ORAL COMMENTS AT PUBLIC MEETING

September 27, 2019

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

I am Steven Gendel, Senior Director of Food Science for the Food Chemicals Codex. The FCC, which is published by the U.S. Pharmacopeia, is the largest independent source of standards for food substances. Thank you for this opportunity to discuss modernizing Standards of Identity (SOI) and the use of a horizontal approach to modernization.

SOI play a critical role in protecting the integrity of the food supply. The August 29 Federal Register Notice that announced this meeting noted that FDA began establishing SOI shortly after the passage of the FD&C Act in 1938 to promote honesty and fair dealing in the interest of consumers. This FR notice also says that a primary agency priority is to protect consumers against economic adulteration. Similarly, the Codex Alimentarius says that food standards in general are established to protect the health of consumers and to ensure fair practices in the food trade. When considering modernization of existing SOI, it is important that we protect what consumers have gained from the current standards.

Standards are foundational for supply chain transparency, allowing for accurate communication from primary producers to consumers around the world. To quote Deputy Commissioner Yiannis, transparency leads to greater accountability and incentivizes every stakeholder in the food system to do the right thing every time. Preserving a clear link between product names and composition that is provided by current SOI is essential for efficacious communication when supply chains are long and complex, involving ingredients from many sources that undergo multiple treatments at different steps.

The FCC was created by the FDA and the National Academy of Medicine and has served as a repository of public standards for food substances for more than 50 years. The FCC contains standards developed through an open, transparent process with participation from academia, industry, and government volunteers. Standard development includes an opportunity for, and consideration of, open public comment on draft standards. All comments are considered in preparing final standards.

The current edition of the FCC contains more than 1250 standards, over 200 of which are cited by reference in FDA regulations. FCC standards are used by industry and governments internationally and are explicitly recognized in the laws and regulations of many other countries. Over the past 50 years, the content of the FCC has changed in response to industry innovation such as the introduction of new types of ingredients, evolving production methods, and new analytic technologies. We have also actively participated in standard setting processes at JECFA and AOAC.

We will be submitting written comments that discuss these subjects in greater detail and look forward to an opportunity to work with FDA in using SOI to help protect the integrity of the food supply.