



U.S Food and Drug Administration (FDA) Public Meeting Horizontal Approaches to Food Standards of Identity Modernization

Introduction

Background:

FDA issues standards of identity (SOI) to “promote honesty and fair dealing in the interest of consumers.”¹ SOI typically set forth permitted ingredients, both mandatory and optional, and many specify a method of production or formulation. In the past, FDA has taken into account public health goals, innovation, and industry practices when establishing or revising SOI.

Because many SOI were issued decades ago, various stakeholders have expressed concerns that SOI may be outdated and impede a manufacturer’s ability to take advantage of innovations in, for example, manufacturing, technology, and use of new ingredients when producing standardized foods. Stakeholders have also highlighted in public comments the growing consumer demand for a wider variety of food products and noted that new flexibility in SOI could help industry meet those demands. When we announced the Nutrition Innovation Strategy (NIS) in March 2018, FDA stated its interest in modernizing SOI to: (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 nutritious foods.

Meeting Overview:

Today’s meeting is focused on FDA’s efforts on modernizing SOI and identifying specific changes we could make to current SOI, particularly changes that could be made across categories of standardized foods (i.e., horizontal changes), to meet the goals of the NIS. We want to focus on efficient modernization approaches that will have the greatest potential impacts. As such, we are interested in learning more about horizontal approaches to SOI modernization that will encourage production of more nutritious foods and facilitate innovation, specifically allowing for use of new production methods and new ingredients. We believe this focus supports the NIS goals of reducing the burden of chronic disease through improved nutrition and using FDA’s tools and authorities to facilitate industry innovation toward producing more nutritious foods that meet consumer expectations. Furthermore, this will allow FDA to provide manufacturers with additional flexibility without adversely impacting the basic nature and essential characteristics of standardized foods.

We also want to better understand the consumer perspective – specifically, consumer expectations with respect to standardized foods. We are interested in learning what flexibility we can provide in a horizontal approach to modernization that will ensure standardized foods continue to meet consumer needs and expectations.

To learn more about these important topics, FDA will hold three breakout sessions during the public meeting that will focus on nutrition, innovation, and consumer expectations regarding standardized foods.

¹ 21 U.S.C. § 341

Horizontal Approaches to SOI Modernization: Nutrition Breakout Session

Session Overview:

At this breakout session, FDA is interested in exploring specific changes we could make across categories of standardized foods (i.e., horizontal changes) to provide flexibility to encourage manufacturers to produce more nutritious foods. We are interested in hearing stakeholder perspectives regarding the role of nutrition in SOI modernization. Our goal is to modernize SOI in ways that will allow manufacturers to produce more nutritious versions of standardized foods. We want to learn if SOI impose barriers to producing more nutritious versions of standardized foods and what specific changes FDA could make across categories of SOI to address any identified barriers toward achieving our modernization goal.

In various forums, stakeholders have proposed a variety of specific changes to current SOI for nutrition-related purposes and we have listed several of these proposals below. Please note, FDA is listing these proposals to help generate discussion at the public meeting and inclusion of the below proposals is not an endorsement by the Agency.

- *Proposal 1: Permit ingredient substitution or reduction to improve the nutritional profile of the food (e.g., substituting non-nutritive for nutritive carbohydrate sweeteners or salt substitutes for sodium chloride)*
- *Proposal 2: Permit enrichment to replace ingredients lost during processing (e.g., adding sources of calcium to standardized foods to restore calcium lost through processing)*
- *Proposal 3: Permit fortification to add beneficial ingredients (e.g., adding whole grains and fiber to standardized foods)*
- *Proposal 4: For foods subject to 21 CFR 130.10, permit nutrients at levels that do not meet the threshold in the relevant nutrient content claim regulation (e.g., reducing salt in standardized foods by a level less than required to make a “reduced sodium” claim)*
- *Proposal 5: Eliminate requirements and/or minimums in current standards for salt, sugar, oil, and fat (e.g., eliminating milkfat requirements in standardized products)*
- *Proposal 6: Permit changes to meet consumer dietary needs (e.g., permitting “gluten free” versions of standardized foods for consumers with food allergies or intolerances)*

At this session, we are interested in learning more about stakeholder perspectives regarding these proposals, or any other specific horizontal change(s) that would improve the healthfulness or nutrition of a standardized food. We are also interested in learning how we could design a horizontal standard to provide manufacturers of standardized foods with the flexibility to reflect future advances in science and technology as they relate to improved nutrition.

Discussion Questions:

1. Do SOI pose barriers to the production of nutritious foods?
 - a. If yes, which specific SOI, or categories of SOI, and what are the barriers?
2. We are interested in exploring changes that could be made across categories of standardized foods to improve the nutrition or healthfulness of those foods. Please share your ideas for

specific horizontal change(s) that would help FDA achieve its nutrition-related goals by answering the following questions:

- a. What specific change or changes could FDA make to existing SOI regulations to improve the healthfulness or nutrition of standardized foods?
 - b. Which standardized foods or food categories would be impacted by the change or changes?
 - c. How would the change improve the nutrition or healthfulness of the food?
 - d. What are appropriate limits to this flexibility to ensure standardized foods continue to meet consumer expectations?
3. Are there existing food standards, for example, those established by voluntary standard-setting bodies or regulatory counterparts, that would be an appropriate model for FDA to use in order to achieve our nutrition goals?
 4. How can we make changes across categories of SOI that would accommodate future advances in, for example, science and technology as they relate to improved nutrition, to avoid the need for frequent SOI revision?

Horizontal Approaches to SOI Modernization Innovation Breakout Session

Session Overview:

At this breakout session, FDA is interested in exploring specific changes we could make to existing SOI across categories of standardized foods (i.e., horizontal changes) to better facilitate industry innovation. Our goal is to modernize SOI to allow manufacturers new flexibility to take advantage of advances in science, manufacturing, and technology, while maintaining the basic nature, essential characteristics, and nutritional integrity of standardized foods. In particular, we want to learn if and how SOI may impose barriers to industry innovation and what specific changes would help remove these barriers.

In various forums, stakeholders have proposed a variety of specific changes to current SOI to better facilitate innovation and we have listed several of these proposals below. Please note, FDA is listing these proposals to help generate discussion at the public meeting and inclusion of the below proposals is not an endorsement by the Agency.

- *Proposal 1: Permit flexibility to add or substitute ingredients to achieve a technical, nondistinctive effect (e.g., substituting emulsifiers, binders, stabilizers, preservatives, or antimycotic agents not currently permitted in specific SOI categories)*
- *Proposal 2: Permit flexibility to add or substitute characterizing ingredients to meet consumer demand for greater product variety (e.g., adding vegetables or spices not currently permitted in specific SOI categories to create more variety of a standardized food)*
- *Proposal 3: Permit changes to appearance, shape, or form to meet consumer demand for greater product variety (e.g., permitting “chunky” or “whipped” forms of products not currently permitted in specific SOI categories)*
- *Proposal 4: Permit flexibility to add or substitute safe and suitable ingredients (e.g., substituting flavors, sweeteners, salt substitutes, vegetable fats or oils not currently permitted in specific SOI categories)*
- *Proposal 5: Permit use of innovative or more efficient technologies to produce ingredients (e.g., enzyme technologies to enhance properties of ingredients used in standardized foods)*
- *Proposal 6: Permit use of alternate manufacturing processes to produce standardized foods (e.g., minimum aging periods required for certain standardized foods)*

At this session, we are interested in stakeholder perspectives about these proposals, or any other specific change(s) that would improve the healthfulness or nutrition of a standardized food. We are also interested in learning how horizontal changes could provide the flexibility necessary to accommodate future industry innovation while ensuring standardized foods continue to meet consumer expectations.

Discussion Questions:

1. Do SOI pose barriers to industry innovation?
 - a. If yes, which specific SOI, or categories of SOI, and what are the barriers?

2. We are interested in exploring change(s) that could be made across categories of standardized foods to better promote industry innovation. Please share your ideas for specific change(s) that would help FDA achieve its innovation-related goals by answering the following questions:
 - a. What change or changes could FDA make to existing SOI regulations to better promote industry innovation?
 - b. Which standardized food or food categories would be impacted by the change or changes?
 - c. How would the change better promote industry innovation?
 - d. What are appropriate limits to this flexibility to ensure the standardized food(s) continue to meet consumer expectations?
3. Are there existing food standards, for example, those established by voluntary standard-setting bodies or regulatory counterparts, that would be an appropriate model for FDA to use in order to achieve our goal of facilitating industry innovation?
4. How can we make changes across categories of SOI that would accommodate future industry innovation in, for example, production methods or development of new ingredients, to avoid the need for frequent SOI revision?

Horizontal Approaches to SOI Modernization: Consumer Expectations Breakout Session

Session Overview:

At this breakout session, FDA is interested in discussing issues relating to consumer expectations of foods that are standardized. Many categories of standardized foods, such as milk products, cheeses, cereal flours, and macaroni and noodle products, are commonly consumed and are a regular part of the diet of many American consumers. We want to learn about consumer expectations of these foods and how new flexibility to categories of standardized foods (i.e., horizontal changes) could allow innovation and product reformulation to meet such expectations. For example, comments to the NIS public meeting docket highlighted that consumers now demand healthier foods and products that meet specific dietary needs (e.g., “gluten free” products). As SOI are established to “promote honesty and fair dealing in the interest of consumers,”² we believe the consumer perspective is critical to understanding what factors and approaches we should consider when exploring horizontal changes to categories of standardized foods. We would also like to discuss what, if any, limitations are appropriate to ensure standardized foods continue to meet consumer expectations.

Discussion Questions:

1. Are consumers aware that some foods are standardized?
2. What attributes of standardized foods are important to consumers? For example, if the nutrient profile of standardized foods is important to consumers, are there specific aspects, such as fiber content or caloric count, that are the most critical?
 - a. In which standardized foods are these specific attributes important? (e.g., vitamin and mineral levels found in enriched flour and cereal products.)
3. What nutrition goals are important to consumers?
 - a. What specific changes can FDA make to SOI to better reflect the nutrition goals that are important to consumers?
4. What data are available to help FDA evaluate and consider consumer expectations? (e.g., consumption data, consumer surveys, etc.)
5. Are there changes to certain standardized foods, categories of standardized foods, or attributes of standardized foods that would make it so the product no longer meets consumer expectations? If so, why?
6. If FDA creates horizontal flexibility to allow manufacturers to, for example, use new manufacturing processes or add or substitute ingredients, should information beyond what is specifically required by FDA regulations be conveyed to consumers?
 - a. If yes, what information should be conveyed?
 - b. If yes, how could such information be clearly and consistently conveyed?

² 21 U.S.C. § 341