



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 130

[Docket No. FDA-1995-N-0062 (formerly 1995N-0294)]

RIN 0910-AC54

Food Standards; General Principles and Food Standards Modernization; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the proposed rule, published in the *Federal Register* of May 20, 2005, entitled “Food Standards; General Principles and Food Standards Modernization,” to establish a set of general principles for food standards for FDA to use when considering whether to establish, revise, or eliminate a food standard. The proposed rule was issued jointly with the United States Department of Agriculture (USDA) and, while FDA will continue to engage with USDA regarding the proposed rule, we are reopening the comment period to receive new data, information, or further comments only on FDA-specific aspects of the proposed rule, including FDA’s 13 general principles.

DATES: We are reopening the comment period on the proposed rule that published in the *Federal Register* of May 20, 2005 (70 FR 29214). Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-1995-N-0062 (formerly 1995N-0294) for “General Principles and Food Standards Modernization; Reopening of the Comment Period.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets

Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.”

Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rumana Yasmeen, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-6060.

SUPPLEMENTARY INFORMATION:

I. Background on the Proposed Rule

In the *Federal Register* of May 20, 2005 (70 FR 29214), FDA and USDA jointly issued a proposed rule entitled “Food Standards; General Principles and Food Standards Modernization,” as a first step in instituting a process to modernize FDA definitions and standards of identity (and standards of quality and fill of container) consistent with section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), and USDA’s definitions and standards of identity or

composition under the Federal Meat Inspection Act and the Poultry Products Inspection Act (21 U.S.C. 607(c) and 457(b)) (and standards of fill of container). The proposed rule, if finalized, would establish general principles that FDA and USDA would consider when determining whether to establish, revise, or eliminate a food standard.

Although the general principles were mostly consistent between FDA and USDA, a few principles were not identical. Because FDA and USDA regulate different products under different statutory authorities, some principles were developed to reflect specific FDA or USDA regulatory needs and perspectives. FDA and USDA stated that adherence to principles identified in the proposed rule would result in standards that would (1) better promote honesty and fair dealing in the interest of consumers and protect the public; (2) allow for technological advances in food production; (3) be consistent with international food standards to the extent feasible; and (4) be clear, simple, and easy to use for both manufacturers and the agencies that enforce compliance with the standards.

The Preliminary Regulatory Impact Analysis (PRIA) of the proposed rule anticipated that the associated social costs of finalizing both FDA and USDA principles would be small, however would likely yield substantial benefits. The PRIA noted that:

Standards that contain unnecessary elements or that fail to provide flexibility in terms of allowable food technology, may generate unnecessary production costs, and impede technological innovation in the food industry. Such standards may also serve as effective barriers to competition, thereby raising product prices and transferring resources from consumers to producers. Finally, some standards may be inconsistent with international standards, which may impede international trade. Impeding international trade may also restrict competition and lead to higher product prices.

The PRIA stated that applying the principles set forth in the proposed rule could help address these issues and that the benefits of establishing the proposed principles outweighed the costs.

Interested persons were originally given until August 18, 2005, to comment on these proposed general principles and to provide additional information as described in the Request for Comments section of the proposed rule. While comments received were generally supportive, FDA and USDA did not finalize the proposed rule due to resource constraints and competing priorities.

II. FDA Principles in the Proposed Rule

In the proposed rule, FDA proposed a set of 13 general principles we would consider when establishing, revising, or eliminating a food standard (see 70 FR 29214 at 29234 to 29235 (proposed 21 CFR 130.5(b))). The first four general principles stated the purpose or function of a food standard and were the most fundamental principles addressing consumer economic protection. Therefore, if a food standard is inconsistent with any one of these four principles, we would consider eliminating it. The proposed rule also would revise or establish a new food standard if it was consistent with the full set of 13 principles:

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.

III. FDA's Current Food Standards Modernization Efforts

Since publication of the proposed rule, FDA announced our Nutrition Innovation Strategy (NIS) with the goal of helping to reduce preventable death and disease related to poor nutrition. The NIS focuses on, among other things, providing incentives for food manufacturers to produce products that have more healthful attributes. Under the NIS, FDA is seeking to modernize food standards in a manner that will achieve three primary goals: (1) protect consumers against economic adulteration; (2) maintain the basic nature, essential characteristics, and nutritional integrity of food; and (3) promote industry innovation and provide flexibility to encourage manufacturers to produce more healthful foods.

In July 2018, FDA held a public meeting on the NIS.¹ At the meeting, we led a breakout session to discuss our food standards modernization goals and, among other things, to learn from stakeholders what FDA should be aware of when reviewing our food standard regulations and exploring how to modernize. At this public meeting, and in comments submitted to the public meeting docket, stakeholders expressed general support for FDA continuing its work with USDA to finalize the proposed rule. However, stakeholders also shared that, given the time that has passed since its publication, we should reopen the comment period to allow the public the opportunity to provide data and information on changes that have occurred in manufacturing, food technology, market trends, and nutrition science that FDA should consider when determining next steps for the proposed rule.

¹ For more information, please visit FDA's website at: <https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/public-meeting-discuss-fdas-nutrition-innovation-strategy-07262018-07262018> or see the public docket FDA-2018-N-2381.

While FDA intends to work with USDA if we pursue finalization of the proposed rule, for purposes of this notice we are only interested in comments, data, and information on FDA-specific aspects of the proposed rule, including the 13 general principles listed above.

IV. Additional Issues for Consideration

In response to stakeholder comments and to inform our decision regarding whether to proceed with finalizing the proposed rule, we seek new information and public comment on how we could create general principles for establishing new food standards and for revising or eliminating existing food standards. While FDA and USDA jointly issued the proposed rule, we are only seeking comments on the FDA-specific aspects of the proposal. We encourage comments to be as specific as possible and, when possible, to provide data and information for FDA to consider.

While the public may comment on any FDA aspects of the proposed rule, we are particularly interested in comments on 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.
 - 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?

Dated: February 13, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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