



Alliance for a Stronger FDA Budget Priorities Webinar Series  
Summary of Webinar with Dr. Susan Mayne, Director of CFSAN  
April 12, 2022 | Moderated by Kyle Kinner and Alison Bodor

On April 12, 2022, The Alliance for a Stronger FDA continued its FY 23 budget priorities webinar series with Dr. Susan Mayne, the Director of the Center for Food Safety and Applied Nutrition (CFSAN). During this wide-reaching event, Dr. Mayne spoke about CFSAN’s priorities under the FY 23 budget proposal, reviewed final FY 22 funding levels provided by the Consolidated Appropriations Act, focused on the importance of nutrition issues within CFSAN, and addressed supply chain challenges.

She spoke very directly about the value of providing more resources for CFSAN with 97% of funding coming from budget authority, and the challenges of what she described as a limited CFSAN staff. She also responded to criticisms of CFSAN made in a recent *Politico* article, saying she takes all criticism seriously.

CFSAN is responsible for overseeing 80% of the nation’s food supply, along with cosmetics and dietary supplements. CFSAN does not receive user fees. She said that two-thirds of CFSAN’s funding is transferred to the Office of Regulatory Affairs (ORA) for field activities.

Dr. Mayne highlighted additional funding provided as part of the final FY 22 appropriation with increases for Maternal and Infant Health and Nutrition; Emerging Chemical and Toxicology Issues New Era of Smarter Food Safety; and for Standards of Identity. She suggested these increases were a “down payment” and that the funds requested for FY 23 bridges the resource gap.

With respect to FY 23 priorities, she said nutrition is one of CFSAN’s priorities, but only 7% of the CFSAN budget. She highlighted Health Equity through Nutrition, dietary guidance, work with vulnerable populations, and nutrition labeling. She said CFSAN is advancing its partnership with sister agencies regarding the *Dietary Guidelines for Americans*. She spoke about research on the development of a healthy symbol to help consumers quickly identify healthy foods. She said toxicological and chemical work is important as the public’s attention increases as new issues emerge.

With respect to other issues, she identified work on food additives; increasing the use of recycled plastics; and reducing sodium consumption with a prediction that a 40% reduction over the next decade could save many lives and reduce health care costs by more than \$100 billion. She talked

about the Food Allergen Safety, Treatment, Education, and Research Act (FASTER Act) adding sesame as a major food allergen, with plans to update guidance documents and identify new allergens of concern. She also spoke about CBD and Hemp, needing a modernized approach to how these substances may be included in foods.

Dr. Mayne emphasized her view that there needs to be increased personnel available to work on CFSAN's issues. The FY 22 Appropriations bill allows for an increase from 9 to 13 FTEs for work on infant formula matters.

She also spoke about new authorities being sought by FDA that deal with labeling for dietary supplements and cosmetics, as well as requiring industry to conduct toxic element testing of final products marketed for consumption by infants and young children and maintain records of these testing results for FDA inspection; and provide FDA with new authority to remotely access records of these test results and to review these test results whenever necessary.

With respect to supply chain issues Dr. Mayne said the challenge is dealing with a concentrated industry with a limited number of producers, using infant formula as an example. Both the recall and the situation in Ukraine highlight, in her view, the need for requested authority to require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods.

With respect to the *Politico* report, recognizing the criticisms provided in that report, she did emphasize that the United States has one of the safest food supplies in the world. The challenge is available resources. She said the entire nutrition group has only seventy personnel. Tobacco is thirty times larger than the CFSAN nutrition budget, so there are opportunities for improvements. The regulatory authorities being sought as part of the budget request will streamline work.

She went on to say that more has been done at CSFAN in the past 7 years than at any time in history despite 4 years of deregulation and the pandemic. Some of the most important nutrition policies involving added sugars, trans fat, sodium labeling and the reduction of sodium in restaurant foods has taken place. She said that the World Health Organization has said FDA's work has been "enormously helpful." Even though CFSAN is the busiest compliance shop at FDA with personnel demonstrating a strong work ethic, more work can be done with more resources.

Dr. Mayne responded to a number of questions:

- *Impact of the pandemic on CFSAN operations* – The supply chain is global and high case counts elsewhere impact supplies. She expects challenges to continue for months if not longer. The flexibilities that have been put in place will remain as long as necessary to support the food supply. She expects a phased approach to returning to prior practices, having an on-going dialogue with industry. CFSAN will use every available resource and integrate new methods.
- *Nutrition education with partnering organizations* – Tools such as labeling are needed. FDA will leverage activities with CDC, NIH, and private industry. FDA does not have

the resources to manage an education campaign, but can work with others, particularly with a whole-of-government approach.

- *Constrained resources limiting CFSAN* – CFSAN has 1,100 people with two-thirds of resources being transferred to ORA for field activities. The budget does not correlate with CFSAN’s work. A modest budget means that they cannot always meet consumers’ expectations.
- *Did CFSAN ask for enough* – There are constraints on what can be requested. They can do more with more. People are free to advocate for more beyond the President’s budget request.
- *Impact of FSMA* – FDA is extremely far along with implementation. There have been eight major rules and more than fifty guidance documents. The food traceability rule must be out by the fall. The ability to trace foods will facilitate more rapid responses when needed. CFSAN needs to collaborate with stakeholders to be sure the rules are feasible.
- *Baby Food* – CFSAN has been looking at toxic elements in baby food for an exceptionally long time. The exposure to toxic elements has been reduced dramatically, some of which is due to FDA action. She spoke about inorganic arsenic in rice cereal, the need to work on cadmium. She could not comment on a question about the Abbott recall since it is still an open investigation.
- *Asking Congress for new hiring authorities* – While CFSAN has had a very low attrition rate, there is a need for new staff with advanced skills in a new generation of scientists. CFSAN would benefit from the hiring authorities given for medical products in 2016. CFSAN is starting to have personnel return to its facility from remote work but knows they must remain flexible. Flexibilities enable hiring.
- *Technology to transform CFSAN* – Machine learning and artificial intelligence will get more “bang for the buck.” There is a need for understanding what happens with food borne outbreaks. Using analytics and modeling, e.g., experiences with leafy greens, shows how improvements can be made. On the chemical side there is a need to be sure that chemicals approved under GRAS continue to remain safe. There is a desire to expand the decision tree to prioritize concerns.