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Horizontal Approaches to Food Standards of Identity Modernization

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Food, Drugs, and Devices

FDA hosted a public meeting on September 27, 2019 entitled "Horizontal Approaches to Food Standards of Identity Modernization." The purpose of the meeting was to discuss changes FDA could make across food standards to afford manufacturers greater flexibility and to facilitate innovation. Most existing standards of identity were promulgated in the mid-20th century following the passage of the 1938 Food, Drug, and Cosmetic Act. Since that time, rapid innovation in food and technology has tested the limits and continued relevance of these standards. FDA recognized as early as 1995 that significant changes to food standards of identity were needed, and even proposed a rule with FSIS in 2005 that would create general principles for the modernization of food standards. Almost 15 years have passed without further Agency action on this issue.

This meeting signaled FDA's renewed commitment to retrofitting an outdated system to accommodate the modern food supply. FDA promised to revisit the 2005 general principles and to propose a "horizontal" change to the standards of identity, affording manufacturers greater flexibility across all or a broad category of standardized foods in order to improve nutrition in accordance with the Agency's Nutrition Innovation Strategy. Below are our key takeaways from the meeting.

FDA did not substantively address plant-based versions of standardized foods

Stakeholders came prepared to discuss how FDA's standards of identity either stifle the development of plant-based alternatives to standardized foods or protect the integrity of such foods. After an extensive public comment period largely consumed by this topic, the concluding speaker, Megan Velez, Acting Director of the Office of Regulations and Policy at CFSAN, clarified that FDA views plant-based foods as a *separate issue* that it does not plan to address with its horizontal approach. Manufacturers of plant-based alternatives and the dairy and meat industry alike, therefore, may have left the meeting dissatisfied.

While FDA did not reveal how it *does* plan to address plant-based alternatives, the Agency offered that it was actively reviewing comments and consumer perception studies submitted in in response to its 2018 request for information, and was considering how the issue could potentially be resolved through food labeling rather than standards of identity.

FDA's "horizontal approach" may give manufacturers flexibility to improve food products' nutritional profiles and accommodate innovations in food and technology

FDA officials made clear that the status quo is not working, and that standards of identity need to be revised to afford greater flexibility. But what form will this flexibility take? FDA indicated

that it wants to grant manufacturers greater flexibility in two key areas: improving nutritional profiles and accommodating innovation.

- Improving nutritional profiles. A horizontal rule could allow manufacturers to reduce levels of "unhealthy" ingredients, substitute "healthier" ingredients, and add beneficial ingredients to fortify foods. The oft-repeated example was permitting salt substitutes to be used in either all or a category of standardized foods, such as cheeses. Other examples include fortifying standardized foods with whole grains, eliminating minimum requirements for salt, sugar, oil, and fat content, and permitting changes to meet dietary needs, such as "gluten free" versions of standardized products. FDA will have to grapple, however, with how such changes should be communicated to consumers through labeling, particularly when the change does not meet the standards for a nutrient content claim and when changes are made to "junk" foods with poor nutritional profiles.
- Accommodating innovation. A horizontal rule could also give manufacturers flexibility to include new technical ingredients in products (e.g. emulsifiers, binders, and stabilizers), to use new, more efficient technologies, and to make use of alternate manufacturing processes. Further, a horizontal rule could permit new characterizing ingredients and new appearances/shapes/forms to meet consumer demand for greater product variety. Stakeholders shared seemingly countless examples of how outdated standards frustrate their business's ability to adopt new technology for or new variations of the specific standardized food they manufacture; Agency officials seemed to appreciate industry's frustration and appetite for change.

FDA appears ready to afford flexibility so long as consumer expectations are met

Overall, FDA's remarks demonstrated the Agency's recognition of the significant barriers outdated food regulations pose, and its desire to afford greater flexibility, particularly to improve nutritional profiles. The Agency also recognized the distinction between what the law strictly requires and what consumers expect from their food — consumers may not be aware of a standard or its specific requirements, but they do have expectations about how a food will taste and how it can be used. The Agency resolved to retain the "basic nature" of standardized foods, but allow some deviations so long as those deviations are clearly communicated to and understood by consumers, as evidenced by consumer perception studies. This could signal FDA's future willingness to afford flexibility in complying with other food requirements when such deviations are adequately communicated to and understood by consumers.

Next steps

Interested stakeholders may wish to submit comments to FDA on horizontal approaches to standard of identity modernization. The comment period is open through November 12, 2019. FDA did not indicate when it plans to propose a rule or take other concrete action on this topic. The Agency also intends to reopen for comments its 2005 proposed rule on general principles for the modernization of food standards, and plans to do so in the near term. After accepting and reviewing comments, FDA will either finalize that rule or issue a new proposed rulemaking. Stakeholders interested in FDA's approach to plant-based alternatives to standardized foods should continue to watch for potential Agency action outside of these standard of identity work streams. Covington will continue to provide updates regarding such FDA activities.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Drugs, and Devices practice:

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