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MEMORANDUM

From: Elizabeth Barr Fawell
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Re: FDA Reopens Comments on Proposed Rule to Modernize Food Standards of Identity

The U.S. Food and Drug Administration (FDA) announced that it is reopening the comment period on a 2005 proposed rule to establish a set of general principles to use when considering whether to establish, revise, or eliminate a food standard of identity (SOI). ^{1/} The 2005 proposed rule adopted the approach of elaborating a set of 13 general principles (listed in Appendix 1 below) that would shape FDA's consideration of petitions to establish, revise, or eliminate standards. This approach to modernizing SOIs relies on industry and other groups to draft petitions consistent with the general principles for the agency to review in making standards determinations. FDA is seeking new information and public comment on its proposal to create general principles for establishing new food standards and for revising or eliminating existing food standards. Written comments are due by April 21, 2020 and can be submitted to the *Federal Register* docket number FDA-1995-N-0062.

Background

In 1995, FDA and the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) began reviewing their procedures and requirements for food standards to determine whether the food standards were still necessary and, if so, whether they should be refined or streamlined. FDA and FSIS issued advance notices of proposed rulemaking (ANPRMs) on food standards in December 1995 and September 1996, respectively, presenting alternatives to existing food standards and requesting feedback on ways in which food standards could be revised to provide greater flexibility for development and marketing of new products, while still providing consumer protection.

Following the ANPRMs, FDA and FSIS established a joint Food Standards Work Group, which weighed several options related to modernizing food standards. Ultimately, the agencies tentatively concluded that relying on external groups (e.g., consumer, industry, commodity, or other groups) to draft recommended revisions to existing food standards but retain the agencies' authority to establish the final food standards was the best approach. Together, FDA and FSIS issued a proposed rule in 2005 proposing general principles for establishing new food standards and for revising or eliminating existing food standards. These proposed principles would be used in conjunction with the agencies' proposed approach of establishing principles for assessing standards,

^{1/} 85 Fed. Reg.10107. The *Federal Register* notice announcing the original 2005 proposed rule is available at <https://www.federalregister.gov/documents/2005/05/20/05-9958/food-standards-general-principles-and-food-standards-modernization>.

while allowing third parties (i.e., industry) to administer those principles (e.g., through petitions to the agencies). ^{2/}

FDA's reopening of the 2005 proposed rule is part of its multi-year Nutrition Innovation Strategy, launched in 2018, which includes the objective of promoting industry innovation by giving manufacturers the flexibility to produce healthier foods. On September 27, 2019, the agency held a public meeting to obtain stakeholder input on potential changes to existing SOIs, particularly "horizontal" approaches – changes that could be made across categories of standardized foods. ^{3/} Although the original proposed rule was jointly published with FSIS, FDA only is reopening the comment period for the FDA-specific aspects of the proposed rule.

FDA Request for Comments

Comments are welcome on any aspect of the proposed rule but FDA states that the agency is particularly interested in comments that address the following questions:

1. Should FDA finalize the proposed rule? Why or why not?
2. Are there general FDA principles that should be added, eliminated, revised, or retained?
 - a. What is the specific principle?
 - b. Why should the principle be added, eliminated, revised, or retained?
 - c. Are there specific product examples that illustrate why a principle should be added, eliminated, revised, or retained?
3. What specific revisions should FDA make to the proposed rule's principles or framework to better reflect our modernization goals of:
 - a. Protecting consumers against economic adulteration?
 - b. Ensuring standardized foods continue to meet consumer expectations?
 - c. Maintaining the basic nature, essential characteristics, and nutritional integrity of food?
 - d. Promoting industry innovation?
 - e. Providing flexibility to produce more healthful foods?
 - f. Facilitating additional flexibility across all or broad categories of standardized foods?
4. How should FDA weigh the general principles?
 - a. The proposed rule stated that the first four principles were the most fundamental to addressing consumer economic protection and therefore, FDA would consider eliminating a food standard if it is inconsistent with any of these four principles.
 - i. Please explain whether you agree with this framework.
 - ii. If you do not agree, what principles should FDA consider when deciding whether to eliminate a food standard?
 - b. The proposed rule explained that FDA would consider revising or establishing a new food standard only if it was consistent with all 13 principles.
 - i. Please explain whether you agree with this framework.

^{2/} In response to this proposal, in 2006 the Grocery Manufacturers Association (GMA) filed a citizen petition proposing an alternative approach that would not rely on petitions to modernize individual standards. GMA's petition requested that FDA and FSIS establish flexible SOIs in six categories to modernize food standards. See HL Memo - Horizontal Approaches to Food Standards of Identity Modernization at <https://www.hfoodlaw.com/wp-content/uploads/sites/357/2019/10/HL-Memo-FDA-Public-Meeting-on-Horizontal-Approaches-to-Food-Standards-of-Identity-Modernization.pdf>.

^{3/} See HL Memo - Horizontal Approaches to Food Standards of Identity Modernization at <https://www.hfoodlaw.com/wp-content/uploads/sites/357/2019/10/HL-Memo-FDA-Public-Meeting-on-Horizontal-Approaches-to-Food-Standards-of-Identity-Modernization.pdf>.

- ii. If you do not agree, what principles should FDA consider when deciding whether to revise or establish a new food standard?
5. What explanation is needed to provide more clarity, certainty, or context regarding:
 - a. The rationale for the principles?
 - b. How FDA will consider the principles when evaluating whether to eliminate, revise, or establish a new food standard?
 - c. How stakeholders should use the principles to inform the preparation of petitions requesting that FDA eliminate, revise, or establish a new food standard?
 6. What additional information should FDA consider when evaluating the costs, benefits, and estimates of the annual reporting burden of the proposed rule?

The agency is encouraging comments to be as specific as possible and, when possible, to include data and information for FDA to consider.

* * *

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

Appendix 1:

Proposed 13 General Principles for Establishing, Revising, or Eliminating a Food Standard

1. Promotes honesty and fair dealing in the interest of consumers.
2. Describes the basic nature of the food to ensure that consumers are not misled by the name of the food and to meet consumers' expectations of product characteristics and uniformity.
3. Reflects the essential characteristics of the food—or those that define or distinguish a food or describe the distinctive properties of a food and that may contribute to achieving the food's basic nature or may reflect relevant consumer expectations of a food product.
4. Ensures food does not appear to be better or of a greater value than it is. May be used as a vehicle to improve the overall nutritional quality of the food supply.
5. Contains clear and easily understood requirements to facilitate compliance by food manufacturers.
6. 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.
7. Harmonizes with international food standards to the extent feasible.
8. Is simple, easy to use, and consistent among all food standards. Includes only those elements that are necessary to define the basic nature and essential characteristics of a particular food, without unnecessary details.
9. Allows for variations in the physical attributes of the food. Where necessary to provide for specific variations in the physical attributes of a food within the standard, variations are consolidated into a single food standard.
10. Incorporates general requirements that pertain to multiple food standards of a commodity group into general regulatory provisions that address the commodity group whenever possible.
11. Considers other relevant regulations. Any specific requirements for foods intended for further manufacturing are incorporated within the reference standard rather than provided as a separate standard.
12. Provides terms that can be used to name a food and allows terms to be used in any order that is not misleading to consumers.
13. Names of ingredients and functional use categories in a food standard should be consistent with other food standards and relevant regulations in this chapter, and, when appropriate, incorporate current scientific nomenclature.