

VIA ELECTRONIC SUBMISSION

November 7, 2019

Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2018-N-2381; Horizontal Approaches to Food Standards of Identity Modernization; Request for Comments

Dear Sir/Madam,

Thank you for the opportunity to submit comments on the horizontal approaches to food standards of identity (SOI) modernization. These comments are being submitted on behalf of the Food Science Program of the Food Chemicals Codex (FCC), which is published by the United States Pharmacopeia (USP).¹ FCC food standards are developed through an open, transparent, expert-based process, offering the ability to adjust standards to keep up with evolving science and technology, adapt to new industry practices, and address public health issues. The process utilizes the work of independent experts in close collaboration with stakeholders and government agencies, such as FDA.

The FCC was first published in 1966 by the FDA and the National Academy of Medicine to define the quality of food-grade chemicals. This effort recognized the need for collaboration among government, industry, academics, and consumers to create public quality standards for food-grade substances. Since that time, the FCC has expanded to include more than 1250 standards for all types of food-related substances, including identity standards for complex substances such as pomegranate juice and refined olive oil. Over 200 FCC standards are cited in FDA regulations, and the FCC is recognized by international regulatory authorities, including Canada, Australia, New Zealand, Israel, and Brazil.

SOI have been recognized as essential for protecting the integrity of the food supply in the United States since the passage of the Federal Food, Drug, and Cosmetic Act (FD&C Act) in 1938. Section 401 of the FD&C Act states that SOI should be established to promote “fair dealing in the interest of consumers.” FDA regulations also state that “[a]ny petition for a food standard shall show that the proposal, if adopted, would promote honesty and fair dealing in the interest of consumers” (21 CFR 130.5(b)). The ongoing importance of these goals is reiterated in the Federal Register Notice² requesting these comments, which states that a primary agency priority is to protect consumers against economic adulteration.

Standards in general, and SOI in particular, are foundational for supply chain transparency, supporting accurate communication from primary producers to

¹ USP is an independent, scientific, nonprofit organization dedicated to improving health through the development of public standards for medicines, foods, and dietary supplements.

² 84 FR 45497 (Aug. 29, 2019).

consumers around the world. Preserving a clear link between product names and composition, such as provided by current SOI, is essential for effective communication when supply chains are long and complex, involving ingredients from many sources that undergo multiple treatments at different steps. SOI also support producers as objective criteria for quality. Some SOI would benefit from carefully designed modernization, where appropriate. However, it is important that consumers do not lose the protection gained from current SOI against adulteration and misrepresentation.

SOI protect both consumers and manufacturers along multinational food supply chains. Changes to SOI could impact harmonization in the global food marketplace.³ As one example, SOI modernization in the United States may affect whether a U.S. food product meets the standard articulated in Article 8 of European Commission Regulation 178/2002 (General Food Regulations) which highlights “prevention of: (a) fraudulent or deceptive practices; (b) the adulteration of food; and (c) any other practices which may mislead the consumer.”

The U.S.D.A. Economic Research Service and the Mintel Global New Product Database shows that there was an average of more than 19,900 new food and beverage products introduced in the United States yearly between 2011 and 2016.⁴ New SOI are needed to support the quality of new products, new ingredients, and new processing technologies to ensure transparency for consumers and manufacturers.

Due to FCC’s recognition in FDA regulations, the Food Science Program is uniquely positioned to collaborate with FDA in support of updating existing SOI, and other standards, and to develop new SOI and approaches that consider consumer needs and practical implementation.

Again, thank you for the opportunity to comment. For more information, please contact Elizabeth Miller, Vice President, U.S. Public Policy and Regulatory Affairs, at ehm@usp.org; (240) 221-2064.

Sincerely yours,



Jaap Venema, Ph.D.
Executive Vice President and Chief Science Officer
jpv@usp.org
(301) 230-6318

³ Under the Safe Foods for Canadians Act, the Canadian Food Inspection Agency (CFIA) has established more than 150 SOI. Under the Food Standards Code, the Food Standards Australia New Zealand (FSANZ) has established more than 30 SOI. The Codex Alimentarius has published more than 200 food standards and several hundred ingredient standards.

⁴ See U.S.D.A. Economic Research Service, New Product webpage, at <https://www.ers.usda.gov/topics/food-markets-prices/processing-marketing/new-products.aspx> (Aug. 20, 2019).