

## MEMORANDUM

**From:** Steven B. Steinborn  
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**Date:** September 4, 2019

**Re:** **FDA Announces Public Meeting on Modernizing Food Standards of Identity**

The U.S. Food and Drug Administration (FDA) recently announced it will be holding a full day public meeting on September 27, 2019, to address “Horizontal Approaches to Food Standards of Identity Modernization.” <sup>1/</sup> As explained in more detail below, FDA’s “horizontal” approach to standards reform would look at amending wide groups of standards rather than evaluating standards on a case-by-case basis. Requests to make oral comments are due by September 12th and in-person attendees should register by September 20th. <sup>2/</sup> Written comments are due by November 12, 2019 and can be submitted to FDA docket number FDA-2018-N-2381-1371.

### Background

Since 1938, FDA has established over 280 standards of identity (SOIs) codifying prescribed ingredients and manufacturing processes for a variety of food products. <sup>3/</sup> FDA has suggested revisiting SOIs multiple times throughout the decades, though the agency has not taken broad action to implement changes to the system as a whole (with the exception to its 1993 allowances for certain modifications to standardized foods that qualify for an express nutrient content claim). <sup>4/</sup> In March 2018, FDA indicated it was considering revisiting these established standards when it announced a Nutrition Innovation Strategy (“NIS”) focused, in part, on incentivizing food manufacturers “to produce more healthful foods that are still affordable.” <sup>5/</sup> Commissioner Gottlieb’s speech announcing the NIS emphasized that modernized standards of identity would still play a key role in

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<sup>1/</sup> 84 Fed. Reg. 45497 (Aug. 29, 2019).

<sup>2/</sup> To register, visit the Event Page, Public Meeting on Horizontal Approaches to Food Standards of Identity Modernization, <https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/public-meeting-horizontal-approaches-food-standards-identity-modernization-09272019-09272019>.

<sup>3/</sup> 21 CFR Parts 130 – 169.

<sup>4/</sup> 21 CFR § 130.10.

<sup>5/</sup> Speech by FDA Commissioner Scott Gottlieb, M.D., “Reducing the Burden of Chronic Disease” (Mar. 29, 2018), available at <https://www.fda.gov/news-events/speeches-fda-officials/reducing-burden-chronic-disease-03292018>.

protecting against economic fraud and advancing public health by maintaining the “basic nature and nutritional integrity of products,” but suggested that added flexibility in standards could allow industry innovation that would bring “products with more healthful attributes” to consumers.

Following the March announcement, FDA held a public meeting in July 2018 to discuss the NIS. According to FDA, the July meeting yielded significant stakeholder support for and interest in modernization of SOIs. A key outcome of the July 2018 meeting was that FDA identified that a “horizontal” approach (e.g., revisions that provide “flexibility across all or a broad category of standardized foods”) as opposed to a vertical approach (updating individual standards) would be the more efficient way of maximizing the agency’s limited resources.

## **Public Meeting**

The September 26<sup>th</sup> meeting is aimed at learning how horizontal approaches could accommodate the use of new technologies and new or novel ingredients in foods subject to a current SOI. FDA’s meeting announcement states that “modernizing SOI can give manufacturers the flexibility to improve the nutrition and healthfulness of standardized foods, promote honesty and fair dealing in the interest of consumers, and help achieve the goals of the NIS.”

Although a formal agenda has not yet been published, at this time FDA has identified three breakout sessions addressing broad categories of discussion: (1) nutrition topics, (2) accommodating innovation and changes in science and technology, and (3) consumer expectations and standardized foods. The first breakout session will explore what barriers exist in current standards of identity and how changes to standards of identity could encourage production of more nutritious foods. The second breakout session will explore the types of flexibility that advances in science and technology necessitate, including changes to permitted processes and ingredients that could promote innovation, as well as changes to specific food standards of identity. The third breakout session will discuss the vital role that consumer expectations play in the standards of identity regime and how horizontal modernization could meet new consumer demands while preserving consumer confidence in existing standards. In its announcement regarding the public meeting, FDA explains that in addition to the opportunity to comment at the public meeting, there will be an opportunity for interested stakeholders to submit written comments following the meeting.

The formal meeting agenda will be posted by FDA in mid-September, approximately two weeks before the scheduled meeting.

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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.