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MEMORANDUM

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Re: **FDA Public Meeting: Horizontal Approaches to Food Standards of Identity Modernization**

On September 27, 2019 the U.S. Food and Drug Administration (FDA) hosted a public meeting to gather information from stakeholders on changes the agency could make to existing standards of identity (SOIs), particularly changes that could be made across categories of standardized foods (i.e., "horizontal" changes), to provide flexibility for the development of healthier foods and facilitate innovation. 1/ Though FDA primarily was in listening mode during the meeting, comments by agency representatives suggested FDA's commitment to SOI modernization. In particular, the agency encouraged stakeholder comments to the docket, indicating interest in highly-detailed proposals for establishing horizontal approaches to SOIs that eliminate barriers to improvements in product nutrition profiles, spur innovation, and provide flexibility to allow emerging technology to reach consumers while ensuring sufficient transparency. Written comments are due by November 12, 2019 and can be submitted to FDA docket number FDA-2018-N-2381-1371. This memorandum provides a high-level summary of the agency statements and stakeholder comments made during the meeting.

Background

The Federal Food, Drug, and Cosmetic Act ("FFDCA") established SOIs to "promote honesty and fair dealing in the interest of consumers." 2/ SOIs define the composition of a food, typically prescribing mandatory, prohibited, and optional ingredients, and manufacturing processes. Since 1938, 280 SOIs have been established for specific foods; most were promulgated from the 1940s through the 1960s. Modernizing food standards and proposals for a more systematic approach have been considered before several times. A few key developments are as follows:

- 1995: FDA and the U.S. Department of Agriculture's Food Safety and Inspections Service (FSIS) jointly issued an Advanced Notice of Proposed Rulemaking (ANPR) on food standards and common or usual name regulations regarding whether these regulations should be retained, revised, or revoked. 3/

1/ See our memo on FDA's notice of the public meeting at https://www.hlfoodlaw.com/wp-content/uploads/sites/357/2019/09/HL-Memo-FDA-Announces-Public-Meeting-on-Modernizing-Food-Standards-of-Identity.pdf.
2/ 21 U.S.C. § 341.
3/ 60 Fed. Reg. 67492 (Dec. 29, 1995).

- 2005: FDA and FSIS jointly issued ANPR on food standards modernization proposing to establish a general set of principles for food standards. 4/
- 2006: The Grocery Manufacturers Association (GMA) filed a citizen petition requesting that FDA and FSIS establish flexible SOIs in six categories to modernize food standards. 5/
- 2018: The agency launched a multiyear Nutrition Innovation Strategy (NIS), which is designed to encourage industry innovation to improve the nutrition and healthfulness of food. A July 2018 public meeting on the NIS identified horizontal modifications to food SOIs as a priority area for follow-up.
- 2019: FDA's Unified Agenda underscored the agency's commitment to modernizing food standards, citing forthcoming final rules on yogurt and the revocation of SOIs on low fat and nonfat yogurt. 6/ Moreover, as reported at the public meeting, FDA and FSIS are reopening the comment period to the 2005 ANPRM.

Meeting Scope

In introductory remarks, agency speakers stressed that the impetus for modernizing SOIs was rooted in the NIS and the goal to eliminate barriers to improved nutritional content in foods. The agency also acknowledged that keeping pace with industry innovation and consumer expectations are key components of any SOI modernization efforts. 7/ Breakout sessions were structured accordingly, with two sets of repeating breakouts covering the following three areas: "Role of Nutrition in Standards of Identity Modernization," "Industry Innovation," and "Consumer Expectations of Standardized Foods."

Whereas updating individual standards (sometimes referred to as a "vertical" approach) may be time consuming and too resource intensive to be practical, the agency hopes that the development of "horizontal" approaches to SOI modernization would permit flexibility across all or broad categories of standardized foods. A potential model for a horizontal approach is FDA's regulation, "Requirements for foods named by use of a nutrient content claim and a standardized term" (21 CFR

4/ 70 Fed. Reg. 29214 (May 201, 2005).

5/ Docket Number FDA-2007-P-0463, https://www.regulations.gov/document?D=FDA-2007-P-0463-0367. The petition identified six categories of flexible approaches to modernizing SOIs as follows: (1) Addition of ingredients intended solely for technical, nondistinctive effects, such as emulsifiers, stabilizers, or antimycotic agents; (2) Use of safe and suitable flavors and flavor enhancers in foods generally, and use of safe and suitable ingredients such as salt substitutes, sweeteners, and vegetable fats and oils where appropriate; (3) Use of advanced or more efficient technologies to produce ingredients of all types, such as enzyme technologies that enhance the properties of egg yolk used in mayonnaise; (4) Use of alternate manufacturing processes, also known as "alternate make" procedures, for those standards that specify particular processes; (5) Changes to a product's basic shape in response to consumer demands, such as "chunky" stewed tomatoes; and (6) Improvements in nutritional properties that do not rise to the level of a defined nutrient content claim (e.g., reducing calories by 10% rather than requiring a minimum 25%), or use of nutritious ingredients like whole grains.

6/ 2019 Spring Unified Agenda Reflects FDA's Continuity and Consistency (May 24, 2019) at https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/2019-spring-unified-agenda-reflects-fdas-continuity-and-consistency.

7/ *See* Remarks by Dr. Susan Mayne at the Public Meeting on Horizontal Approaches to Food Standards of Identity Modernization (September 27, 2019) at https://www.fda.gov/news-events/speeches-fda-officials/remarks-dr-susan-mayne-public-meeting-horizontal-approaches-food-standards-identity-modernization. Dr. Mayne indicated that the agency wants to modernize the SOI program in a manner that will protect consumers against economic adulteration; maintain the basic nature, essential characteristics, and nutritional integrity of food, and promote industry innovation, and provide flexibility to encourage manufacturers to produce more healthful foods.

130.10), which provides for modified versions of certain standard foods using descriptors such as "fat free" or "low calorie."

FDA clarified that modification of SOIs is under review separately from the agency's Request for Information on the use of names of dairy foods for plant-based products. 8/ This issue nonetheless arose frequently, often in the context of the relationship between SOIs and labeling requirements for consumer transparency, a recurring general theme at the meeting.

FDA officials indicated that as the agency reviews public comments on horizontal approaches to modernization, the Temporary Marketing Permit (TMP) process and review of individual petitions will continue. In response to a question on timing, FDA noted that although there is no established timeline for developing horizontal solutions to modernization, the momentum of bringing the meeting only a year after the NIS public meeting suggests commitment to keeping the initiative on track for development.

Key Issues Addressed

Facilitators collated responses to a series of discussion questions for each of the breakout themes, which were summarized at the end of the meeting. Following is a brief overview of the key issues that emerged from the discussion.

Role of Nutrition in Standards of Identity Modernization

This session focused on how horizontal changes might contribute to FDA's nutrition-related goals. The agency queried participants whether (and how) SOIs pose barriers to the production of nutritious foods, and asked for stakeholders to identify specific potential changes across categories of foods to encourage production of more nutritious foods. The agency sought feedback on six specific proposals, summarized below:

1. Permit ingredient substitution or reduction to improve nutritional profile, such as for sugars or salts.
2. Permit enrichment to replace ingredients lost during processing.
3. Permit fortification to add beneficial ingredients.
4. For nutrient content claims subject to 21 CFR 130.10, permit nutrients at lower levels than required (e.g., reducing salt to a level that is less than required to make a "reduced sodium" claim).
5. Eliminate requirements and/or minimums in current standards for salt, sugar, oil, and fat.
6. Permit changes to meet consumer dietary needs, such as "gluten free."

The key themes from the two listening sessions included:

- Ingredients have a variety of purposes. Participants noted that attributes such as flavor, texture, and function are salient to consumers, and thus in some instances may be more relevant than nutrition as factors in SOI promotion of "honesty and fair dealing."

- Consumer nutritional needs are diverse. Variation across the lifecycle and specific nutritional needs posed by chronic health conditions need to be taken into account. Several stakeholder comments, for example, urged FDA to keep in mind the potential health effects

8/ 83 Fed. Reg. 49103 (September 28, 2018). The docket closed on November 27, 2018 and FDA is currently reviewing the 13,000 comments received.

for individuals with renal disease that could result from substitution of potassium chloride for sodium chloride.

- The interplay between food standards, public health policy, and consumer perception is complex. Changes in standards may generate the need to address related areas, such as fortification.

- There is potential for unintended consequences, especially in making horizontal changes around substitutions and additives, such as for sugars, salts, and fats. The nutritional effects across individual products may vary, and the context of the total diet may be relevant.

Several stakeholder comments supported FDA providing flexibility for the use of salt substitutes, such as potassium chloride for sodium chloride, and non-caloric sugar substitutes for advancing nutrition goals. For juice, in particular, the Brix standards were identified as a component that could be relaxed to facilitate improvements in nutrition. Fortification with Vitamin D was also cited as a more flexible standard that could have significant nutritional benefit.

Industry Innovation

FDA used this session to learn from industry stakeholders if and how SOIs pose barriers to industry innovation. The agency sought input on ideas for specific changes that could be made across categories of standardized foods to better promote industry innovation. At the same time, the session explored the appropriate limits to this flexibility to ensure standardized foods continue to meet consumer expectations.

The key themes from the two listening sessions included:

- The need for FDA to adopt a broad and flexible framework. Given the time involved in developing rules, typically lagging the pace of innovation, FDA representatives noted the importance of crafting standards that can accommodate new and novel technologies. However, commenters throughout the day expressed wide disagreement on the degree and desirability of horizontal approaches to standards modernization.

  Some spoke in favor of broad changes across categories. For instance, while FDA considered this topic outside the scope of the meeting, several members of the public encouraged FDA to state expressly that it will not take enforcement action against the use of qualifying terms in conjunction with standardized terms, provided the label clarifies how the food differs from the standardized food (e.g., for plant-based alternatives to meat or dairy products, or for standardized foods produced with flavoring agents not currently permitted in the standard).

  For others, such relaxed standards posed a business challenge that could create an "unfair competitive disadvantage," especially if the existing standards are enforced against some, but not all, foods. Some industry and consumer representatives raised more technical objections that were thought to be better addressed on an individual basis, rather than through broad categories.

- Appropriate "guardrails" to flexibility are necessary to ensure that consumers still recognize products that have been modified.

- Flexibility with ingredients may face technical problems. Ingredient substitution presents the challenge that ingredients often do not allow for just one-to-one exchanges, and substitutions may have varying impacts on diverse products.

Stakeholder comments addressed the potential for further innovation if FDA were to relax requirements for particular ingredients such as enzymes, emulsifiers, or preservatives in standardized foods to allow for functional equivalents. For instance, it was noted that dairy products such as sour cream could be made using enzymes other than rennet, if the relevant standards were revised to allow these enzymes. Members of the public also encouraged FDA to loosen standards to accommodate different manufacturing processes, provided the final product continues to adhere to the standard.

Consumer Expectations

In this session FDA asked if consumers are aware that some foods are standardized, what standardization attributes and nutrition goals are important to consumers, and what SOI changes might impair a product's meeting consumer expectations. The agency also questioned what information beyond current regulatory requirements should be communicated to consumers if horizontal flexibility allows manufacturers to, for example, use new processes, or add or substitute ingredients.

The key takeaways from the two listening sessions included:

- Consumers are highly diverse. Children, pregnant women, and people with food allergies or health and social or environmental concerns, for instance, all have different reasons for selecting products.

- Transparency is a key concern: consumers need to know about changes in standardized foods.

- Stakeholder engagement is very valuable to the agency. FDA needs to draw on data sources from industry, consumer groups, academia, and federal and state governments.

- Consumers may not be aware of specific SOIs, or even the existence of the formal regulations, but they still may have expectations about products (taste, look, feel, function, dietary guidelines). For example, the expectation that cheese melts, drinking milk provides health benefits, and that "eggrolls" might contain egg (a potential allergen), all are relevant to consumer awareness of standards.

Conclusion and Next Steps

FDA is actively listening to stakeholders and seeking input on specific strategies to modernize food SOIs, with a particular emphasis on exploring "horizontal" strategies that encompass changes across categories of food. The agency appears to be very open to a variety of viewpoints and approaches, and is seeking to address the multiple goals of eliminating barriers to innovation in manufacturing nutritious food, protecting consumers against economic adulteration, and providing for a flexible scheme that can accommodate new and novel foods that meet consumer expectations.

FDA is encouraging the public to submit detailed comments and to address potential counter-arguments that could be made to the proposals. FDA will continue to accept comments through November 12, 2019.

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We will continue to monitor FDA's updates related to this public meeting, as well as other guidance and rulemaking generally related to food standards of identity. Please contact us with any questions regarding this or other matters.