CENTER FOR
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Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: FDA-1995-N-0062; Food Standards; General Principles and Food Standards Modernization; Reopening of the Comment Period

The Center for Science in the Public Interest (CSPI) respectfully submits the following comments on the establishment of general principles for FDA to use when considering whether to establish, revise, or eliminate a food standard.

The food marketplace is rapidly evolving, with innovative, non-standardized products proliferating on supermarket shelves. But food standards continue to play a key role in the American diet by defining the contents of staples like bread, pasta, milk, and cheese. While CSPI supports the FDA's efforts to re-examine the standards of identity, we believe there are very few cases in which updating the standards would promote public health or honesty and fair dealing in the interest of consumers. Moreover, we are concerned that certain changes to the standards could introduce unintended negative consequences and/or confuse consumers about the quality or nutritional value of foods. We urge FDA to consider and prioritize the health and safety of consumers to the full extent possible under its regulatory authority as the agency endeavors to amend existing food standards and introduce new ones.

In this comment, we list some potential benefits and risks of amending the food standards; propose modifications to the principles to ensure that only updates to food standards that will benefit consumer understanding or public health will be made; and discuss additional steps FDA must take to promote honesty and transparency in the food system. Specifically, we call on FDA to:

- Amend food standards only when evidence clearly shows that benefits to public health outweigh any potential harms, such as by permitting sodium substitutes and eliminating milkfat minimums
- Require robust evidence of safety for any ingredient proposed to be added to a standardized food
- Implement a mandatory review process for claims describing deviations from food standards to prevent unauthorized nutrient content claims on foods with modest reductions in unhealthful nutrients
- Ensure transparency and opportunities for public participation in all processes of updating food standards when the nutrients, ingredients, additives, or other food characteristics of interest to consumers may be affected
- Avoid focusing excessive resources on food standards modernization and instead focus on more impactful efforts, such as issuing regulations requiring declaration of the amount of key healthful ingredients such as whole grains, fruits, and vegetables on packaged foods.

I. Food standards modernization presents potential benefits as well as risks to the healthfulness and safety of the U.S. food supply.

a. Benefits

As FDA acknowledged at its public meeting on the agency's Nutrition Innovation Strategy, modernization of food standards presents opportunities to "promot[e] industry innovation and provid[e] flexibility to encourage manufacturers to produce more healthful foods."[1] We agree. Specifically, in our previous communications to the agency on this topic, including a letter to Dr. Susan Mayne sent on January 6, 2020[2] and comments submitted in 2018 to FDA's docket on the Nutrition Innovation Strategy,[3] we urged FDA to leverage its existing authority to modernize food standards by permitting the use of sodium substitutes in bread, cheese, and other standardized foods, and also consider eliminating milkfat minimums where they appear as part of a standard of identity. CSPI supports horizontal changes to food standards in these discrete cases to the extent that the evidence clearly shows that the benefits to public health outweigh any potential harms.

1. Reducing sodium in the food supply by permitting sodium substitutes

Permitting the use of sodium substitutes, such as potassium chloride, in bread, cheese, and other standardized foods would benefit the overall health of the American public. The FDA could achieve this effectively by creating a new "horizontal" regulation through notice-and-comment rulemaking that would allow sodium substitutes to be used across all standardized foods.

Excess sodium consumption is associated with elevated blood pressure, which is a risk factor for life-threatening conditions including heart disease and stroke.[4] According to data from the National Health and Nutrition Examination Survey, only 23 percent of American adults adhere to dietary sodium intake recommendations,[5] and mean daily sodium consumption among individuals age 20 years and older was 3,540 mg in 2015-2016,[6] compared with the recommended consumption limit of 2,300 mg per day for adults. Meanwhile, nearly half of Americans have high blood pressure.[7] This is despite decades of public health efforts to reduce population sodium intake. There is a clear need for novel approaches, including

[1] U.S. Food and Drug Administration. FDA Public Meeting: FDA's Comprehensive, Multi-Year Nutrition Innovation Strategy—Facilitated Breakout Session: Modernizing Standards of Identity & Ingredients Lists on Labels. 2018. https://www.fda.gov/media/114860/download. Accessed March 17, 2020.
[2] Center for Science in the Public Interest. Letter to Dr. Susan Mayne, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, Re: Horizontal Approaches to Food Standards of Identity Modernization (Docket No. FDA-2018-N-2381-0317). January 6, 2020. https://cspinet.org/sites/default/files/attachment/Letter_to%20_FDA_re_Meeting_on_Horizontal_Standards.pdf. Accessed March 3, 2017.
[3] Center for Science in the Public Interest. Comments 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. https://cspinet.org/sites/default/files/attachment/nis-cspi-comments-with-appendix_0.pdf. Accessed March 17, 2020.
[4] U.S. Centers for Disease Control and Prevention. Sodium. December 9, 2019. https://www.cdc.gov/heartdisease/sodium.htm. Accessed March 17, 2020.
[5] Brouillard AM, Kraja AT, Rich MW. Trends in dietary sodium intake in the United States and the impact of USDA guidelines: NHANES 1999-2016. *Am J Med.* 2019; 132(10):1199-1206.e5.
[6] U.S. Department of Agriculture Agricultural Research Service. What We Eat In America Data Tables- Nutrient Intakes from Food and Beverages, 2015-2016. November 26, 2019. https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/wweia-data-tables/. Accessed April 10, 2020.
[7] U.S. Centers for Disease Control and Prevention. Facts About Hypertension. February 25, 2020. https://www.cdc.gov/bloodpressure/facts.htm. Accessed March 17, 2020.

ones that facilitate a reduction of sodium in the food supply rather than relying solely on individuals to change their dietary patterns.

Potassium chloride can be used as a partial substitute for sodium chloride in foods due to its similar taste and functionality. Research shows that increasing potassium chloride and decreasing sodium chloride in the food supply would have a positive impact on public health. One modeling study estimated that if Americans reduce their sodium intake to 2,300 mg per day, the result would be 11 million fewer cases of prevalent hypertension and $18 billion saved in health care costs each year.[8] A systematic review of studies on potassium intake and health found that higher potassium intake was associated with reduced blood pressure in people with hypertension and a 24 percent lower risk of stroke.[9]

It should be noted that an increase in potassium in the food supply may pose a risk to some individuals, including people living with reduced kidney function, for example from advanced kidney disease or acute kidney failure, infants, older adults, and those on potassium-sparing diuretics and some other medications. A review by the United Kingdom Department of Health's Scientific Advisory Committee on Nutrition and Committee on Toxicology found that if 15 to 25 percent of sodium chloride in food were replaced with potassium chloride, the benefits (reduction in hypertension and number of strokes) would outweigh the potential risks (increase in cases of hyperkalemia and resultant arrhythmia, adverse cardiac effects, or death).[10] Still, to protect vulnerable subpopulations, FDA should use the notice-and-comment rulemaking process as an opportunity to solicit feedback on additional measures that would reduce or minimize their risk, including limitations in some products, labeling requirements, and educational efforts.

There is sufficient evidence to indicate that amending food standards to permit the use of sodium substitutes, such as potassium chloride, in bread, cheese, and other standardized foods would benefit the overall health of the American public, especially when paired with steps to reduce risks to potassium-sensitive subpopulations.

2. Reducing saturated fat in the food supply by eliminating milkfat minimums

The FDA could also improve public health by amending its regulations to eliminate milkfat minimums across the food standards, provided milkfat is not replaced by other sources of saturated fat or substitutes that have not been reviewed for safety by FDA.

Saturated fat is another nutrient overconsumed by Americans and is associated with increased levels of LDL cholesterol, which increases risk of heart disease and stroke. According to the 2015-2020 Dietary Guidelines for Americans ("The Dietary Guidelines"), only 29 percent of individuals in the U.S. consume amounts of saturated fats consistent with the recommended limit of less than 10 percent of calories.[11] At the same time, approximately 29 percent of American adults have high LDL ("bad") cholesterol, and many more have additional risk factors for heart disease and stroke.[12]

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[8] Palar K, Sturm R. Potential societal savings from reduced sodium consumption in the U.S. adult population. *Am J Health Promot.* 2009; 24(1):49-57.
[9] Aburto NJ, et al. Effect of increased potassium intake on cardiovascular risk factors and disease: systematic review and meta-analyses. *BMJ.* 2013; 346: f1378.
[10] 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.
[11] U.S. Department of Health and Human Services & U.S. Department of Agriculture. 2015-2020 Dietary Guidelines for Americans. https://health.gov/sites/default/files/2019-09/2015-2020_Dietary_Guidelines.pdf. Accessed March 17, 2020.
[12] Virani SS, et al. Heart disease and stroke statistics—2020 update: a report from the American Heart Association. *Circulation.* 2020; 141(9): e139-e596.

CSPI has been urging FDA to leverage food standards to achieve saturated fat reduction for decades. Meanwhile, manufacturers have been requesting leeway to permit fat reduction in standardized foods. In 1990, CSPI raised concerns that milkfat minimums in standardized products like ice cream force healthier alternatives to bear unfamiliar, pejorative names like "frozen dairy dessert."[13] In 1995, we jointly filed a successful petition, along with the Milk Industry Foundation, asking FDA to eliminate the standards of identity for low-fat milk and several other dairy products that permitted "low fat" claims on products than permitted "low fat" claims on products that did not meet the criteria to bear a "low fat" nutrient content claim.[14] That same year, the Calorie Control Council (a trade group representing the low- and reduced-calorie food and beverage industry) also petitioned FDA to permit the removal of fat from standardized foods.[15] On multiple occasions, the International Dairy Foods Association has requested the elimination of the milkfat minimum requirement in yogurt to allow for the introduction of new, reduced fat yogurt options not presently permitted.[16] And in its 2006 petition to modernize food standards, the Grocery Manufacturers Association (GMA) appealed to FDA to allow reductions in saturated fat that are less than those required in the standard version of a product but too high to bear a "less" or "reduced" nutrient content claim.[17]

Several standardized products, such as certain cheeses,[18] cacao products,[19] and frozen desserts,[20] still require minimum levels of milkfat in order for a product to bear a standardized name. CSPI supports the idea of providing manufacturers with the flexibility to make reductions in milkfat content that will reduce levels of saturated fat in the food supply. Eliminating milkfat minimums in standardized cheeses, so long as this change does not lead to the addition of other sources of saturated fat, could be particularly impactful, as cheese is a top source of saturated fat in the American diet.[21] While we oppose permitting standardized foods to contain milkfat substitutes that have not been reviewed for safety by FDA, some reductions can be made without necessitating additional ingredients or additives. Food standards should not hold industry back from reformulating products to promote public health, so long as products continue to conform with consumer expectations and present no new, unevaluated, or disproportionate risks to the public.

b. Risks

Aside from these two targeted instances in which changes to standards of identity present opportunities to improve the healthfulness of the food supply, CSPI foresees little by way of significant public health benefit associated with more sweeping changes to the food standards, and significant risks. Even changes that may seem beneficial to public health at face value may have unintended consequences.

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[13] Comments of the Center for Science in the Public Interest at 39, FDA Docket No. 89N-0026 (Jan. 5, 1990).
[14] Docket No. 95P-0250; 61 Fed. Reg. 58991 (November 20, 1996). Lowfat and Skim Milk Products, Lowfat and Nonfat Yogurt Products, Lowfat Cottage Cheese: Revocation of Standards of Identity; Food Labeling, Nutrient Content Claims for Fat, Fatty Acids, and Cholesterol Content of Food (to be codified at 21 C.F.R. § 101, 131, and 133).
[15] Docket No. 95P-0078
[16] International Dairy Foods Association. Comments Re: Docket No. FDA-2000-P-0126; Milk and Cream Products and Yogurt Products; Petition to Revoke Standards for Lowfat Yogurts and Nonfat Yogurt and to Amend the Standards for Yogurt and Cultured Milk; Proposed Rule & Docket No. FDA-2018-N-2381; Multi-Year Nutrition Innovation Strategy; Public Meeting; Request for Comments. October 8, 2018.
[17] Grocery Manufacturers Association. Citizen Petition to Modernize Food Standards. October 25, 2006.
[18] 21 C.F.R. § 133. Cheeses and Related Cheese Products.
[19] 21 C.F.R. § 163. Cacao Products.
[20] 21 C.F.R. § 135. Frozen Desserts.
[21] National Cancer Institute. Identification of Top Food Sources of Various Dietary Components. Updated November 30, 2019. https://epi.grants.cancer.gov/diet/foodsources. Accessed April 6, 2020.

In its 2006 petition, GMA requested flexibility in food standards for six categories of variations: 1) Addition of ingredients intended solely for technical, nondistinctive effects; 2) Use of safe and suitable flavor, flavor enhancers, and ingredients; 3) Use of advanced or more efficient technologies; 4) Use of alternate manufacturing processes; 5) Changes to a product's basic shape; and 6) Improvements in nutritional properties that do not rise to the level of a defined nutrient content claim. The following are some key areas of concern raised by GMA's proposal, which we hope FDA will consider in developing and implementing principles for establishing, revising, or eliminating food standards.

1. Unsafe ingredients in standardized foods

We are concerned that flexible and broad standards will be utilized by manufacturers as yet another pathway to add new and unsafe chemicals to our foods. In fact, one company has already proposed that FDA allow sugar substitutes like allulose, a substance self-approved as Generally Recognized As Safe (GRAS) by industry, be permitted in standardized foods,[22] despite evidence that it is one of several poorly digested carbohydrates that can cause nausea, bloating, headache, diarrhea, and abdominal pain.[23, 24]

As CSPI described in past comments to FDA, major flaws in the current system for determining which substances are GRAS have already allowed unsafe chemicals into many of our foods.[25] The present system permits manufacturers to secretly self-approve new ingredients for safety, without review by FDA.[26] This process is rife with conflicts of interest and exposes the food system to health and safety risks from new food chemicals that lack third-party oversight. For example, industry has designated as GRAS the chemical o-phenylphenol despite its classification as a carcinogen by the state of California.[27, 28] Industry has also decided the chemical 2,4-hexadienal is GRAS, despite classification as possibly carcinogenic to humans by the International Agency for Research on Cancer.[29, 30]

Providing broad flexibility to industry would carry the risks presented by the "secret GRAS loophole" over to standardized foods. Including ingredients that entered the food supply through the secret GRAS loophole would run counter to the intended purpose of food standards: to promote honesty and fair dealing in the interest of consumers. We urge FDA to avoid jeopardizing the advantages of standardized

[22] Bonumose LLC. Comments Re: Horizontal Approaches to Food Standards of Identity Modernization, Docket No. FDA-2018-N-2381-1371. October 14, 2019.
[23] Center for Science in the Public Interest. Comments Re: Docket No. FDA-2019-D-0725; The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts Labels, Draft Guidance for Industry. June 17, 2019. https://cspinet.org/sites/default/files/attachment/allulose%20final%20from%20CSPI.pdf. Accessed March 18, 2020.
[24] Grabitske HA, Slavin JL. Gastrointestinal effects of low-digestible carbohydrates. *Critical Reviews Food Science and Nutrition*. 2009; 49:327–60.
[25] Center for Science in the Public Interest. Comments Re: Docket No. FDA-1997-N-0020; Substances Generally Recognized as Safe (GRAS). April 15, 2015. https://cspinet.org/sites/default/files/attachment/GRAS%20Comment%20FINAL_0.pdf. Accessed March 18, 2020.
[26] *Id*. at 12.
[27] Flavor & Extract Manufacturers Association (FEMA) Expert Panel and Staff (P. Newberne, R.L. Smith, J. Doull, V.J. Feron, I.C. Munro, P.S. Portoghese, W.J. Waddell, B.M. Wagner, C.S. Weil, T.B. Adams and J.B. Hallagan). GRAS Flavoring Substances 19 (FEMA No. 3906-3963). *Food Technology*. 2000; 54(6): 66-84.
[28] California Office of Environmental Health Hazard Assessment. O-Phenylphenol Listed as Known to the State of California to Cause Cancer. August 4, 2000. https://oehha.ca.gov/proposition-65/crnr/o-phenylphenol-listed-known-state-california-cause-cancer. Accessed March 18, 2020.
[29] Flavor & Extract Manufacturers Association (FEMA) Expert Panel (R.L. Smith, S.M. Cohen, J. Doull, V.J. Feron, J.I. Goodman, L.J. Marnett, P.S. Portoghese, W.J. Waddell, B.M. Wagner, and T.B. Adams). GRAS Flavoring Substances 21 (FEMA No. 4024-4068). *Food Technology*. 2003; 57(5): 46-59.
[30] International Agency for Research on Cancer. 2,4-Hexadienal. n.d. https://monographs.iarc.fr/wp-content/uploads/2018/06/mono101-012.pdf. Accessed March 18, 2020.

foods in the name of innovation or convenience to industry. Instead, the agency should continue to review proposals that would allow new ingredients into standardized foods on a case-by-case basis.

2. Confusing labeling and representation of standardized foods

Figure 1. HyVee Cottage Wheat Bread is among the many bread products using caramel color and molasses rather than predominantly whole grains to achieve a wholesome appearance.

Changes to labeling or representation of standardized foods present another threat to honesty and fair dealing in the food system. Some of the changes proposed by industry would result in confusing or misleading labeling and representation. For example, GMA has requested that, "[f]or maximum flexibility, any product colors deemed acceptable based on recognized testing procedures should be permitted [in standardized foods],"[31] and the American Bakers Association has requested the same for colorings used in bread "as long as the colors do not promote deception."[32] We support the current prohibition on use of colorings in the standard of identity for bread.[33] Yet even under the present standard, companies use ingredients like caramel color and molasses to darken bread products made primarily with refined grains, misleadingly conferring a health halo associated with whole grain foods (Figure 1).

Companies are knowingly deceiving customers into purchasing less nutritious products. In a 2006 survey of 1,000 mothers commissioned by Sara Lee Food & Beverage, 64 percent of respondents reported believing brown bread is better for you than white bread and 25 percent reported using a bread's color to determine how healthy it is.[34] The problem of misrepresentation through coloring is exacerbated by the lack of clear labeling indicating the percent of grains that are whole grains in food products. Without such labeling, consumers have no way of knowing whether their diets promote their compliance with the Dietary Guidelines' advice to consume at least half of one's daily servings of grains from whole grains. Allowing colorings in bread would further permit the misrepresentation of refined wheat bread as whole wheat bread, confusing consumers and reducing the likelihood that Americans meet dietary recommendations for whole grain intake.

GMA has also requested flexibility to make modest reductions in nutrients such as saturated fat and cholesterol that do not meet the criteria for "low" or "reduced" nutrient content claims, and increases in whole grain content that do not qualify a product for being labeled "whole grain."[35,36] While we have

[31] Grocery Manufacturers Association. Citizen Petition to Modernize Food Standards. October 25, 2006.
[32] 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.
[33] 21 C.F.R. § 136.110.
[34] Businesswire. New Sara Lee Soft & Smooth 100% Whole Wheat Bread Offers Consumers Taste, Texture They Prefer with 100% Whole-Grain Nutrition. December 29, 2006. https://www.businesswire.com/news/home/20061229005025/en/New-Sara-Lee-Soft-Smooth-100-Wheat
[35] Grocery Manufacturers Association. Citizen Petition to Modernize Food Standards. October 25, 2006.
[36] Grocery Manufacturers Association. Comments Re: Horizontal Approaches to Food Standards of Identity Modernization; Public Meeting; Request for Comments; Docket No. FDA-2018-N-2381-1371. November 12, 2019.

noted above that some of these reductions may be beneficial for public health, we are also concerned that these changes would discourage more significant nutritional improvements and present new opportunities for misleading labeling.

Standardized foods are already permitted to depart from standards, but still bear standardized names, in order to qualify for nutrient content claims.[37] Therefore, GMA's request only relates to foods with such modest reductions that they would not qualify for nutrient content claims.

It is difficult to see how such changes would be conveyed to consumers without making an express or implied nutrient content claim that would signify unjustified health benefits. For example, GMA contradicts itself in its 2006 petition, at the same time proposing labeling declarations such as "Regular mayonnaise, 11 g fat per serving, this product 9 g" that strongly resemble nutrient content claims, while also claiming that they are "NOT seek[ing] the ability to 'claim' modest reductions in food labeling. There is no intention to create a competing claim structure to the existing nutrient content claim regulations."[38] If FDA permits the modest nutrient reductions or ingredient increases proposed, industry cannot be trusted to self-regulate against misleading claims.

These claims may divert consumers from seeking out products that are truly low in nutrients to limit, or assist products marketed with minimal "improvements" in competing with the 100 percent whole grain foods, whole fruits and vegetables, low fat dairy products, and water that make up the core of a healthy eating pattern. Any benefits of minor reductions in overconsumed nutrients or minor increases in beneficial ingredients in standardized foods could be undermined or negated by misleading marketing of these foods. CSPI urges FDA to either prohibit claims based on any modest nutritional improvements permitted, or to exercise careful oversight over such claims, including by providing a mandatory review process for claims describing deviations from a food standard.

3. Lack of transparency regarding changes to standardized foods

A third significant risk of changes to the food standards is a lack of transparency and communication with the public about changes to the foods they consume every day. In its citizen petition, GMA requested that FDA issue new regulations amending 21 C.F.R. Part 130 by establishing a new process for updating food standards.[39] Based on GMA's Draft Regulation for Standard of Identity Reform, manufacturers would be able to market any food that deviates from the applicable food standards for one of several broad "beneficial purpose[s]," so long as the food is not "nutritionally inferior," has "equivalent or superior performance characteristics" (*e.g.* flavor, shelf life), continues to perform "at least one of the principal functions of the standardized product substantially as well as the standardized product," does not add an ingredient that is "specifically prohibited by the standard," and does not replace an ingredient that is "specifically required by the standard."[40] Such a rule would essentially replace the current notice and comment rulemaking process with an industry-led self-determination process mirroring the disastrous GRAS loophole.

FDA has not indicated any intention to issue such a regulation adopting GMA's proposed process. But the proposal highlights the important issue of changes being made to food standards without sufficient public awareness. CSPI urges FDA to maintain its current process of notice-and-comment rulemaking for any changes to food standards that may affect the nutrients, ingredients, additives, or other food characteristics of interest to consumers. This is critical to ensuring that foods continue to align with consumer expectations.

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[37] 21 C.F.R. § 130.10. Requirements for foods named by use of a nutrient content claim and a standardized term.
[38] Grocery Manufacturers Association. Citizen Petition to Modernize Food Standards. October 25, 2006.
[39] *Id.*
[40] Grocery Manufacturers Association. Citizen Petition to Modernize Food Standards - Appendix A. October 25, 2006.

II. FDA's principles for establishing, revising, or eliminating food standards should prioritize public health.

CSPI appreciates that FDA's 13 proposed general principles put consumers first, prioritizing honesty and fair dealing in the interest of consumers (Principle 1), and ensuring consumers are not misled by product names or characteristics (Principle 2). Most of the proposed principles are compatible with efforts to leverage food standards to improve the health and safety of the food supply, but we propose the following amendments to strengthen the principles such that they can be most effectively used by FDA to achieve these goals.

A. Amendment to Principle 4

First, we propose that Principle 4 be amended to state:

> Ensures food does not appear to be better or of a greater value**, including nutritional value,** than it is. May be used as a vehicle to improve the overall nutritional quality of the food supply **provided evidence shows nutritional benefits will outweigh any potential risks to public health**.

Explicitly including 'nutritional value' provides necessary clarification that changes to standardized foods may not be used to misrepresent the healthfulness of products. This would ensure, for example, that any additional ingredients or colorings allowed in bread may not be used to deceptively portray bread made from refined grains as having higher whole-grain content. The agency may also consider incorporating additional clarifying text covering other forms of value that are in the interest of consumers, such as "economic" value.

The added text at the end of this principle addresses the issue of changes to food standards that purport to be focused on public health and nutrition, but may have unintended negative consequences or contribute to consumer confusion. Any proposal for a new or revised food standard that affects the nutritional quality of a food should be accompanied with a robust evaluation of potential impacts on consumer health and the nutritional quality of the food supply. Based on FDA's assessment of the evidence, only those changes for which the nutritional benefits clearly outweigh any potential risks should be considered. Permitting the use of sodium substitutes in standardized foods is an example of a proposal with sufficient evidence to warrant implementation.

B. Amendment to Principle 6

Additionally, we propose that Principle 6 be struck and replaced with:

> ~~Permits maximum flexibility in the technology used to prepare the food provided the technology does not alter the basic nature or essential characteristics, or adversely affect the nutritional quality or safety, of the food. Provides for any suitable, alternative manufacturing process that accomplishes the desired effect, and describes ingredients as broadly and generically as feasible.~~
>
> **Ensures that any ingredient permitted or required in the food or used to prepare the food will not adversely affect the nutritional quality or safety of the food. Prior to use, manufacturers must demonstrate to the FDA or USDA that any ingredient that has never been used before in the standardized food or any technology that has never been used before in the manufacturing process is reasonably certain to do no harm based on the highest quality and most up-to-date available science.**

The sixth principle currently proposed by FDA suggests an entirely new approach to establishing food standards. It would replace precise specifications with overly broad definitions, thereby sacrificing transparency and making the standards far less important or meaningful. As seen with the secret GRAS loophole, allowing manufacturers to introduce novel ingredients to foods without safety review, transparency, or oversight can lead to unsafe innovations that pose risks to consumers' health.[41]

Broadening definitions and increasing flexibility of food standards would allow manufacturers to use self-designated, secret GRAS ingredients in standardized foods. For example, using broad, generic terms such as "emulsifying agents," as proposed by GMA,[42] would allow any emulsifying agent into standardized foods, including those self-determined to be GRAS in secret. However, standards that require specific emulsifying agents that are listed as GRAS or are approved food additives would not permit this.

Allowing the use of self-determined, secret GRAS ingredients in standardized foods would introduce some of the very safety risks that food standards were established to address. In the late 1800s and well into the 1900s, foods marketed to U.S. consumers were often adulterated with unsafe ingredients such as formaldehyde, borax, and other dubious preservatives.[43] When the food standards were first established through the Food, Drug, and Cosmetic Act of 1938, they helped to ensure that foods met consumer expectations for quality and that they were produced using good manufacturing practices.[44]

Decades after the food standards were first conceived to promote honesty, safety, and transparency in the food supply, we face new challenges to the safety of food ingredients. Thousands of new ingredients have entered the food supply through the secret GRAS loophole. Of the roughly 10,000 additives used in food, an estimated 3,000 have never been substantively reviewed by FDA.[45] For an estimated 1,000 of these substances, safety decisions were made by the food industry without any notice at all to FDA.[46] As Deputy FDA Commissioner for Foods, Michael Taylor, remarked in August 2014, "We simply do not have the information to vouch for the safety of many of these chemicals."[47] Currently, both FDA and the public are in the dark when it comes to knowing what safety risks are associated with the thousands of secret GRAS substances that are consumed every day.

Once the door is open for these substances, FDA and the public would also be in the dark with respect to the safety of standardized foods. Instead of a principle that opens the door to these untested, unsafe technologies and ingredients, FDA should be guided by a principle that will ensure all ingredients permitted in the foods must undergo public review for safety. Furthermore, when a manufacturer wishes to incorporate an ingredient or technology that has never been used for a standardized food, that

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[41] *See* discussion on unsafe ingredients in standardized foods, *supra* at section I.b.1.

[42] Grocery Manufacturers Association. Citizen Petition to Modernize Food Standards. October 25, 2006.

[43] 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.

[44] Food and Drug Administration. Food Standards Under the 1938 Food, Drug, and Cosmetic Act: Bread and Jam. January 31, 2018. https://www.fda.gov/about-fda/histories-product-regulation/food-standards-under-1938-food-drug-and-cosmetic-act-bread-and-jam. Accessed April 15, 2020.

[45] The Pew Charitable Trusts. *Fixing the Oversight of Chemicals Added to Our Food*. Nov. 2013. http://www.pewtrusts.org/en/research-and-analysis/reports/2013/11/07/fixing-the-oversight-of-chemicals-added-to-our-food. Accessed April 16, 2020.

[46] *Id.*

[47] Kimberly K. Food additives on the rise as FDA scrutiny wanes. Washington Post. Aug. 17, 2014. http://www.washingtonpost.com/national/food-additives-on-the-rise-as-fda-scrutiny-wanes/2014/08/17/828e9bf8-1cb2-11e4-ab7b-696c295ddfd1_story.html. Accessed April 16. 2020.

manufacturer should be required to demonstrate to FDA that those new ingredients and technologies are reasonably certain to do no harm, the applicable safety standard under law.[48]

C. Amendment to Principle 12

Finally, we propose that Principle 12 be amended to state:

> Provides terms **and claims** that can **and cannot** be used to name **or describe** a food and allows terms to be used in any order that is not misleading to consumers.

This amendment would encourage proposals for new or revised food standards to explicitly state which terms and claims will *not* be used on standardized foods following any changes. The intended effect is to prevent the use of descriptive terms or claims that resemble nutrient content claims on foods that do not qualify for such regulated claims. This would be a step towards holding industry accountable for its assertion that in seeking permission to make minor improvements to nutritional content of standardized foods, it is not seeking the ability to claim modest nutrient reductions through food labeling.

III. Additional steps to promote honesty and fair dealing in the food system.

Regulation of standardized foods is only one of several ways that FDA can promote honesty and fair dealing in the food system. CSPI has previously urged FDA to issue regulations requiring that the amount of key healthful ingredients, including whole grains, fruits, and vegetables, be declared on the labels of packaged foods (Figure 2).[49,50,51] Such declarations would eliminate the deception and confusion surrounding both standardized and non-standardized foods bearing claims such as "Made with real fruit" and "Made with whole grain," or using terms and depictions implying presence of whole grains, fruits, and vegetables on products containing little or none of these ingredients. They would also ensure that any changes to these key ingredients that result from updates to food standards are conveyed in a clear, honest, and uniform way.

Figure 2. Examples of potential front-of-package declarations for whole grains and fruit.

Standardized foods frequently specify minimum levels of key characterizing ingredients. Non-standardized foods need not conform to these requirements, meaning consumers are generally left in the dark as to the levels of healthful ingredients like whole grains and fruits. This allows products like "made

[48] 21 CFR 170.3(i). Stating, "Safe or safety means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the conditions of its intended use."
[49] 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. Accessed March 24, 2020.
[50] Center for Science in the Public Interest. Letter to Dr. Susan Mayne, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, Re: Horizontal Approaches to Food Standards of Identity Modernization (Docket No. FDA-2018-N-2381-0317). January 6, 2020. https://cspinet.org/sites/default/files/attachment/Letter_to%20_FDA_re_Meeting_on_Horizontal_Standards.pdf. Accessed March 3, 2017.
[51] Center for Science in the Public Interest. Comments 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. https://cspinet.org/sites/default/files/attachment/nis-cspi-comments-with-appendix_0.pdf. Accessed March 17, 2020.

with whole grain" bread or "multigrain pasta," which may contain minimal amounts of whole grains, to compete unfairly with standardized products like 100 percent whole grain bread and pasta. FDA should prioritize rules that address this problem prior to considering any amendments that would further loosen the standards of identity.

Other strategies CSPI endorses to promote honesty and fairness through updates to food labels include the development of a consistent, evidence-based, interpretive front-of-package labeling system; an improved definition of "healthy;" clear declarations of high levels of sodium, saturated fat, and added sugars on products bearing nutrient content claims; and a stronger standard of scientific evidence for structure-function claims.[52]

Industry alleges that food standards modernization will allow them to innovate and improve the nutritional quality of the food supply. But if the goal is to promote public health, FDA should not have to tie itself up in a project with such minimal potential for impact. Rather than focusing its resources on food standards modernization, CSPI calls on FDA to first prioritize regulations on healthful ingredient declarations and advance other initiatives with greater potential for public health impact.

IV. Conclusion

With these comments, CSPI seeks to convey the limited potential of using modernization of food standards to promote honesty, transparency, and nutritional improvements to the food supply. We urge FDA to take advantage of those few opportunities where broad changes to food standards will have unequivocal benefits by issuing regulations that horizontally amend all food standards to permit the use of sodium substitutes and eliminate milkfat minimums.

Beyond those discrete actions, we caution against sweeping changes to food standards. We ask that FDA bolster its general principles for considering new and revised food standards to comprehensively address the health and safety risks posed by changes to food standards. We also encourage the agency to focus on other approaches to promoting honesty and fair dealing in the interest of consumers, namely by issuing regulations requiring declarations of whole grain, fruit, and vegetable quantities.

Finally, we ask that FDA preserve the important role of food standards in providing consumers with a set of foods that consistently meet expectations for characteristics and quality. This means that any changes to standardized foods must be implemented through a transparent process with opportunities for public participation.

CSPI appreciates the opportunity to comment on the FDA's general principles for establishing, revising, and eliminating food standards, and we look forward to working with the agency on efforts to promote honesty and transparency, and improve the nutritional quality of the food supply.

[52] Center for Science in the Public Interest. Comments 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. https://cspinet.org/sites/default/files/attachment/nis-cspi-comments-with-appendix_0.pdf. Accessed March 17, 2020.

Appendix A

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

CENTER FOR
Science IN THE
Public Interest
The nonprofit publisher of
Nutrition Action Healthletter

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.

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[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 spred," 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 spred" 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 cocktail[20]"), 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 juice[26]
- Colorings in bread "as long as the colors do not promote deception"[27]
- Sodium substitutes in bread, cheese, and other standardized foods[28]

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[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 foods[29]
- Alternative defoaming agents in pineapple juice[30]
- New flavor ingredients (*e.g.*, "chipotle") and packing mediums (e.g., "packed in avocado oil") in canned tuna and canned pacific salmon[31]
- Fruit preserves and jams with 45 (as opposed to 65) percent sugar[32]
- Palm oil as a stabilizer in peanut butter[33]
- Alternative vegetable oils as cocoa butter substitutes in chocolate[34]
- Antifungal natamycin as a mold inhibitor in Colby cheese[35]
- Expanded use of ultra-filtered milk in cheesemaking[36]

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

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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

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[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 ≥ 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 hummus[53] and olive oil.[54]

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[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

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