FDA Public Meeting:
FDA's Comprehensive, Multi-Year Nutrition Innovation Strategy
Facilitated Breakout Session:
Modernizing Standards of Identity & Ingredients Lists on Labels

Modernizing Standards of Identity

Topic Overview: This session will discuss modernizing FDA's standards of identity (SOI) program. FDA is interested in modernizing the SOI program in a manner that will achieve three primary goals: (1) protecting consumers against economic adulteration; (2) maintaining the basic nature, essential characteristics, and nutritional integrity of food; and (3) promoting industry innovation and providing flexibility to encourage manufacturers to produce more healthful foods. Participants are asked to provide ideas on how to achieve these goals and help FDA identify pros and cons associated with potential paths forward. FDA is also interested in learning what changes have occurred in food production that impact industry's ability to comply with the SOI program and what FDA should be aware of when reviewing its SOI regulations and exploring how to revise them.

Background: Many foods have definitions and standards of identity (SOI) established by law. FDA began establishing SOI shortly after the Federal Food, Drug, and Cosmetic Act (FD&C Act) was enacted in 1938 to "promote honesty and fair dealing in the interest of consumers"[1] and, since this time, has established more than 280 SOI for a wide variety of food products.[2] SOI are established under the common and usual name of a food. They also typically set forth permitted ingredients, both mandatory and optional, and sometimes describe the amount or proportion of each ingredient. Many SOI also prescribe a method of production or formulation.

SOI protect consumers against economic adulteration and maintain the integrity of food. They also reflect consumers' expectations about food. As consumers continue to seek more nutritious and healthful food options, the agency seeks to ensure that standards of identity meet these expectations. Our intent is that modernizing SOI to improve the nutrition and healthfulness of standardized foods will promote honesty and fair dealing in the interest of consumers and achieve the goals of the Nutrition Innovation Strategy.

Discussion Questions:

1. Can the SOI regulations be used to encourage production of more healthful foods, and if so, what changes can be made to accomplish this? How can the SOI regulations act as a barrier to development of healthier foods?

2. What has changed – for example, in manufacturing, food technology, nutritional science, or marketing trends – that FDA should be aware of when reviewing SOI regulations?

3. Other than maintaining the basic nature, essential characteristics, and nutritional integrity of food, what factors might be included in SOI to promote honesty and fair dealing in the interest of consumers?

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[1] 21 U.S.C. § 341.

[2] SOI for specific food products may be found in 21 C.F.R. Chapter I, Subchapter B.

4. When an existing SOI is under review, how should the agency assess whether the SOI reflects consumer expectations about that food?

5. In 2005, a proposed rule was issued as a first step in instituting a process to modernize SOI.[3] This rule proposed a set of 13 general principles to consider when establishing, revising, or eliminating a SOI. (See Appendix A) (70 FR 29214 at 29234-35, available at: https://www.gpo.gov/fdsys/pkg/FR-2005-05-20/pdf/05-9958.pdf).
    - Should previously proposed principles be updated to better promote innovation and encourage production of more healthful foods?
    - Are there other principles FDA should consider?

6. Other than the approach proposed in question five, how else could FDA modernize its SOI program, including revising its SOI regulations? How do proposed approaches satisfy FDA's three SOI modernization goals?

[3] "Food Standards; General Principles and Food Standards Modernization," 70 FR 29214 (May 20, 2005). Available at: https://www.gpo.gov/fdsys/pkg/FR-2005-05-20/pdf/05-9958.pdf.

Ingredients Lists on Labels

Topic Overview: FDA is interested in learning about ingredient statements on food labels and changes that would make ingredient statements more user-friendly and balanced, while continuing to comply with the statutory requirement that ingredients be declared by their common and usual names.[4]

Background: Food manufacturers are required to list ingredients for food on the label for both standardized and non-standardized foods. On a product label, the ingredients are listed by their common or usual names, with the ingredients used in the greatest amount by weight first, followed in descending order by those in smaller amounts. Ingredients include substances that are used to flavor and color food. Some of these substances can be listed collectively as "natural flavors," "spices," "artificial flavors," or in the case of color additives exempt from certification, "artificial colors," without declaring the common or usual name of each one. Declaration of a major food allergen in a collective or single color, flavor, or spice can be accomplished by naming the allergen in the ingredient list, including the use of a parenthetical.

FDA is planning to re-evaluate the ingredient information on food labels in light of consumer preference for simple labels that are readable and understandable. The FD&C Act and FDA regulations require that the information appear prominently and conspicuously on the label so it can be easily read by the consumer and that the information be placed in a type size no smaller than 1/16 of an inch in height.

In addition to readability, we are considering whether certain ingredients are declared by their common or usual names and whether the names are confusing or misleading. For example, we could consider whether use of the name “vitamin B6” for “pyridoxine” and “vitamin B12” for “cyanocobalamin” might reflect common usage and help people better understand what is in their food.

Discussion Questions:

1. Are there particular features of the food label that can be improved to enhance consumer understanding of ingredients? Do you have any evidence or examples to support the changes?

2. FDA has heard concerns that ingredient lists are challenging to read. What changes could be made to increase clarity and balance the limited space available on food labels?

[4] 21 U.S.C. § 343(i).

Appendix A: General Principles & Food Standard Modernization

In 2005, a proposed rule was issued as a first step in instituting a process to modernize SOI.[5] This rule proposed a set of 13 general principles to consider when establishing, revising, or eliminating a SOI. The first four general principles stated the purpose or function of a food SOI and were the most fundamental principles addressing consumer economic protection. Therefore, if a SOI is inconsistent with any one of these four principles, the agency would consider eliminating it. The rule also proposed revising or establishing a new SOI 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.

To date, this proposed rule has not been finalized.

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[5] "Food Standards; General Principles and Food Standards Modernization," 70 FR 29214 (May 20, 2005). Available at: https://www.gpo.gov/fdsys/pkg/FR-2005-05-20/pdf/05-9958.pdf.