FDA U.S. FOOD & DRUG ADMINISTRATION

Mr. Donald Bice
Acting Deputy Assistant Secretary for Administration
Office of Budget and Program Analysis
U.S. Department of Agriculture
Jamie L. Whitten Building, Room 101-A
1400 Independence Avenue, SW
Washington, DC 20250

RE: Improving Customer Service; Request for Information (82 FR 42781; September 12, 2017)

Dear Mr. Bice:

The Food and Drug Administration (FDA or the Agency) appreciates the opportunity to provide comments to the U.S. Department of Agriculture's (USDA) Request for Information (RFI) titled "Improving Customer Service." The RFI solicits comment on several proposed USDA reorganization actions, including the move of the Codex Alimentarius program (i.e., the U.S. Codex Office) from USDA's Food Safety and Inspection Service (FSIS) to the mission area of the Under Secretary for Trade and Foreign Agricultural Affairs (U/Sec TFAA).

FDA values its longstanding partnership and collaboration with USDA in Codex activities and welcomes the opportunity to work with the U/Sec TFAA to improve coordination on trade activities involving FDA-regulated food commodities. We appreciate your request that we share our views on this matter concerning the Codex Office in comments to the public docket, and that we use that docket as a vehicle to offer constructive feedback on the proposal. The Agency shares USDA's goal of improving the efficiency, effectiveness, and accountability of the executive branch. FDA, nonetheless, has significant concerns about the proposed transfer of the U.S. Codex Office from a science-based food safety mission USDA component to a trade promotion mission USDA component, for the reasons explained below. FDA requests the opportunity to discuss its concerns and to explore other options with USDA before a final decision is reached on the proposed transfer and reorganization of the U.S. Codex Office.

Background

Codex Alimentarius (Codex) plays a critical role at the intersection of food safety and trade by developing science-based, voluntary food standards that governments may use to protect consumer health and provide a level playing field for food trade. To this end, Codex has developed hundreds of standards, guidelines, and codes of practice and has defined thousands of permitted levels of additives, contaminants, and chemical residues in foods. Many nations adopt Codex standards, guidelines, and codes into their laws and regulations to ensure food safety and

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

quality. As the Food and Agriculture Organization (FAO)-World Trade Organization (WTO) publication "Trade and Food Standards"[1] notes:

> "Trade in food is difficult to imagine without standards. Food Standards give confidence to consumers in the safety, quality and authenticity of what they eat. By setting down a common understanding on different aspects of food for consumers, producers and governments, standards enable trade to take place. If every government applies different food standards, trade is more costly, and it is more difficult to ensure that food is safe and meets consumers' expectations. …. The WTO provides a set of rules for multilateral trade, and a forum to resolve disputes and negotiate new rules. Since standards are essential for smooth trade, the WTO Agreements strongly encourage governments to harmonize their requirements based on international standards. In the area of food safety and quality, the WTO's Agreement on the Application of Sanitary and Phytosanitary Measures and WTO's Agreement on Technical Barriers to Trade rely on Codex Standards by setting these out as the benchmark for harmonization."

Codex standards have proved an important reference point for WTO's dispute settlement mechanism, benefitting from the contributions of scientific experts and specialists to ensure that the standards withstand the most rigorous scientific scrutiny.[2]

Independent Panel Opposes Reorganizing the U.S. Codex Office into the Trade Mission

In the fiscal year 2015 appropriations, Congress directed the National Academy of Public Administration (the Academy) to assess options for reorganizing USDA in light of the creation of the U/Sec TFAA. After 7 months of extensive independent research, including more than 140 interviews with USDA officials, a wide variety of external stakeholders, congressional staff, and several former USDA Secretaries and other department officials, an independent panel convened by the Academy recommended against moving the U.S. Codex Office from its current location in the FSIS food safety mission area.[3]

The Academy panel advised that "putting the U.S. Codex Office in the trade promotion mission area will increase the likelihood that health and safety regulatory decisions would be unduly influenced by trade promotion priorities, rather than protecting human, animal, and plant safety." The Academy panel also noted as follows:

> "[T]he U.S. is a leader internationally in advocating and supporting science-based trade policy. Conflating science and trade by putting them in the same mission area will, at a

---

[1] FAO-WTO, Trade and Food Standards, available at https://www.wto.org/english/res_e/booksp_e/tradefoodfao17_e.pdf.

[2] World Trade Organization, "The WTO and the FAO/WHO Codex Alimentarius," available at https://www.wto.org/english/thewto_e/coher_e/wto_codex_e.htm.

[3] National Academy of Public Administration, *Advancing U.S. Agricultural Trade: Reorganizing the U.S. Department of Agriculture*, October 2015, available at http://napawash.org/images/reports/2015/USDA_Report_2015.pdf, pp. 48-52.

minimum, affect perceptions of scientific integrity and undermine the U.S. trade positions."

FDA Endorses Independent Panel's Recommendations

While USDA oversees meat, poultry, egg products, and catfish, FDA is the regulatory authority for the vast majority of food consumed in the United States. As a science-based regulatory agency, FDA has been a strong and active participant in Codex since its inception in the early 1960s. FDA agrees with the findings of the Academy report and believes that folding U.S. Codex under trade leadership could undermine the scientific credibility of U.S. delegations and U.S. positions at Codex.

The strength of the U.S. Codex efforts rests on its scientific expertise. For example, U.S. Codex delegates have been successful in helping to establish standards that are consistent with U.S. standards in several areas, such as arsenic in rice, the Code of Hygienic Practice for Fresh Fruits and Vegetables, and specifications for identity and purity of food additives. Codex committees, when developing standards, apply risk analysis and rely on the independent scientific advice provided by expert bodies organized by the FAO/World Health Organization (WHO), including the Joint FAO/WHO Expert Committee on Food Additives, the Joint FAO/WHO Meeting on Pesticide Residues, and the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment. The Joint FAO/WHO Expert Meeting on Nutrition will soon participate in this process as well. Maintaining the U.S. Codex Office within FSIS, an organizational structure with the technical knowledge and expertise necessary to interpret data and risk assessment results, provides the best position for U.S. science-based regulatory agencies to maintain credibility and scientific integrity to promote standards that are protective of public health.

FDA strongly believes that moving Codex to the oversight of a trade promoting, non-science organization could undermine the credibility of U.S. Codex as a science-based enterprise. Transfer of the U.S. Codex Office under a trade umbrella would build a perception that the United States places a stronger priority on advancing trade over public health. This perception would be damaging to U.S. credibility, and FDA is highly concerned that this would compromise the effectiveness of U.S. delegates who participate in Codex, a majority of whom are from FDA. The utility of Codex for trade purposes depends on it being and remaining a credible source of science-based standards that protect consumers. As a point of reference, the Codex contacts for 54 member nations reside within the regulatory divisions of those nations' agriculture ministries; in addition, 72 member nations have their Codex contacts within public health or food safety agencies, 52 nations have their Codex contacts within their national standards bureaus, and 3 nations maintain Codex contacts within their international relations/state departments. Of the remaining nations, only five—Congo, Guinea, Lesotho, Madagascar, and Samoa—have their Codex oversight residing within a trade agency. Moreover, our concerns would not be remedied by the transfer of FSIS experts to the U/Sec TFAA mission, as this does not mitigate the underlying concern that the proposed transfer could undermine the credibility of the U.S. Codex science-based enterprise and create the perception that trade interests are being prioritized in a manner that marks a departure from the Codex Office's historical mission.

FDA Seeks Additional Dialogue with USDA on Options and Opportunities for Collaboration with U/Sec TFAA

FDA has worked closely with the U.S. Codex Office for decades and continues to contribute to, and invest in, the following Codex activities, among others:

- FDA provides the vast majority of delegates and/or alternate delegates for the Codex committees/task forces (i.e., 18 of 25) and provides the Chair for one committee. In Codex committees and activities, FDA scientists and technical experts work in partnership with scientists and technical experts from FSIS; USDA's Agricultural Marketing Service; USDA's Grain Inspection, Packers & Stockyards Administration; and the Environmental Protection Agency.

- FDA provides a significant proportion of the U.S. contribution to the joint FAO/WHO scientific advice/risk assessment bodies that provide scientific advice to Codex. In addition, FDA and FSIS scientists participate as experts in these bodies.

- FDA scientists and technical experts participate in outreach activities to increase understanding of the scientific basis for Codex standards amongst developing nations. The Codex outreach activities serve to develop a common understanding of the role of science, which is the foundation of consensus building in standards setting.

Activities such as these demonstrate FDA's investment in science-based decision making at Codex and in ensuring that the U.S. Codex Office and U.S. Codex delegations retain their well-deserved reputations for scientific expertise.

In recent testimony before the U.S. Senate Committee on Agriculture, Nutrition, and Forestry,[4] U/Sec TFAA nominee Ted McKinney said that non-scientific trade barriers—many of them sanitary-phytosanitary—were "perhaps the biggest challenge" to U.S. agriculture exports. Mr. McKinney criticized the politicization and rejection of some newer agricultural products and technologies and spoke of working with government scientists and trade experts to return to "science-based decision making" at Codex Alimentarius. FDA agrees that the key to optimal outcomes at Codex is to adhere to these ideals, but we believe this outcome is best achieved when the function resides in a science-based component of USDA.

In initially approaching USDA with our concerns, we appreciate very much USDA's request that we submit our comments as part of this public docket. FDA looks forward to discussing opportunities for greater collaboration with the U/Sec TFAA, such as through the U.S. Codex Policy Committee, which has representatives from both public health and trade agencies.

---

[4] Testimony of Ted McKinney, U.S. Department of Agriculture Under Secretary for Trade and Foreign Agricultural Affairs Nominee Before the United States Senate Committee on Agriculture, Nutrition, and Forestry, September 19, 2017, available at https://www.agriculture.senate.gov/imo/media/doc/Testimony_McKinney.pdf.

Representation from both the trade and public health federal agencies has allowed for a dynamic balance and open forum for the development of U.S. Codex policy.

Conclusion

- FDA requests that USDA re-consider and rescind the planned move of the U.S. Codex Office, retaining the U.S. Codex Office in its current location within FSIS.

- FDA encourages USDA continue to engage in a transparent, inclusive public process to consider how U.S. Codex activities and the U.S. Codex Office can be strengthened to ensure public health and trade interests are properly represented.

- FDA recommends that USDA explore opportunities for the new U/Sec TFAA, along with the Under Secretary for Food Safety (the historic chair of the U.S. Codex Policy Committee), to help enhance the effectiveness of the U.S. Codex office and the U.S. Codex Policy Committee, while retaining the U.S Codex Office within FSIS.

In closing, FDA strongly believes that the effectiveness of the United States in Codex rests with our ability to balance myriad interests and to demonstrate a solid basis in science for U.S. positions. Placing the U.S. Codex Office under a trade umbrella could undermine our engagement in Codex and would ultimately threaten to erode U.S. trade positions.

Thank you for consideration of these comments.

Sincerely,

Stephen Ostroff, M.D.
Deputy Commissioner for Foods and Veterinary Medicine