and Jam. January 31, 2018. www.fda.gov/about-fda/histories-product-regulation/food-standards-under-1938-food-drug-and-cosmetic-act-bread-and-jam.

² Food and Drug Administration. Food Standards Under the 1938 Food, Drug, and Cosmetic Act: Bread and Jam. January 31, 2018. www.fda.gov/about-fda/histories-product-regulation/food-standards-under-1938-food-drug-and-cosmetic-act-bread-and-jam.

Nutrition Labeling and Education Act of 1990 mandated uniform labeling of Nutrition Facts and the declaration of ingredients in the order of their predominance, it did not require manufacturers to disclose information about the quantity per serving of high-value ingredients, including healthy ingredients like whole grains, fruits, and vegetables.³

Likewise, the Food Additives Amendment of 1958 provided the agency with authority to review the safety of new food additives independently of the standards of identity.⁴ Yet since 1998 the agency has permitted food manufacturers to circumvent mandatory approval by self-certifying ingredients as Generally Recognized as Safe (GRAS). Companies can do so without even notifying the agency.⁵

In light of these regulatory gaps, the standards of identity continue to play an important role in maintaining fixed minimums for quality ingredients and ensuring the safety of additives in standardized foods.

Standards of identity also play an important role in ensuring that vitamin supplementation of standardized foods is guided by evidence-based public health principles. For example, in the 1990s, the FDA amended the standards of identity for enriched cereal flours to include folic acid, first on a voluntary, then mandatory basis. Population studies have shown a remarkable 19 percent decrease in the prevalence of neural tube defects in the U.S. since these changes went into effect.⁶ If not for mandatory folic acid fortification of enriched cereal grain products, an estimated 1,326 additional babies would be born with neural tube defects (NTDs) each year.⁷

Simply permitting voluntary fortification of foods, without developing a food standard, may not produce the same results. In 2016, for example, the FDA issued a regulation permitting folic acid to be added to corn masa flour, the key ingredient in corn tortillas.⁸ This policy was intended to encourage reformulation of products largely consumed by Latinx populations, who continue to experience significantly higher rates of NTDs than the rest of the U.S. population. Unfortunately, since the voluntary rule took effect, few manufacturers of corn masa flour have begun adding folic acid. Developing a standard of identity for “enriched corn masa flour” could be one additional way to incentivize fortification.

These developments suggest that standards of identity offer a unique regulatory tool to help ensure that consumers are offered clear choices, empowering them to easily select the healthiest foods.

³ The Nutrition Labeling and Education Act, Pub. L No. 101-535, 104 Stat. 2353 (1990).

⁴ Food Additives Amendment, Pub. L. No. 85-929, 72 Stat. 1784 (1958).

⁵ Substances Generally Recognized as Safe (GRAS), Final Rule. 81 Fed. Reg 54960 (Aug. 17, 2016). CSPI is among the groups that have challenged this regulation, which provides consumers no assurance that new additives proposed for use in standardized foods—or any foods—meet applicable safety standards.

⁶ Honein MA, Paulozzi LJ, Mathews TJ, *et al* Impact of Folic Acid Fortification of the US Food Supply on the Occurrence of Neural Tube Defects. *JAMA* 2001;285(23):2981-2986.

⁷ Williams J, Mai CT, Mulinare J, *et al* Updated Estimates of Neural Tube Defects Prevented by Mandatory Folic Acid Fortification – United States, 1995-2011. *MMWR* 2015;64(01);1-5.

www.cdc.gov/mmwr/preview/mmwrhtml/mm6401a2.htm?s_cid=mm6401a2_w.

⁹ 318 U.S. 218, 232 (1943).

II. Prior Horizontal Changes to Food Standards Promoted Innovation, but Failed to Deliver Promised Transparency and Public Health Benefits

Although standards of identity offer clear benefits, the FDA has made key horizontal changes to the standards over the past century that dramatically reduced their efficacy. These changes facilitated the proliferation of new packaged foods over the past four decades, but also largely failed to deliver on promised transparency and public health benefits.

Far too many of the novel packaged foods that were introduced as a result of these changes are simply variations on the same basic unhealthy ingredients, resulting in attractive new products that are high in added sugars, refined grains, unhealthy fats, and sodium. This wave of new, non-standardized products has also created new opportunities for consumer confusion, undermining our efforts to eat well.

a. *The Original Food Standards Offered Clarity, But Did Not Keep Up with a Changing Marketplace*

Under the 1938 law that created FDA's current food standards authority, Congress authorized federal food regulators to pursue enforcement action against any manufacturer selling a product that "purported to be" a standardized product, provided that product did not meet the relevant standards. This authority prevented companies from inventing new, distinctive names for products like "bred spread," or "peanut spread," which were marketed to compete with foods made from higher-quality and more expensive ingredients, like jam or peanut butter (*Fig. 1*).



Figure 1: Inferior food products marketed under so-called "distinctive names" prior to passage of the FDCA in 1938. Image Source: FDA

A key element of the 1938 law was that it empowered federal regulators to prohibit the marketing of products that failed to meet the relevant food standard, even if clearly labeled as such.

For example, in *Federal Security Administrator v. Quaker Oats Co.*,⁹ the Supreme Court upheld the agency's authority to prevent the sale of "farina enriched with vitamin D" because it did not contain the other micronutrients required to meet the standard for "enriched farina" (including thiamine, riboflavin, and niacin), a product with which it could

readily be confused. In doing so, the court recognized that having a single standard aligned with public health criteria offers value by defining the marketplace clearly and promoting fair competition based on quality and nutrition.

⁹ 318 U.S. 218, 232 (1943).

b. *Initial “Horizontal” Changes in the 1970s Fostered Innovation, but Fell Short on Promised Transparency*

In spite of these benefits, standards development was a resource-intensive process with complicated procedural requirements.¹⁰ As the century progressed, the food standards also came under fire for failing to keep pace with advances in nutrition science, and were perceived as standing in the way of development of more healthful substitutes for standardized foods.¹¹

By the 1970s, it had become clear that food regulators would be unable to keep pace with the food industry’s creativity in supplying new products. The 1970 report of the White House Conference on Food, Nutrition, and Health sharply criticized the food standards and rules around “imitation” foods, which were perceived to impede the development of more healthful new foods.¹²

To address this, the agency proposed new regulations in 1972 outlining a process by which new products could be marketed using a “common or usual name” that was distinct from existing standardized names.¹³ In some ways, these changes turned the clock back to a pre-1938 era of “distinctive names” on substitute products.

Undoubtedly recognizing the risks invited by this approach, the agency included guardrails to ensure that consumers could distinguish between products of higher or lower quality. Key among these was a provision requiring companies to declare the percentage of any “characterizing” ingredient, defined as any ingredient that had a “material bearing on the price or consumer acceptance” of the product.¹⁴ In addition, so that the name would not be misleading, the agency indicated that the term “imitation” would still be required for “nutritionally inferior” foods, as defined by a reduction in certain essential nutrients when compared to the reference food.¹⁵

These changes were intended to implement a new system based on informed consumer choice, rather than strict requirements. The approach was succinctly summarized by the FDA’s then-Chief Counsel Peter Barton Hutt, who had participated in drafting the 1970 White House Conference report.¹⁶ Using the agency’s standard for cherry pies as an example, he reasoned that “[t]here are two ways of going about it. You can set a standard of identity and standard of quality for cherry pies, which is a long horrendous procedure; the other way of going about it is requiring on the label that the percent by weight of the cherries be labeled, so that I would have three cherry pies there and I could pick the one with the highest quality, namely the greatest

¹⁰ Merrill, RA, “Like Mother Used to Make”: An Analysis of FDA Food Standards of Identity. 74 Colum. L. Rev. 561 (1974).

¹¹ Lorman AJ, Food Standards and the Quest for Healthier Foods. In: Porter DV, Earl RO, eds. *Nutrition Labeling: Issues and Directions for the 1990s*. Washington, DC: National Academies Press (US); 1990.

¹² White House Conference on Food, Nutrition and Health. Final Report. Washington, DC: U.S. Government Printing Office. 1970:120.

¹³ Nonstandardized Foods: Proposed Common or Usual Names. Proposed Rule. 37 Fed. Reg. 12327 (June 22, 1972).

¹⁴ *Ibid.*

¹⁵ 21 C.F.R. § 101.3 (2019).

¹⁶ See White House Conference on Food, Nutrition and Health. Final Report. Washington, DC: U.S. Government Printing Office. 1970:116.

amount of cherries per weight of the total pie.”¹⁷ Under Mr. Hutt’s leadership, the agency embarked on the later approach, allowing for new products to compete with the standard recipes, but requiring a declaration for characterizing ingredients as a guarantee of quality.

These regulatory changes helped ease the way for an explosion of new products in the decades that followed. Between 1975 and 2008, the number of products in the average supermarket increased from under 9,000 to almost 47,000.¹⁸

Not all of these products were marketed as substitutes for standardized foods, but many directly competed with these foods, often without clear nutritional improvements. Some of these new competing products were also deceptively marketed. For example, in 2003, CSPI highlighted deceptive labeling claims on a line of “spreadable fruit” that contained less of the advertised fruit than standardized fruit preserves, harkening back to the “bred spread” of an earlier era.¹⁹

The new era in food innovation also fell short on promised transparency. In practice, “characterizing” food ingredients only rarely have been declared as part of the common or usual name for foods, impairing consumers’ ability to shop for higher-quality products. This is because, apart from a few specific required declarations (including juices and a certain standardized foods, e.g. “seafood cocktail²⁰”), the agency has left it up to food manufacturers to decide when a particular ingredient is a “characterizing” ingredient.

Too often, manufacturers have chosen not to label the amount of key healthful ingredients, leaving consumers in the dark. For example, in the bread aisle, products with minimal amounts of whole wheat mimic 100% whole wheat bread, a standardized product. These competing breads are sold under distinctive names like “Wheat Bread,” or “made with Whole Wheat Bread,” which are easily confused with genuine whole grain bread (*Fig. 2*).



Figure 2: Products with minimal whole grain content are easily confused with “whole wheat bread.”

Similarly, food manufacturers make claims like “contains real fruit” or “made with real fruit.”

¹⁷ Background Conference: “Nutrition Labeling” FDA (February 1973), personal archives of Hutt, Peter Barton.

¹⁸ Consumer Reports. What to Do When There are Too Many Product Choices on the Store Shelves? January 2014. www.consumerreports.org/cro/magazine/2014/03/too-many-product-choices-in-supermarkets/index.htm

¹⁹ Center for Science in the Public Interest. Smucker’s Spreading Deception, Says CSPI. May 13, 2003. <https://cspinet.org/new/200305131.html>.

²⁰ 21 C.F.R. § 102.54.

Yet “made with real fruit” can mean “made with very little real fruit,” and the “fruit” that does appear in these products may be in the form of a juice, paste, or concentrate. These processed ingredients are not as healthful as whole or cut-up fruits or vegetables because they lack the low calorie density, cell structure, intact fiber, and other factors that contribute to healthfulness and satiety.²¹

Likewise products like “veggie chips” present themselves as containing a variety of nutritious vegetables, yet they are often made primarily of highly processed potato ingredients, dyed red or green to resemble other vegetables. And the “yogurt” coating on nuts, fruit, bars, and other products is often sugar and palm oil, with little more than a touch of heat-treated yogurt powder to support the claim.

Such labeling and product design is misleading, and frequently allows products with minimal nutritional value to compete with the whole grains, fruits, vegetables, and low-fat dairy that form the core of a healthy eating pattern.

These challenges suggest that the promises of FDA’s initial “horizontal” changes have never been fully realized. The changes were intended to promote healthful innovation while requiring clear declarations that would allow consumers to shop for quality products. Instead, much of the new innovation prompted by these changes was in products of very little nutritional value. And too often, consumers also have not been provided with the information they need to select foods based on quality and health.

c. Additional Horizontal Changes In the 1990s Also Failed to Deliver Anticipated Benefits



Figure 3: In the 1990s, the FDA changed the rules for standardized products to allow nutrient content claims like “no sugar added” in standardized foods like ketchup.

The agency again experimented with horizontal changes to the food standards in the 1990s. Following passage of the Nutrition Labeling and Education Act, FDA began expressly authorizing nutrient content claims such as “low fat,” and “no sugar added,” ensuring these terms met specific requirements.

Yet makers of some standardized foods struggled to achieve the requirements of some of the newly-authorized claims while also meeting the recipe requirements laid out in the food standards. For example, the standard of identity for Ketchup does not permit the use of non-nutritive sweeteners, which are used to produce a “No Sugar Added” Ketchup. (Fig. 3)

To promote such reformulation, the agency promulgated 21 CFR § 130.10, which permitted manufacturers of standardized foods to add any “safe and suitable” ingredient to the recipe in order to develop products that would qualify for an authorized nutrient content claim.

²¹ Haber GB, Heaton KW, Murphy D, Burroughs LF. Depletion and disruption of dietary fibre. Effects on satiety, plasma-glucose, and serum-insulin. *Lancet*. 1977;2(8040):679-82; Mattes RD, Campbell WW. Effects of food form and timing of ingestion on appetite and energy intake in lean young adults and in young adults with obesity. *J Am Diet Assoc*. 2009;109(3):430- 7; Bolton RP, Heaton KW, Burroughs LF. The role of dietary fiber in satiety, glucose, and insulin: studies with fruit and fruit juice. *Am. J. Clin. Nutr*. 1981;34(2):211-7; Flood-Obbagy JE, Rolls BJ. The effect of fruit in different forms on energy intake and satiety at a meal. *Appetite*. 2009;52(2):416-22.

As with the changes in an earlier era, these latest horizontal changes helped to support a booming era of product reformulation. Yet even with the FDA setting careful requirements for making approved nutrient content claims, the changes have in some cases done little more than promote less-unhealthy versions of the same processed foods.

Such changes also ultimately did little to assist consumers in maintaining a healthy eating pattern. Rather than policies authorizing modest improvements in the recipe for ketchup, consumers would have been better served by policies encouraging us to eat more fresh, whole tomatoes.

III. Further Horizontal Changes Should be Targeted, Clearly Defined, and Support Specific Public Health Priorities.

Members of the food industry have now urged the FDA to look to these past regulatory changes as a model for further “horizontal” changes to the food standards. In particular, various groups representing the food industry submitted a petition in 2006 asking the agency to allow new modifications modeled on 21 CFR § 130.10, but without the requirement that the modified food qualify for an approved nutrient content claim.²² Given that past efforts to loosen food standards have served to promote new processed foods that largely failed to transform the American diet, we encourage the agency to regard the projected benefits of this proposal with skepticism.



Figure 4: Modified versions of standardized products are already freely marketed, such as “Gluten Free Pasta” and “Albacore Tuna with Chipotle & Olive Oil.” Image Source: Label Insight

The explosion of new products that began in the 20th century has shown no signs of abating in the 21st. An average of more than 21,000 new food and beverage products were introduced annually to U.S. consumers between 2011 and 2016.²³ This furious pace of new product development makes one thing abundantly clear: while Americans continue to face many challenges as we struggle to follow a healthy dietary pattern, lack of new food products is not one of them.

And existing rules contain ample flexibility to allow these new products—both healthier and less healthy—to be marketed as substitutes for standardized products, either by using distinctive names (“frozen dairy dessert” instead of “ice cream”), offering food in a different form (tuna

²² Citizen Petition to Modernize Food Standards. October 25, 2006. Docket ID: FDA-2007-P-0463-0367.

²³ U.S. Department of Agriculture Economic Research Service. New Products. August 20, 2019. <https://www.ers.usda.gov/topics/food-markets-prices/processing-marketing/new-products.aspx>.

packets instead of canned tuna (*Fig 4*), or by qualifying for a nutrient content claim under 21 CFR § 130.10. Manufacturers may also apply for Temporary Marketing Permits (“TMP”), allowing manufacturing practices that deviate from the standard of identity.²⁴

In some cases, the FDA has even permitted portions of the name of standardized foods to be incorporated as part of the common or usual name of a food that fails to conform to the standard. This enforcement practice has permitted the marketing of “gluten free pasta” (*Fig 4*) or “almond milk,” provided the overall labeling of such products will not lead consumers to confuse them with standardized foods.

Food manufacturers nevertheless express frustration with the food standards, primarily because standardized food names often serve as a means of gaining consumer acceptance. As ingredient manufacturer Bonumose stated in comments to the docket on the Meeting on Horizontal Approaches: “[w]hile a frozen dairy dessert may evoke in the consumer a similar experience as ice cream, the alternative labeling may not be trusted.”²⁵

Food manufacturers continue to complain that in order to access the benefits of a standardized name, they must comply with a variety of outdated requirements. These include restrictions on alternative manufacturing practices that may be more efficient, ingredients used to achieve technical effects (emulsifiers, stabilizers, antimycotic agents), and novel shapes, flavors, colors, etc. that are more appealing, nutritious, or meet a targeted health need (e.g. “gluten free”).

Comments to the current docket make clear that while some changes to the standards may be warranted, permitting sweeping horizontal amendments also has the potential to open a Pandora’s Box of changes to standardized foods, doing unintended harm.

Various proposals submitted in comments to the recent meeting docket, many of which were no doubt selected for submission because they appear to suggest public health benefits, have included:

- Sugar reductions of 10-20% in standardized juices, particularly orange juice²⁶
- Colorings in bread “as long as the colors do not promote deception”²⁷
- Sodium substitutes in bread, cheese, and other standardized foods²⁸

²⁴ Food and Drug Administration. Inventory of Temporary Marketing Permits Granted under 21 U.S.C. 341 for Definitions and Standards of Identity for Food. March 12, 2018. www.fda.gov/food/labeling-nutrition-guidance-documents-regulatory-information/inventory-temporary-marketing-permits-granted-under-21-usc-341-definitions-and-standards-identity. The food industry has made only limited use of this provision. Currently there are only three temporary marketing permits in effect, all for canned tuna. *Ibid.*

²⁵ Comment by Bonumose LLC Re: Horizontal Approaches to Food Standards of Identity Modernization, Docket No. FDA-2018-N-2381-1371. October 14, 2019.

²⁶ Comment by the American Beverage Association Re: Horizontal Approaches to Food Standards of Identity Modernization; Request for Comments (Docket No. FDA-2018-N-2381). November 12, 2019. While the sugar levels in orange juice are not particularly high among juices, citrus greening disease has resulted in increasing difficulties producing oranges with sufficient sweetness to meet the existing BRIX standards for this juice. Comment by the Florida Citrus Processors Association Re: Docket # FDA-2018-N-2381 Horizontal Approaches to Food Standards. November 10, 2019.

²⁷ Comment by the American Bakers Association Re: Horizontal Approaches to Food Standards of Identity Modernization; Request for Comments (Docket No. FDA-2018-N-2381). November 12, 2019.

²⁸ *Ibid.*; See also, Comment by the National Milk Producers Federation and International Dairy Foods Association Re: Docket No. FDA-2014-D-0055. Voluntary Sodium Reduction Goals: Target Mean and

- “Rare sugars” like tagatose and allulose in yogurt, ice cream, and other foods²⁹
- Alternative defoaming agents in pineapple juice³⁰
- New flavor ingredients (e.g., “chipotle”) and packing mediums (e.g., “packed in avocado oil”) in canned tuna and canned pacific salmon³¹
- Fruit preserves and jams with 45 (as opposed to 65) percent sugar³²
- Palm oil as a stabilizer in peanut butter³³
- Alternative vegetable oils as cocoa butter substitutes in chocolate³⁴
- Antifungal natamycin as a mold inhibitor in Colby cheese³⁵
- Expanded use of ultra-filtered milk in cheesemaking³⁶

Some of these changes would indeed benefit public health and may be well warranted. For example, substitution of potassium chloride for sodium chloride has the potential help the food industry meet FDA’s sodium reduction targets, reducing rates of hypertension and stroke.³⁷ While increased potassium also has potential risks for adults with chronic kidney disease, a review by the United Kingdom Department of Health found that the benefits of modest sodium substitution would outweigh the risks.³⁸ Furthermore, mandatory declaration of potassium content on the new Nutrition Facts label will allow consumers with chronic kidney disease to avoid foods made with potassium chloride that are high in potassium. Based on this evidence, horizontal changes across food standards to allow potassium chloride to be used in bread, cheese, and other standardized foods would provide clear public health benefits.

Yet these changes do not justify broad deregulation of the standards for poorly-defined purposes. Many of the other submitted changes offer no guarantee of health benefits, and may even promote harm. For example, the food industry has suggested loosening food standards to allow vegetable oils to be added to chocolate. While some vegetable oils may indeed result in reductions in saturated fat content for this food, others could have neutral or even negative impacts on both consumer and environmental health. In particular, palm oil’s saturated fat raises blood levels of atherogenic LDL (“bad”) cholesterol, and studies have reported that higher

Recommended Maximum Concentrations for Sodium in Commercially Processed, Packaged and Prepared Foods. 81 Fed. Reg. 35363 (June 2, 3536-35367). October 17, 2016.

²⁹ Comment by Bonumose LLC Re: Horizontal Approaches to Food Standards of Identity Modernization, Docket No. FDA-2018-N-2381-1371. October 14, 2019.

³¹ Comment by Bumble Bee Foods, LLC. Re: Horizontal Approaches to Food Standards of Identity Modernization; Public Meeting; Request for Comments, FDA-2018-N-2381-1371 (August 29, 2019). November 12, 2019.

³¹ Comment by Bumble Bee Foods, LLC. Re: Horizontal Approaches to Food Standards of Identity Modernization; Public Meeting; Request for Comments, FDA-2018-N-2381-1371 (August 29, 2019). November 12, 2019.

³² Comment by the Grocery Manufacturers of America. Re: Horizontal Approaches to Food Standards of Identity Modernization; Public Meeting; Request for Comments; Docket No. FDA-2018-N-2381-1371 (August 29, 2019). November 12, 2019.

³³ *Ibid.*

³⁴ *Ibid.* Comment by the Guittard Chocolate Company Re: Horizontal Approaches to Food Standards of Identity Modernization; Public Meeting; Request for Comments, FDA-2018-N-2381-1371 (August 29, 2019). November 11, 2019.

³⁵ Comment by Kraft Heinz Re: Docket No. FDA-2018-N-2381; Horizontal Approaches to Food Standards of Identity Modernization; Public Meeting; Request for Comment; 84 Fed. Reg. 45497 (Aug. 29, 2019). November 12, 2019.

³⁶ *Ibid.*

³⁷ Aburto NJ, et al. Effect of increased potassium intake on cardiovascular risk factors and disease: systematic review and meta-analyses. *BMJ*. 2013; 346: f1378.

³⁸ Scientific Advisory Committee on Nutrition and Committee on Toxicity. Potassium-based sodium replacers: assessment of the health benefits and risks of using potassium-based sodium replacers in food in the UK. 2017.

consumption of palm oil is linked with higher mortality from ischemic heart disease. Palm oil production also requires large-scale deforestation, often accomplished by slash-and-burn practices, with devastating impacts on the health of humans, other animals, and the environment.³⁹

A few of the proposed changes even more clearly run counter to public health goals. For example, colorings can be used to darken bread made primarily with refined grains, making it appear higher in whole grain and therefore healthier. The standard of identity for bread currently prohibits the use of colorings,⁴⁰ yet even with this restriction, companies make dubious use of caramel color and molasses to darken bread products that are made of mainly refined grains, conferring a health halo (*Fig 5*). Expressly authorizing colorings in bread would exacerbate this existing problem, further misleading consumers.



Figure 5. “Our Famous ‘Brown Bread’” from Cheesecake Factory uses caramel color and molasses rather than whole grains to achieve its “brown” appearance.

Even some of the proposals directly aimed at improving the nutrition profile of foods may lead to unintended harm. For example, members of the food industry have requested additional flexibility to allow the use of rare sugars or processed fibers to replace sweetness and bulk in standardized foods like yogurt, ice cream, and chocolate.⁴¹ Rare sugars like allulose and tagatose, as well as processed fibers like fructooligosaccharides and isomaltooligosaccharides, provide much of the sweetness of sugar, but are poorly absorbed. This means they contain fewer calories, but their use is also tied to adverse effects, including nausea, bloating, headache, diarrhea, and abdominal pain.⁴²

These new ingredients are typically self-certified by manufacturers as GRAS without adequate premarket safety review. The FDA should not allow industry to substitute such ingredients in standardized foods in the name of nutrition without evaluating whether they are safe.⁴³

In addition, CSPI is concerned with proposals that would permit claims describing nutritional

³⁹ Kadandale S, Marten R, Smith R, The palm oil industry and noncommunicable diseases. *Bull. World Health Organ.* 2019;97:118-128.

⁴⁰ 21 CFR § 136.110.

⁴¹ Comment by Bonumose LLC Re: Horizontal Approaches to Food Standards of Identity Modernization, Docket No. FDA-2018-N-2381-1371. October 14, 2019; Comment by the Grocery Manufacturers of America. Re: Horizontal Approaches to Food Standards of Identity Modernization; Public Meeting; Request for Comments; Docket No. FDA-2018-N-2381-1371 (August 29, 2019). November 12, 2019; Comment by the National Confectioners Association Re: Horizontal Approaches to Food Standards of Identity Modernization; Public Meeting; Request for Comments, FDA-2018-N-2381-1371 (August 29, 2019) (undated).

⁴² Center for Science in the Public Interest Re: Docket No. FDA-2019-D-0725; Comments of the Center for Science in the Public Interest (CSPI) on The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts Labels, Draft Guidance for Industry. June 17, 2019; Grabitske HA, Slavin JL. Gastrointestinal effects of low-digestible carbohydrates. *Critical Reviews Food Science and Nutrition.* 2009; 49:327–60.

⁴³ As we have argued separately, the ingredients also should not be allowed without an appropriate warning consumers who may experience gastrointestinal effects from these additives. Center for Science in the Public Interest Re: Docket No. FDA-2019-D-0725; Comments of the Center for Science in the Public Interest (CSPI) on The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts Labels, Draft Guidance for Industry. June 17, 2019

“improvements” that are defined by industry. Such claims may confuse consumers and make it harder to select healthier foods.

For example, members of the juice industry have expressed a desire to communicate minor (10-20 percent) reductions in sugar. They propose that such disclosures would “convey information that is not false or misleading to the consumer through labeling statements.”⁴⁴

The changes proposed will, by definition, not achieve sufficient reductions to meet FDA’s definition for “reduced sugar” or other nutrient content claims. Yet they will be marketed in competition with products that do meet the definition, potentially diverting consumers who might otherwise seek out beverages that are even lower in sugar. More importantly, the new products marketed with minimal “improvements” will also compete with the whole fruits and vegetables, 100 percent whole grain foods, low fat dairy products, and water that make up the core of a healthy eating pattern, meaning consumers could eat fewer of those healthful foods.

In light of the benefits of food standards and current ample regulatory flexibility for development and labeling of new foods, we encourage the agency to proceed with caution as it considers further “horizontal” changes to the standards. In particular, the agency should consider the risks and benefits of each change proposed to improve nutrition, rather than allowing manufacturers to make their own determinations as to which changes might benefit public health.

To the extent that the agency wishes to consider broader horizontal changes that cut across food categories, we specifically recommend that the agency prioritize the following horizontal regulatory changes to promote transparency and public health goals:

1. Issue regulations requiring the amount of key healthful ingredients to be declared

As the agency considers additional horizontal changes that would shift the marketplace still further away from strict enforcement of the food standards, we also encourage the agency to revisit its approach to the characterizing ingredients rule. Addressing declarations for characterizing ingredients is critical because the rule serves as a key guardrail against consumer deception for products that lack a defined recipe. In spite of the agency’s best intentions, the rule has fallen far short of the transparency needed to ensure meaningful consumer choice, and is long overdue for a re-evaluation.

Specifically, we ask the FDA to issue a rule requiring the declaration of whole grain content as a percent of total grains for any product making an express or implied whole grain claim. We also urge the agency to issue a rule requiring disclosure of the quantity of fruits, vegetables, and other healthful ingredients (*e.g.*, yogurt, nuts) in common household measures on products making labeling claims related to these ingredients.⁴⁵ These requirements were previously recommended by CSPI in its Nutrition Innovation Strategy comment, and we have separately petitioned the

⁴⁴ Comment by the Juice Products Association RE: Horizontal Approaches to Food Standards of Identity Modernization (Docket Number FDA-2018-N-2381). November 12, 2019.

⁴⁵ This recommendation is further detailed in CSPI’s comments on the FDA’s nutrition innovation strategy. Comment by Center for Science in the Public Interest Re: FDA-2018-N-238; The Food and Drug Administration’s Comprehensive, Multi-Year Nutrition Innovation Strategy; Public Meeting; Request for Comments. October 11, 2018.

agency requesting a whole grain declaration.⁴⁶

2. Allow salt substitutes to be used in standardized foods where necessary to achieve sodium reduction targets.

We urge the agency to permit the use of potassium salt (potassium chloride) and other sodium substitutes in any standardized food where such use is accompanied by reductions in sodium content. In particular, Americans could benefit from changes to the standards for bread and cheese, which together account for 10 percent of American’s sodium intake.⁴⁷

Cheeses with a federal standard of identity, such as Mozzarella, Cheddar, Processed American cheese and almost all named cheeses, are precluded from using a salt substitute or other functional ingredient not usually allowed by the standard. The National Milk Producers Federation and International Dairy Foods Association have specifically commented that standards of identity serve as a barrier to meeting FDA’s voluntary sodium reduction targets in standardized cheeses.⁴⁸

Similarly the standard of identity for bread allows for “salt” but not potassium salt or other sodium substitutes.⁴⁹ Permitting salt substitutes in standardized bread would allow companies to make modest reductions in sodium in keeping with the FDA’s targets.⁵⁰

3. Maintain and expand key standards for enriched cereal flours.

The standards of identity for “enriched” products remain important to consumers, who may otherwise have difficulty discerning the health value of diverse fortified products. Consumers who regularly consume bread made from “enriched flour,” for example, will not easily understand the impact of the presence or absence of each component (including folic acid, riboflavin, niacin, and thiamine), and could easily be confused by “enriched” products touting diverse combinations of nutrients.

We also encourage the agency to expand the “enriched” definition to corn masa flour, possibly also considering a horizontal standard for “enriched” cereals that includes other grains for which

⁴⁶ Center for Science in the Public Interest. Petition to Prohibit Misbranding of Whole Wheat Products and to Promulgate Food Labeling Regulations Concerning Products Made with Whole Wheat. Center for Science in the Public Interest, 1993. <https://cspinet.org/sites/default/files/1993-petition-misbranding.pdf>.

⁴⁷ Zerleen SQ, Zhao L, Gillespie C, *et al.* Sodium Intake Among Persons Aged \geq 2 Years—United States, 2013-2014. *MMWR* 2017;66(12):324-238. Note that this value (yeast breads plus cheese) underestimates the total contribution of yeast breads because sandwiches (including sandwich fillings) that are identified by a single WWEIA food code are reported separately (5.7 percent).

⁴⁸ Comment by the National Milk Producers Federation and International Dairy Foods Association Re: Docket No. FDA-2014-D-0055. Voluntary Sodium Reduction Goals: Target Mean and Recommended Maximum Concentrations for Sodium in Commercially Processed, Packaged and Prepared Foods. 81 Fed. Reg. 35363 (June 2, 3536-35367). October 17, 2016.

⁴⁹ 21 C.F.R. § 136.110.

⁵⁰ Food and Drug Administration. Draft Guidance for Industry: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods for Voluntary Sodium Reduction Goals. June 2016. Should this change be adopted, we urge the agency to also make clear that products making such changes must still meet the agency’s requirements for making “low sodium,” “reduced sodium,” and other nutrient content claims.

there is currently no standard of identity.

4. Require dairy substitutes to disclose when the product contains less of a key nutrient than the reference dairy food.

We previously urged the FDA avoid any efforts to ban terms like “milk,” “yogurt,” or “cheese” from plant-based dairy substitutes.⁵¹ To ensure that consumers have a clear understanding of the nutritional value of these products, we have asked that the FDA instead require a front-of-package disclosure on the products that fail to provide the levels of key nutrients typically found in milk, yogurt, or cheese—naturally or by fortification—under the agency’s general authority to prevent misleading labeling in 21 U.S.C. § 343(a)(1).⁵² Such a declaration could be applied horizontally across all dairy substitutes, rather than as an amendment to the standard of identity for specific products.

5. Develop a streamlined process for reviewing other changes to food standards on a case-by-case basis.

Other decisions to modify standardized foods should be made on a case-by-case basis. Recognizing that prior efforts to amend standards have proceeded slowly, we recommend that FDA consider establishing, by regulation, a tiered system that would expedite its review of changes to the standards.

Uncontroversial changes, for example, changes to the shape of a food or methods for calculating weight or fill, could receive expedited review under such a proposed system.

In contrast, changes that introduce new ingredients, reduce or eliminate required ingredients, or otherwise modify the nutritional profile of a food should receive more careful consideration under notice-and-comment rulemaking, with priority given to standards most likely to benefit public health. The system should also accommodate changes that apply to multiple standards simultaneously, such as changes to remove minimums for milkfat across multiple dairy products.

In approving changes designed to promote meaningful nutritional improvements, the agency should also specifically consider and define how nutritional improvements that fail to meet requirements for an approved nutrient content claim would be communicated to consumers in the product labeling, to avoid confusion.

Such a system should also include a streamlined process for reviewing and establishing new standards of identity where such a standard would facilitate transparency and product quality. Various proposals from industry include standards for hummus⁵³ and olive oil.⁵⁴

⁵¹ Comment by Center for Science in the Public Interest Re: Use of the Names of Dairy Foods in the Labeling of Plant-Based Products (FDA–2018–N– 3522). January 28, 2019.

⁵² *Ibid.*

⁵³ Sabra Dipping Company, LLC. Sabra Files FDA Petition to Establish Standard of Identity for Hummus. May 19, 2014. www.prnewswire.com/news-releases/sabra-files-fda-petition-to-establish-standard-of-identity-for-hummus-259786851.html.

⁵⁴ Siegner C, Olive Oil Producers Petition FDA to Adopt Enforceable Standards of Identity. *Food Dive*. November 7, 2019. www.fooddive.com/news/olive-oil-producers-petition-fda-to-adopt-enforceable-standards-of-identity/566774/.

At a minimum, we strongly urge the agency not to adopt a “horizontal standard” that allows the addition of self-determined GRAS ingredients to standardized foods, as these ingredients have not been reviewed for safety by the FDA.

IV. Conclusion

The standards of identity were first envisioned as a bold new tool for consumer protection and transparency in the rapidly evolving and loosely regulated food marketplace of the early 20th century. As the century progressed, both the food industry and regulators became more sophisticated in their approaches, leading to reduced reliance on food standards.

Nevertheless, the standards have continued to serve as an important tool for transparency and promotion of public health, filling key gaps not addressed through other regulations.

Prior horizontal changes to the food standards in the 1970s and 1990s helped to open the door to an explosion of new products, but fell short on promised transparency and public health benefits. We urge the agency to ensure that any further efforts to amend the standards be narrowly targeted and clearly defined to support specific public health priorities.

We appreciate your thoughtful consideration of these issues,

Sincerely

Sarah Sorscher, J.D./M.P.H.
Deputy Director of Regulatory Affairs
Center for Science in the Public Interest