American Bakers Association

*Serving the Baking Industry Since 1897*

**By Electronic Submission** February 2, 2018

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Review of Existing Center for Food Safety and Applied Nutrition Regulatory and Information Collection Requirements, Docket No. FDA-2017-N-5094**

Dear Sir or Madam:

The American Bakers Association (ABA)[1] is pleased to submit these comments in response to FDA's request for comments on the agency's review of existing Center for Food Safety and Applied Nutrition (CFSAN) regulatory and information collection requirements.[2] Many of the requests we make herein we have requested in previous comments submitted to the agency.

As CFSAN considers our comments and those of other stakeholders submitted in response to this request, we ask that the agency not publicly propose to revoke or amend regulations, such as standards of identity, without first corresponding with the primary stakeholders regarding such actions. For example, if the agency concludes on its own that a regulation/standard of identity is no longer relevant, it should reach out to the stakeholders most impacted by a revocation/revision to the regulation/standard of identity before taking regulatory action to propose revisions to or revoke such rule(s).

As summarized below and detailed in the comments we previously submitted to FDA in response to FDA's revisions to the nutrition facts label (NFL) and in ABA's citizen petition requesting an immediate stay of the definition of dietary fiber, ABA believes that, more than any other sector in the food industry, bakers are tremendously impacted by FDA's changes to the NFL, as the majority of bakery products must comply with the new definitions of dietary fiber, added sugars, and folic acid, each with significant and unique unintended consequences and each subject to burdensome recordkeeping requirements, requiring ABA members to generate new records. ABA disagrees with the estimated benefits and burdens and believes that,

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[1] ABA is the Washington D.C.-based voice of the wholesale baking industry. Since 1897, ABA has represented the interests of bakers before the U.S. Congress, federal agencies, and international regulatory authorities. ABA advocates on behalf of more than 1,000 baking facilities and baking company suppliers. ABA members produce bread, rolls, crackers, bagels, sweet goods, tortillas and many other wholesome, nutritious, baked products for America's families. The baking industry generates more than $153.1 billion in direct annual economic activity and employs over 799,500 highly-skilled people.

[2] 82 Fed. Reg. 42,503 (Sept. 8, 2017).

particularly for dietary fiber and folic acid, the regulatory burdens imposed by the rules far exceed any public health benefit. The revised requirements for dietary fiber and folic acid do not currently provide Americans with measurably more meaningful nutrition information than the existing requirements to assist them in making healthful dietary choices to justify the tremendous burdens these revised requirements place on industry. Costs that will ultimately be passed on to consumers. Accordingly, ABA respectfully requests that FDA:

- Immediately stay and then revoke the definition of dietary fiber, revert to the chemical definition of dietary fiber, and rescind the accompanying dietary fiber recordkeeping requirements; or, in the alternative, adopt a less burdensome definition of dietary fiber, such as the definition adopted by Health Canada;

- Rescind the folate/folic acid recordkeeping requirement; and

- Rescind the mandatory added sugars declaration and accompanying recordkeeping requirements, or at least stay the declaration until the added sugars declaration and Daily Reference Value (DRV) are based on robust scientific evidence, are supported by consumer research demonstrating that such disclosures will assist consumers in making healthful dietary choices, and are defined with sufficient precision to eliminate the significant difficulties manufacturers currently face in calculating the amount of added sugars in a product.

Alternatively, ABA requests that FDA establish a compliance date for the NFL requirements that is harmonized with the compliance date of the mandatory bioengineered food disclosure, or, in the alternative, provide a two-year extension from the date that FDA issues its final guidance document on dietary fiber.

In addition, ABA respectfully requests that FDA:

- Revoke the definition and standard of identity and quality for frozen cherry pie in 21 C.F.R. 152.126**,** as this standard is obsolete and unnecessary;

- Publish a proposed regulation to amend the definitions and standards of identity for bakery products in 21 C.F.R. Part 136 to simplify these standards;

- Revoke the written assurance provisions of the final rule for hazard analysis and risk-based preventive controls for human food, as these provisions are unnecessary and duplicative;

- Revise the flavor description regulation in 21 C.F.R. 101.22(i) to use internally consistent terms and alleviate some of the confusion associated with this regulation; and

- Issue guidance (1) recognizing that “potassium salt” is an additional common or usual name for potassium chloride and (2) advising that an ingredient that meets the specifications for and uses of potassium chloride in 21 C.F.R. 184.1622 may be labeled as “potassium salt.”

ABA believes the repeal and/or modification of the above requirements represents an opportunity for FDA to achieve meaningful burden reduction while continuing to achieve the agency’s public health mission and fulfill statutory obligations. ABA encourages FDA to reach out to our organization to discuss any of our comments in further detail.

| Dietary Fiber Declaration | |
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| **Name of regulation** | Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 81 Fed. Reg. 33,742 (May 27, 2016). |
| **Type of product or FDA Center regulating the product** | CFSAN |
| **Citation to Code of Federal Regulations (CFR) and, if applicable, statutory citation** | The definition of dietary fiber is codified at 21 C.F.R. 101.9(c)(6)(i), and the accompanying recordkeeping requirements are codified at 21 C.F.R. 101.9(g)(10)(i),(ii), & (iii) and (11). |
| **Approved information collection and OMB Control Number** | |
| **Brief description of concern** | FDA has yet to issue its final guidance on dietary fiber and its final conclusions on the pending fiber citizen petitions and other fibers under its review that cover a significant volume of commonly used dietary fibers, even though the compliance date is approximately six months away. Adding to the lack of clarity and finality, FDA proposed to extend the compliance date for the revisions to the nutrition label, including dietary fiber, until January 1, 2020, but it has yet to confirm this date, which means the compliance date remains July 26, 2018. The lack of finality on dietary fiber and the proposed compliance date extension has created a tremendous burden on how to move forward with the revised nutrition facts label, particularly with respect to dietary fiber. At a minimum, it is imperative that FDA provide manufacturers clarity on a compliance date.<br><br>The final rule entitled Food Labeling: Revision of the Nutrition and Supplement Facts Labels (NFL Rule) includes a new definition of dietary fiber, which is one of the most significant changes to the NFL. Dietary fiber is now defined to mean:<br><br>non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units), and lignin that are intrinsic and intact in plants; isolated or synthetic non-digestible |

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| | carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health.[3]<br><br>Under this new definition, if a fiber ingredient is "intrinsic and intact in plants," it automatically meets FDA's definition of "dietary fiber" and does not require FDA pre-approval to be included in the amount of dietary fiber declared on the NFL. If a fiber is "isolated" *or* "synthetic," it must receive FDA pre-approval that it has a beneficial physiological effect in humans before it can be included in the amount of dietary fiber declared on the NFL. Under the new definition, once FDA approves an "isolated or synthetic" fiber as a dietary fiber, it is mandatory to include it in the amount of dietary fiber declared on the NFL.<br><br>FDA finalized its definition of "dietary fiber" well before it resolved a number of issues that are critical to compliance. FDA still has not resolved these issues. These issues cause the definition to be unworkable, and demonstrate why FDA should revoke this portion of the NFL Rule.<br><br>FDA's regulatory definition of dietary fiber exceeds the agency's statutory authority Congress gave it under section 403(q) of the Federal Food, Drug, and Cosmetic Act (FDCA). In its *Draft Guidance for Industry: Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-digestible Carbohydrates Submitted as a Citizen Petition (21 CFR 10.30)* (Draft Guidance), FDA conveys that in order to demonstrate that a fiber ingredient provides a beneficial physiological effect in humans, it expects a petitioner to submit the results of at least two adequate and well-controlled human clinical studies. The Draft Guidance essentially mirrors FDA's significant scientific agreement (SSA) requirements for health claims. ABA is not aware that any other country has adopted a definition requiring regulatory pre-approval of scientific evidence from two human clinical studies in order for fiber (or any ingredient) to be included in the amount declared in a nutrition label. Moreover, FDA cannot effectively incorporate the SSA standard from FDCA § 403(r) in defining nutrients required to be declared on the NFL. In turn, FDA has no authority to enforce the new |

[3] 21 C.F.R. 101.9(c)(6)(i).

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| | definition of dietary fiber under sections 403(a), 201(n), and 701(a).[4] The agency's definition of dietary fiber therefore violates the Administrative Procedure Act (APA).[5]<br><br>Further, FDA's justification for applying different standards to "intrinsic and intact" and "isolated or synthetic" fibers[6] is groundless and unnecessary under section 403(q) of the FDCA, the purpose of which is to "assist consumers in maintaining healthy dietary practices," because under section 403(q), the NFL *requires* the amount of distinct nutrients—e.g., vitamins, minerals, dietary fiber—to be declared *independently* of other nutrients.[7] FDA's justification for distinguishing between "intrinsic and intact" fibers from "isolated or synthetic" fibers based on the presence of "other food components, such as vitamins and minerals," is meaningless for labeling purposes because vitamins and minerals must be declared independently of fiber on the NFL. Thus, because the NFL already carries information on "other nutrients normally found in food," including "vitamins and minerals," there is no statutory basis or authority for distinguishing between fibers that are or are not "intrinsic and intact" based on the fact that the "intrinsic and intact" fibers "contain other nutrients."<br><br>Finally, FDA has consistently refused to quantify nutrient amounts declared in the NFL using anything except analytical methods based on chemical structure. FDA has expressly rejected physiological-based definitions for declaring nutrients in the NFL because such definitions are unworkable and difficult to enforce. |
| **Available data on cost or economic impact** | In addition to our evaluation below of FDA's estimated costs and benefits, it is clear that FDA's cost estimate does not include the business cost of the uncertainty created by FDA with respect to the pending dietary fiber petitions and the proposed compliance date extension. For example, many ABA members who make dietary fiber ingredients must annually renew their purchasing contracts with their customers. At this time last year, several ABA members' customers had stated they were not inclined to renew contracts given the uncertainty of the status of the dietary fiber ingredients. These members were only able to renew the contracts because FDA proposed an extension of the compliance date, which |

[4] *See* 81 Fed. Reg. at 33,853 (stating statutory authority for FDA's dietary fiber definition).

[5] *See* 5 U.S.C. § 706(2)(C).

[6] FDA justifies distinguishing "intrinsic and intact" fibers from "isolated or synthetic" fibers on the basis that "intrinsic and intact" fibers "also contain other food components, such as vitamins and minerals, which may be associated with beneficial physiological effects" and because they "contain other nutrients normally found in the foods." Draft Guidance at 5.

[7] 21 C.F.R. 101.9(c)(8)(iv).

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| | provided sufficient assurance at that time for the customers to renew their contracts with ABA members. These same members, however, are in exactly the same position this year because their customers again are expressing concern about renewing contracts for ingredients that are pending approval as dietary fiber from FDA.<br><br>Indeed, because FDA has yet to make crucial decisions on the status of dietary fiber ingredients or issue much-needed guidance, many ingredient suppliers have already lost contracts due to uncertainty. With no compliance date in sight other than July 26, 2018, and with less than six months away, finished product manufacturers already have been forced to make difficult, costly, and potentially counterproductive decisions in the face of FDA inaction, as reformulation can take anywhere from 6 months to two years, depending on the formulation, the level and number of testing required, and the ramp up to full production. For instance, one member recently lost one of its largest customers, who said it could not wait for an undetermined length of time for FDA to issue guidance. Another member reports that it already has lost hundreds of thousands of dollars of orders for fibers that are pending FDA review, and expects these uncertainty-driven costs will soon total millions of dollars.<br><br>In addition, the uncertainty created by FDA has slowed product development and innovation. A member who is a leading fiber manufacturer reports that over 90% of its active fiber projects have been put on hold in anticipation of FDA's review of dietary fiber ingredients. Another member has had to stop or put on hold over 20 projects, with a loss of $3 million dollars of new business. Finished product manufacturers likewise are feeling the effects of this uncertainty. FDA has said that manufacturers can simply switch to a new fiber source, but this grossly underestimates the complexities of product formulation. Like other ingredients, fiber ingredients have many functionalities (e.g., providing a source of fiber, texture, and taste), which means when reformulating a product, a manufacturer cannot just swap one fiber ingredient for another. Further, even after a manufacturer has selected a viable alternative formulation and done consumer testing, it then must revise the label and secure new suppliers. Thus, some manufacturers are starting the lengthy process of reformulation even though FDA may, in fact, determine that the fiber they currently use actually should be considered dietary fiber. Others are still in a holding pattern, waiting for FDA to resolve the uncertainty it has created. One member, a large baked-goods manufacturer, reports that up to 65% of some of its product lines are on hold pending further FDA guidance on dietary fiber.<br><br>And the negative effects of this uncertainty extend far beyond fiber ingredient suppliers and finished product manufacturers. For instance, one member reports that flour mills in the Midwest have seen a decrease in demand from fiber suppliers who are losing contracts and therefore producing less fiber ingredients. This, in turn, will lead to significant job losses, with a likely impact to well-paying technical positions, growers, manufacturing plant labor, as well as the support staff in customer service, sales, |

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| | research and development, quality, and finance operations. FDA has not accounted for the business costs associated with the uncertainty it has created.<br><br>For those fibers currently under review by FDA, if FDA does conclude that there is not sufficient scientific evidence to demonstrate a physiological benefit in humans under FDA's scientific review standard (which has yet to be finalized), it would be akin to a regulatory takings if FDA did not allow impacted fiber manufacturers sufficient time to conduct adequate studies that meet the scientific standard FDA ultimately finalizes, given that the scientific standard was not and still is not available for manufacturers to use to develop and conduct appropriate clinical studies.<br><br>FDA estimated in the NFL Rule that its changes to the label—of which the agency's new definition of dietary fiber is clearly the most burdensome provision—will cost industry approximately $0.2 to $0.8 billion annually over the next 20 years (based on 2014 values).[8] Based on several incorrect assumptions and despite comments to the contrary, FDA significantly underestimated the costs and burdens of the new definition of dietary fiber, including the novel recordkeeping requirements and costs of conducting clinical trials (which can cost over $400,000 per trial).<br><br>FDA estimated that the required recordkeeping burden of the dietary fiber declaration would be a mere one hour per manufacturer, for a total of 31,283 recordkeeping hours for the dietary fiber declaration, plus 28 additional hours for the "28" fiber petitions and 216 hours for all declarations related to new products.[9] For impacted products, FDA's estimates do not account for: (1) the new records required because companies do not have records that show the amount of fiber that does not meet FDA's definition of dietary fiber subtracted from the amount of fiber that does meet FDA's definition; (2) the recordkeeping costs incurred as impacted companies remain in a holding-pattern while FDA finalizes its definition of dietary fiber; (3) the calculations, relabeling, and records required if a manufacturer reformulates or tweaks its product, including reformulations due to supply issues; (4) the calculations and new records required for new products other than those identified by FDA; (5) the calculations and new records required if FDA "approves" an "isolated or synthetic" fiber, triggering the mandatory |

[8] *See* Regulatory Impact Analysis for Final Rules on: "Food Labeling: Revision of the Nutrition and Supplement Facts Labels," Docket No. FDA-2012-N-120, and "Food Labeling: Serving Sizes of Foods that Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments," Docket No. FDA-2004-N-0258, at 2.

[9] *Id*. at 110-11.

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| | labeling of that fiber ingredient in the amount of dietary fiber in the NFL; and (6) the number of hours it takes to compile and submit a fiber petition.<br><br>FDA's estimate of "28 hours" in total for fiber petitions exemplifies FDA's erroneous estimates. FDA chose the number "28" because it was only aware of 28 unapproved "isolated or synthetic" fibers.[10] It presumed that all these 28 fibers were the "same" and that it would receive only one petition for each named fiber.[11] (A more accurate description is that each of the 28 named fibers represents a fiber category, and many types of fiber ingredients may be identified for each of the 28 categories.) FDA's estimate of 28-hours total for all fiber petitions does not account for the costs associated with compiling fiber petitions, corresponding with customers in relation to the regulatory status of fiber ingredients, or any subsequent correspondence or submissions with FDA on fiber petitions. It allotted only a single hour of recordkeeping per petition.[12] Additionally, because FDA believed it could not estimate the number of fibers or fiber petitions that might occur in the future, it simply did not include the regulatory burdens and costs associated with such fibers in its final regulatory impact analysis (FRIA) estimates.[13] |
| **Proposed solution** | ABA respectfully requests that FDA promptly revoke the dietary fiber recordkeeping requirements of 21 C.F.R. 101.9(g)(10)(i),(ii), & (iii) in their entirety, and revise 21 C.F.R. 101.9(c)(6)(i) to revoke the definition of dietary fiber and revert to the chemical definition of dietary fiber as follows:<br><br>(i)"Dietary fiber": A statement of the number of grams of total dietary fiber in a serving, indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, declaration of dietary fiber is not required or, alternatively, the statement "Contains less than 1 gram" or "less than 1 gram" may be used, and if the serving contains less than 0.5 gram, the content may be expressed as zero. Except as provided for in paragraph (f) of this section, if dietary fiber content is not required, and as a result not declared, the statement "Not a significant source of dietary fiber" shall be placed at the bottom of the table of nutrient values in the same type size. |

[10] *See, e.g., id.* at 111-12.

[11] *See id.*

[12] *See id.* at 59-60, 111-12.

[13] *See, e.g., id.* at 60.

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| | In the alternative, ABA requests that FDA adopt a less burdensome definition of dietary fiber, such as the definition adopted by Health Canada. Health Canada reviews and accepts dietary fibers if the fiber has "at least one physiological effect demonstrated by generally accepted scientific evidence."[14] Health Canada's non-exclusive list of benefits includes, for example, improved laxation or regularity by increasing stool bulk, reducing blood total and/or low-density lipoprotein cholesterol levels, reducing post-prandial blood glucose and/or insulin levels, and providing energy-yielding metabolites through colonic fermentation.[15] Because Health Canada's definition is in-line with other definitions of dietary fiber in countries that have defined fiber, adopting Health Canada's definition would provide consumers with a consistent definition and provide a workable definition for manufacturers. Additionally, ABA has encouraged FDA to adopt the list of dietary fiber ingredients already approved by Health Canada under its standard (in addition to retaining the list of isolated synthetic fibers already approved by FDA).<br><br>If FDA does not revoke or adopt a less burdensome definition of dietary fiber, ABA requests that the agency fix the existing definition, as detailed in ABA's citizen petition to FDA dated April 7, 2017, including that FDA provide better clarity on what it means for a fiber to be "intact and intrinsic." ABA requests that FDA immediately stay the definition of dietary fiber in the interim. |

[14] *See* Health Canada, Bureau of Nutritional Sciences, Food Directorate, Health Products and Food Branch, *List of Dietary Fibres Reviewed and Accepted by Health Canada's Food Directorate.*

[15] *See id.*

| Folic Acid/Folate Recordkeeping Requirement | |
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| **Name of regulation** | Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 81 Fed. Reg. 33,742 (May 27, 2016). |
| **Type of product or FDA Center regulating the product** | CFSAN |
| **Citation to Code of Federal Regulations (CFR) and, if applicable, statutory citation** | The folic acid/folate recordkeeping requirement is codified at 21 C.F.R. 101.9(g)(10)(vii) and (11). |
| **Approved information collection and OMB Control Number** | |
| **Brief description of concern** | The NFL Rule provides that, if a food contains a mixture of folate and folic acid, the manufacturer must make and keep written records of the amount of synthetic folate and/or folic acid added to the food and the amount of naturally-occurring folate in the finished food. This requirement affects all standardized enriched flours and enriched bakery products, because all enriched-flour products include a mixture of folate and folic acid.<br><br>Bakers have experienced challenges in calculating the amount of folic acid in enriched bakery products because of the variability in intrinsic folate, the many sources of folic acid, and the manufacturing process, among other things. Because there is no analytical method that can distinguish between folate and folic acid, bakers must attempt to theoretically calculate out from intrinsic folate the amount of folic acid. This requires theoretical assumptions in folic acid/folate amounts impacted by factors like dusting flour, moisture loss, intrinsic folate, which are not constants. Thus, this recordkeeping requirement presents significant challenges and regulatory burdens without providing a companion public health benefit. |

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| **Available data on cost or economic impact** | |
| **Proposed solution** | ABA respectfully requests that FDA promptly revoke the folate/folic acid recordkeeping requirement by revoking 21 C.F.R. 101.9(g)(10)(vii) in its entirety. |

| Added Sugars Declaration | |
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| **Name of regulation** | Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 81 Fed. Reg. 33,742 (May 27, 2016). |
| **Type of product or FDA Center regulating the product** | CFSAN |
| **Citation to Code of Federal Regulations (CFR) and, if applicable, statutory citation** | The added sugars declaration requirement is codified at 21 C.F.R. 101.9(c)(6)(iii), and the accompanying recordkeeping requirements are codified at 21 C.F.R. 101.9(g)(10)(iv) & (v) and (11). |
| **Approved information collection and OMB Control Number** | |
| **Brief description of concern** | The NFL Rule includes a requirement that, for the first time, the NFL must include an "added sugars" declaration and an added sugars percent daily value (% DV). The NFL Rule defines the term "added sugars" as follows:<br><br>Added sugars are either added during the processing of foods, or are packaged as such, and include sugars (free, mono- and disaccharides), sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type, except that fruit or vegetable juice concentrated from 100 percent juices sold to consumers, fruit or vegetable juice concentrates used towards the total juice percentage label declaration under §101.30 or for Brix standardization under §102.33(g)(2) of this chapter, fruit juice concentrates which are used to formulate the fruit component of jellies, jams, or preserves in accordance with the standard of identities set forth in §§150.140 and 150.160 of this chapter, or the fruit component of fruit spreads shall not be labeled as added sugars. |

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| | ABA believes that the added sugars declaration is likely to be ineffective because FDA's consumer data do not demonstrate that an added sugars declaration and % DV will assist consumers in maintaining healthy dietary practices. As stated in our comments submitted in response to FDA's original proposed NFL revisions and reiterated in our comments on the agency's supplemental proposal, several peer-reviewed, published studies (not discussed by FDA in the original proposed rule) show that an added sugars declaration is likely to have no effect, or even undesirable effects, on dietary choices. For example, the added sugars declaration might direct consumers away from total calorie count, which would be counterproductive as the current *Dietary Guidelines for Americans* identifies caloric balance as the most meaningful goal in achieving weight management. This evidence directly contradicts and undermines FDA's conclusion that an added sugars declaration will assist consumers in making healthy dietary practices.<br><br>Moreover, for food manufacturers in general and for bakers in particular, the costs and burdens of complying with FDA's mandatory added sugars disclosure far outweigh any perceived benefits FDA might have expected in finalizing this requirement, as discussed below.<br><br>Further, in its haste to include the added sugars declaration in the NFL Rule, FDA neglected to provide itself ample time to seek industry input and conduct adequate research to define the term "added sugars" with sufficient concreteness. It is clear that FDA still is struggling with how to define and regulate "added sugars," especially with respect to fruits and vegetables that have been processed to change the form of the fruit or vegetable, sugars produced through hydrolysis, and products subject to fermentation (e.g., yeast-leavened bread). |
| **Available data on cost or economic impact** | FDA estimated in the NFL Rule that its changes to the label—of which the new added sugars declaration is clearly one of the most burdensome provisions—will cost industry at least $2.47 billion (based on 2014 values). ABA has encountered numerous unintended consequences and unaccounted costs and burdens associated with the added sugars declaration requirement, which are likely a result of FDA's issuance of the NFL Rule prior to thoroughly understanding and addressing the impact of the added sugars declaration and associated recordkeeping requirements. For example, yeast-based bakery products are subject to fermentation and therefore face challenges with respect to the calculation of added sugars, even though added sugars from yeast-based products are not a high contributor to added sugars in the American diet.<br><br>Moreover, in calculating these costs, FDA incorrectly presumed that industry would not need to create additional records to comply with FDA's new requirements. None of these costs were included in FDA's $2.47 billion estimate. In addition, ABA believes that FDA has overestimated the benefits of the added sugars declaration, as the estimated benefits are predicated on the assumption that the content and |

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| | format of the revised NFL will help consumers maintain healthy dietary practices,[16] which is unlikely to be the case for the reasons noted above. |
| **Proposed solution** | ABA respectfully requests that FDA rescind the mandatory added sugars declaration, by revoking 21 C.F.R. 101.9(c)(6)(iii) in its entirety and by revoking the accompanying recordkeeping requirements of 21 C.F.R. 101.9(g)(10)(iv) & (v).<br><br>Alternatively, ABA request that FDA stay the declaration until the added sugars declaration and DRV are based on robust scientific evidence, are supported by consumer research demonstrating that such disclosures will assist consumers in making healthful dietary choices, and are defined with sufficient precision to eliminate the significant difficulties manufacturers currently face in calculating the amount of added sugars in a product.<br><br>If FDA does not take either of these actions, ABA requests that FDA (1) consider a less burdensome option for declaring added sugars; and (2) take into consideration and address the technical issues related to the added sugars declaration, including with respect to (a) the classification of fruits and vegetables that have been processed to change the form of the fruit or vegetable; and (b) calculating the added sugars in products subject to fermentation, such as yeast-leavened bread. |

[16] *See* Final Regulatory Impact Analysis for Final Rules on: "Food Labeling: Revisions of the Nutrition and Supplement Facts Labels" (Docket. No. FDA-2012-N-120) and "Food Labeling: Servings Sizes of Foods that Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments" (Docket No. 2004-N-0258), *available at* https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM506797.pdf.

| Definition and Standard of Identity for Frozen Cherry Pie | |
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| **Name of regulation** | Frozen Cherry Pie; Standards and Establishment of Effective Date, 38 Fed. Reg. 15503 (June 13, 1973). |
| **Type of product or FDA Center regulating the product** | CFSAN |
| **Citation to Code of Federal Regulations (CFR) and, if applicable, statutory citation** | 21 C.F.R. 152.126. |
| **Approved information collection and OMB Control Number** | |
| **Brief description of concern** | The definition and standard of identity and quality for frozen cherry pie in 21 C.F.R. 152.126 was developed and promulgated in the 1960s and 1970s. Although it is denominated as a definition and standard of identity and quality, in fact the sole purpose of this provision was to establish a standard of quality. The essential elements are the requirements that the drained cherry content is not less than 25% of the weight of the pie and that not more than 15% by count of the cherries in the pie are blemished.<br><br>ABA opposes any use of food standards to establish quality characteristics of food in general and frozen cherry pies in particular. Food quality should be left to the decisions of food manufacturers, in determining what type of food products to make available to the public, and food consumers, who must then determine whether they wish to spend more money to purchase products of higher quality or less money to purchase products of lower quality. A product of unacceptably low quality will not long survive.<br><br>There is no basis whatever for singling out frozen cherry pies for a standard of identity, but not similarly standardizing frozen apple, peach, and other fruit pies. The same quality issues that could arise for frozen cherry pies would exist also for other frozen fruit pies. Nor is there any basis for differentiating between frozen and non-frozen fruit pies. Both categories raise the same quality issues. |

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| | ABA does not believe that a common or usual name regulation of this type is justified. Fresh and frozen fruit pies other than frozen cherry pie have been sold in retail stores throughout the country without any evidence of public confusion during the entire time that frozen cherry pies have been subject to a rigid standard. |
| **Available data on cost or economic impact** | |
| **Proposed solution** | ABA respectfully requests that FDA revoke the definition and standard of identity and quality for frozen cherry pie in 21 C.F.R. 152.126 by revoking all of 21 C.F.R. Part 152. |

| Definitions and Standards of Identity for Bakery Products | |
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| **Name of regulation** | Breads and Rolls, 17 Fed. Reg. 4453 (May 15, 1952). |
| **Type of product or FDA Center regulating the product** | CFSAN |
| **Citation to Code of Federal Regulations (CFR) and, if applicable, statutory citation** | 21 C.F.R. Part 136. |
| **Approved information collection and OMB Control Number** | |
| **Brief description of concern** | While ABA believes that it is important to have a uniform definition and standard of identity for bakery products that applies throughout the U.S., there is no need for a standard that goes beyond establishing the name (statement of identity) of the product and its essential characteristics. Any provisions that extend beyond these two essential elements unnecessarily restrict modern food technology, deny consumers important new products in the marketplace, and thus harm the public interest.<br><br>The definitions in current 21 C.F.R. 136.3 serve no useful purposes. The words bread, rolls, and buns have well-established meanings. Some products that are shaped as bread, and that are intended to be used for that purpose, weigh less than one-half pound. Accordingly, these current definitions are unduly restrictive. The current 21 C.F.R. 136.3 should be deleted.<br><br>Many of the bakery products standards continue to specify the various ingredients that must or may be used in making these products. ABA believes that all that is actually needed to characterize these products is to state that they are produced by baking mixed leavened dough prepared from one or more farinaceous ingredients, one or more moistening ingredients, and one or more leavening agents, to which may be added one or more ingredients that do not change the basic identity or adversely affect the |

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| | physical or nutritional characteristics of the food. Anything beyond this reduces innovation and harms the public interest.<br><br>It is important to specify the nutrients and levels that make a bakery product "enriched", the moistening ingredients that characterize milk bread, the amount of egg required for egg bread, the amount of raisins needed for raisin bread, and the amount of whole wheat needed to make whole wheat bread. Beyond this, everything else is superfluous. |
| **Available data on cost or economic impact** | |
| **Proposed solution** | ABA respectfully requests that FDA publish a proposed regulation to amend the definitions and standards of identity for bakery products in 21 C.F.R. Part 136 to simplify these standards, as follows:<br><br>**PART 136 — BAKERY PRODUCTS**<br><br>**§ 136.1 Bread, Rolls, and Buns.**<br><br>(a) Bread, white bread, wheat bread, white wheat bread, rolls, white rolls, buns, and white buns are the foods produced by baking mixed leavened dough prepared from one or more farinaceous ingredients, one or more moistening ingredients, and one or more leavening agents, to which may be added one or more ingredients that do not change the basic identity or adversely affect the physical or nutritional characteristics of the food.<br><br>(b) All ingredients from which the food is fabricated shall be safe and suitable.<br><br>(c) The name of the food is "bread", "white bread", "wheat bread", "white wheat bread", "rolls", "white rolls", "buns", or "white buns", as applicable.<br><br>**§ 136.2 Enriched Bread, Rolls, and Buns.**<br><br>(a) Each of the foods enriched bread, enriched rolls, and enriched buns conforms to the definition and standard of identity in § 136.1. |

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| | (b) Each such food contains in each pound 1.8 milligrams of thiamine, 1.1 milligrams of riboflavin, 15 milligrams of niacin, 0.43 milligrams of folic acid, and 12.5 milligrams of iron.<br><br>(c) Each such food may contain added calcium in such quantity that the total calcium content is 600 milligrams per pound.<br><br>(d) The requirements of subsections (b) and (c) will be deemed to have been met if reasonable overages of the vitamins and minerals, within the limits of good manufacturing practice, are present to ensure that the required levels of the vitamins and minerals are maintained throughout the expected shelf life of the food under customary conditions of distribution and storage.<br><br>(e) The name of the food is “enriched bread”, “enriched white bread”, “enriched rolls”, “enriched white rolls”, “enriched buns”, or “enriched white buns”, as applicable.<br><br>**§ 136.3 Milk Bread, Rolls, and Buns.**<br><br>(a) Each of the foods milk bread, milk rolls, and milk buns conforms to the definition and standard of identity in § 136.1.<br><br>(b) The only moistening ingredient permitted in the preparation of the dough is milk, or a combination of dairy products when in such a proportion that the weight of the nonfat milk solids is not more than 2.3 times and not less than 1.2 times the weight of the milk fat therein, with or without water, in a quantity that provides not less than 8.2 parts milk solids for each 100 parts by weight of flour.<br><br>(c) No buttermilk, buttermilk product, cheese whey, cheese whey product, or milk protein is used.<br><br>(d) The name of the food is “milk bread”, “milk rolls”, or “milk buns”, as applicable.<br><br>(e) If the food meets the definition and standard of identity in § 136.2, the name of the food specified in subsection (d) of this section may be preceded by the word “enriched”.<br><br>**§ 136.4 Egg Bread, Rolls, and Buns.**<br><br>(a) Each of the foods egg bread, egg rolls, and egg buns conforms to the definition and standard identity in §136.1. |

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| | (b) The food contains not less than 2.56 percent by weight of whole egg solids. One medium-sized egg is equivalent to 0.41 ounce of whole egg solids.<br><br>(c) name of the food is “egg bread”, “egg rolls”, or “egg buns”, as applicable.<br><br>(d) If the food meets the definition and standard of identity in § 136.2, the name of the food specified in subsection (c) of this section may be preceded by the word “enriched”.<br><br>**§ 136.5 Raisin Bread, Rolls, and Buns.**<br><br>(a) Each of the foods raisin bread, raisin rolls, and raisin buns conforms to the definition and standard of identity in § 136.1.<br><br>(b) Not less than 50 parts by weight of seeded or seedless raisins are used for each 100 parts by weight of flour.<br><br>(c) Water extract of raisins may be used, but not to replace raisins.<br><br>(d) The name of the food is “raisin bread”, “raisin rolls”, or “raisin buns”, as applicable.<br><br>(e) When the food contains not less than 2.56 percent by weight of whole egg solids, the words “and egg” may be added following the word “raisin” in the name of the food specified in subsection (d) of this section.<br><br>(f) If the food is made with enriched flour, the words “made with enriched flour” may be used as part of the name specified in subsection (d) of this section.<br><br>(g) If the food meets the definition and standard of identity in § 136.2, the name of the food specified in subsection (d) of this section may be preceded by the word “enriched”.<br><br>**§ 136.6 Whole Wheat Bread, Rolls, and Buns**<br><br>(a) Each of the foods whole wheat bread, white whole wheat bread, whole grain bread, graham bread, whole wheat rolls, white whole wheat rolls, whole grain rolls, graham rolls, whole wheat buns, white whole wheat buns, whole grain buns, and graham buns conforms to the definition and standard of identity in § 136.1. |

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| | (b) The dough is made from whole wheat flour, brominated whole wheat flour, or a combination of these. No flour, brominated flour, or phosphated flour is used.<br><br>(c) The name of the food is “whole wheat bread”, “white whole wheat bread”, “whole grain bread”, “graham bread”, “whole wheat rolls”, “white whole wheat rolls”, “whole grain rolls”, “graham rolls”, “whole wheat buns”, “white whole wheat buns”, “whole grain buns”, or “graham buns”, as applicable. |

| FSMA Written Assurances Requirements | |
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| **Name of regulation** | Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food |
| **Type of product or FDA Center regulating the product** | CFSAN |
| **Citation to Code of Federal Regulations (CFR) and, if applicable, statutory citation** | The written assurance provisions of the final rule for hazard analysis and risk-based preventive controls for human food[17] (the PC rule) are codified at 21 C.F.R. 117.136(a)(2)(ii), (3)(ii), & (4)(ii). The related documentation requirements are codified at 21 C.F.R. 117.136(b)(2)-(4) and 117.137. |
| **Approved information collection and OMB Control Number** | 0910-0751 |
| **Brief description of concern** | Under the written assurance provisions of the PC rule, if a manufacturer/processor identifies a hazard requiring a preventive control (PC), does not control the identified hazard, and relies on an entity in its distribution chain to address the hazard (e.g., a manufacturer relies on its customer to apply a kill step to untreated flour), the manufacturer/processor can only sell to others who provide written assurances that they or their subsequent customers will be controlling the hazard.[18]<br><br>The written assurance provisions of 21 C.F.R. 117.136 and related documentation requirements of 21 C.F.R. 117.136 and 117.137 will impose an extraordinary cost on the food industry without providing a companion public health benefit. ABA believes these provisions are unnecessary and duplicative, as the core requirements of the PC rule and existing foodservice practices and obligations are adequate to ensure food safety. Manufacturers are already required, under the PC rule, to understand the nature of |

[17] 80 Fed. Reg. 55,908 (Sept. 17, 2015).

[18] 21 C.F.R. 117.136(a)(2)(ii), (3)(ii), and (4)(ii).

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| | the hazards and what needs to be done to control them, and foodservice establishments understand and handle such hazards under the state and local food safety laws to which they are subject.<br><br>Moreover, written assurances are a meaningless paperwork exercise, as they will not ensure that the customer actually carried out the necessary controls, nor will they provide any guarantee that the customer's controls were effective or validated. FDA has failed to demonstrate sufficient existing risk that would be alleviated to justify a requirement of this extraordinary size and scope. Indeed, the fact that FDA has extended the compliance date of the written assurance requirements by two years demonstrates that there is no existing critical food safety risk. |
| **Available data on cost or economic impact** | FDA's FRIA estimates that the total recordkeeping burden associated with the disclosure and written assurance provisions is approximately 4,070 hours. FDA significantly underestimated the costs and burdens associated with those provisions. |
| **Proposed solution** | On January 4, 2018, FDA announced that it intends to exercise enforcement discretion for the written assurances provisions in all four FSMA preventive controls rules. ABA thanks FDA for and supports this enforcement discretion and requests that FDA rescind the written assurances provisions. For example, FDA could delete 21 C.F.R. 117.137 in its entirety and amend 21 C.F.R. 117.136 to read as follows:<br><br>§ 117.136 Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control.<br><br>(a) *Circumstances*. If you are a manufacturer/processor, you are not required to implement a preventive control when you identify a hazard requiring a preventive control (identified hazard) and any of the following circumstances apply:<br><br>(1) You determine and document that the type of food (e.g., raw agricultural commodities such as cocoa beans, coffee beans, and grains) could not be consumed without application of an appropriate control.<br><br>(2) You (i) rely on your customer who is subject to the requirements for hazard analysis and risk-based preventive controls in this subpart C to significantly minimize or prevent the identified hazard and you (ii) disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]". |

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| | (3) You (i) rely on your customer who is not subject to the requirements for hazard analysis and risk-based preventive controls in this subpart to manufacture, process, or prepare the food in accordance with applicable food safety requirements and you (ii) disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]".<br><br>(4) You (i) rely on an entity in the distribution chain subsequent to your customer to control the identified hazard and you (ii) disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]".<br><br>(5) You have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food product you distribute and you document the implementation of that system.<br><br>(b) *Records*. If you are relying on paragraph (a) of this section to not apply a preventive control for an identified hazard, you must document any circumstance specified in that paragraph that applies to you, including:<br><br>(1) A determination, in accordance with paragraph (a)(1) of this section, that the type of food could not be consumed without application of an appropriate control;<br><br>(2) Your reliance on your customer to control the identified hazard, in accordance with paragraphs (a)(2) or (a)(3) of this section;<br><br>(3) Your reliance on an entity in the distribution chain subsequent to the customer to control the identified hazard, in accordance with paragraph (a)(4) of this section; and<br><br>(4) Your system, in accordance with paragraph (a)(5) of this section, that ensures control, at a subsequent distribution step, of the hazards in the food product you distribute. |

| Flavor Description Requirements | |
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| **Name of regulation** | Foods; labeling of spices, flavorings, colorings and chemical preservatives |
| **Type of product or FDA Center regulating the product** | CFSAN |
| **Citation to Code of Federal Regulations (CFR) and, if applicable, statutory citation** | 21 C.F.R. 101.22(i)(1) |
| **Approved information collection and OMB Control Number** | |
| **Brief description of concern** | If a food label, labeling, or advertisement makes any direct or indirect representation about the flavor of the food (using words, graphics, images, etc.), FDA provides specific requirements for describing the flavor. Almost all packaged food labels do in some way identify the flavor of the food, which means that essentially all packaged foods must comply with these flavor description requirements. These requirements are set out in 21 C.F.R. 101.22(i) and may be particularly confusing for foods that include natural flavors because the provisions of this regulation applicable to describing flavors derived from natural flavors do not use internally consistent terms. Hence, there can be lack of clarity on how to assess what flavor descriptions to use when the taste of the food is imparted by natural flavors. |
| **Available data on cost or economic impact** | |
| **Proposed solution** | ABA respectfully request that FDA revise 101.22(i)(1) as follows, to improve the clarity of the regulation (the revisions are shown in redline). Although these revisions may appear insignificant, the revisions |

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| | will drastically improve the clarity and utility of the regulation and will significantly simplify the analysis that goes into assessing how to describe flavor names:<br><br>(i) If the label, labeling, or advertising of a food makes any direct or indirect representations with respect to the primary recognizable flavor(s), by word, vignette, e.g., depiction of a fruit, or other means, or if for any other reason the manufacturer or distributor of a food wishes to designate the type of flavor in the food other than through the statement of ingredients, such flavor shall be considered the characterizing flavor and shall be declared in the following way:<br><br>(1) If the food contains no artificial flavor which simulates, resembles or reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., "vanilla", in letters not less than one-half the height of the letters used in the name of the food, except that:<br><br>(i) If the food is one that is commonly expected to contain a characterizing food ingredient, e.g., strawberries in "strawberry shortcake", and the food contains natural flavor derived from ~~such~~ the characterizing food ingredient and an amount of the characterizing food ingredient insufficient to independently characterize the food, or the food contains no such characterizing food ingredient, the name of the characterizing flavor may be immediately preceded by the word "natural" and shall be immediately followed by the word "flavored" in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "natural strawberry flavored shortcake," or "strawberry flavored shortcake".<br><br>(ii) If none of the natural flavor used in the food is derived from the ~~product~~ characterizing food ingredient whose flavor is simulated, the food in which the flavor is used shall be labeled either with the flavor of the product from which the flavor is derived or as "artificially flavored."<br><br>(iii) If the food contains both a ~~characterizing~~ natural flavor derived from the ~~product~~ characterizing food ingredient whose flavor is simulated and other natural flavor which simulates, resembles or reinforces the characterizing flavor, the food shall be labeled in accordance with the introductory text and paragraph (i)(1)(i) of this section and the name of the food shall be immediately followed by the words "with other natural flavor" in letters not less than one-half the height of the letters used in the name of the characterizing flavor. |

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| **Name of regulation** | Common or Usual Name for Nonstandardized Foods |
| **Type of product or FDA Center regulating the product** | CFSAN |
| **Citation to Code of Federal Regulations (CFR) and, if applicable, statutory citation** | 21 C.F.R. 101.4(a)(1) (listing of ingredients); 21 C.F.R. 102.5 (general principles for common or usual name for nonstandardized foods); and 21 C.F.R. 184.1622 (GRAS affirmation for potassium chloride). |
| **Approved information collection and OMB Control Number** | |
| **Brief description of concern** | Consumer study data show that consumers are unfamiliar with the term "potassium chloride" and often misassociate it with chlorine or other chemicals. This confusion undermines FDA's goal of decreasing consumers' sodium intake, as potassium chloride can be used instead of sodium chloride as a sodium reduction technique. It likewise undermines the agency's goal of increasing consumers' potassium intake, as potassium chloride is also used to increase the potassium content of processed foods. The term "potassium salt" more closely reflects reasonable consumer expectations of the ingredient. Further, such term more accurately describes the nature of the ingredient, which can replicate the taste, preservation, and functionality of sodium chloride (which is defined by FDA and known to consumers as "salt"). |
| **Available data on cost or economic impact** | |
| **Proposed solution** | ABA respectfully requests that FDA issue guidance (1) recognizing that "potassium salt" is an additional common or usual name for potassium chloride and (2) advising that an ingredient that meets the |

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| | specifications for and uses of potassium chloride in 21 C.F.R. 184.1622 may be labeled as “potassium salt.” |

Respectfully submitted,

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