

June 6, 2019

Dear State Agriculture Commissioners, Secretaries, and Directors:

It is a pleasure to be writing to you today. As many of you know, I was brought into the FDA fold in late 2018 by Dr. Scott Gottlieb, and he passed the baton to me to keep you informed about the status of work we are doing together to protect the American food supply, particularly our work on the FDA Food Safety Modernization Act (FSMA).

This is a role I am happy to step into because, even in the short time that I have been FDA's Deputy Commissioner for Food Policy and Response, the importance of FDA's partnership with the National Association of State Departments of Agriculture (NASDA) has been crystal clear.

FDA's Acting Commissioner, Dr. Ned Sharpless, also recognizes the importance of NASDA's partnership. Dr. Sharpless has a strong interest in food safety and is committed to working with you on matters of shared responsibility.

I know many of you because in 30 years of a private-sector career in food safety, much of the work I've done has been with state public health officials. I have seen first-hand the importance of state-level actions to keep Americans safe from contaminated foods.

Before I update you on new policy and FSMA implementation developments since Dr. Gottlieb's February letter, I would like to describe what you can expect from our new Office of Food Policy and Response.

THE OFFICE OF FOOD POLICY AND RESPONSE (OFPR)

The Office of the Commissioner was reorganized at the end of March to more directly support the work of the Centers and the Office for Regulatory Affairs (ORA). The Office of Foods and Veterinary Medicine has been restructured and refocused as the Office of Food Policy and Response.

OFPR was created to fulfill FDA's commitments to implement a modernized approach to food safety for both domestically produced and imported foods. OFPR will focus on cross-Center collaboration to advance important food policies, specifically those regarding food safety.

In leading OFPR, I have assumed a critical set of charges related to food safety, first and foremost leading the continued implementation of FSMA. In this role, OFPR will work in close collaboration with the leadership of Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), and the food components of ORA. Additionally, OFPR will help lead and coordinate certain cross-cutting and/or high-priority food safety policy activities, focusing predominantly on human food safety activities. Issues such as the Nutrition Innovation Strategy and animal safety concerns will be handled by CFSAN and CVM.

We will have opportunities to talk more about this new office and the areas in which we will be leading some new program-wide initiatives. For example, Dr. Sharpless and I recently issued a statement announcing that we are developing a [“New Era of Smarter Food Safety Blueprint”](#) to outline how we will build on our efforts to implement important FSMA requirements while also leveraging, among other things, the use of new and emerging technologies to create a more digital, traceable, and safer food system. We will also be holding a public meeting on this topic later this year. We hope that you will be able to participate in this meeting and bring your ideas on how we can collectively address topics, including enhancing traceability, harnessing the capabilities of digital technologies, and preparing our systems for evolving food business models.

IMPLEMENTATION PREPAREDNESS

- Produce Safety

Routine inspections to help ensure compliance with the Produce Safety Rule have begun this spring for covered farms other than sprouts operations. As you know, states will conduct the majority of these inspections under their cooperative agreements with FDA. We applaud the work that so many have done to get us to this point, and at FDA, we are eager to continue hearing from the states on how inspections are going. We want to be an active partner in addressing any new challenges that are discovered as we implement this new program.

Thousands of farmers have been trained on the rule’s requirements through the Produce Safety Alliance and FDA’s other collaborative training partners. Hundreds of domestic, foreign and territorial farms have participated in voluntary On-Farm Readiness Reviews developed by NASDA in collaboration with FDA. Even as inspections begin, our outreach and technical assistance efforts will continue.

Our [Produce Safety Inspections page](#) offers more information, including related documents and information on training and technical assistance. In addition, we continue to look for ways to make the FSMA rules the best they can be for both consumers and stakeholders, including the following recent actions:

- [Issuance of final rule to extend compliance dates for the agricultural water provisions for produce covered by the Produce Safety Rule other than sprouts.](#)
- [Intent to exercise enforcement discretion for the Produce Safety Rule requirements as they apply to entities growing, harvesting, packing and holding wine grapes, hops, pulse crops and almonds.](#)

Our work also continues on the agricultural water provisions in anticipation of the new compliance dates.

- Imported Food Safety Strategy

On February 25, we released the [“FDA Strategy for the Safety of Imported Foods.”](#) Food

imported from abroad is held to the same standards as food produced domestically, and this strategy describes how FDA is integrating our new import oversight tools with existing tools as part of a comprehensive approach to imported food safety.

The Foreign Supplier Verification Program under FSMA is a powerful tool in our import toolkit that helps to provide parity of oversight between domestic and foreign processors. We began inspecting importers of processed foods under FSVP in June 2017 and have conducted more than 1,000 inspections to date. We intend to begin routine FSVP inspections of produce importers this fall. Foreign inspections of large farms covered by the Produce Safety Rule have already begun.

OTHER AGRICULTURE ISSUES

- Leafy Greens

I arrived at FDA in the middle of an outbreak of *E. coli* O157:H7 tied to the consumption of romaine lettuce, the second such outbreak last year. These two outbreaks drive home the importance of our produce safety mission. The outbreak that began in Spring 2018 resulted in 210 illnesses in 36 states and five deaths. The second, in Fall 2018, made 62 people sick in 16 states and the District of Columbia.

[Our investigation highlighted the need for better traceability and source labeling.](#) For this reason, we participated in discussions with industry that led to voluntary product labeling and dating to identify the origin of the romaine based on harvest region. FDA has also strongly encouraged the leafy greens industry to adopt best practices for real-time, farm-to-fork traceability to assure quick and easy access to key data when leafy greens are involved in a potential recall or outbreak.

In addition, we are working to enhance the safety of leafy greens in a number of ways.

- FDA is working with the produce industry's Romaine Task Force -- a collaboration of growers, industry, trade associations, advocacy groups, academia, and regulatory officials – to identify steps to minimize the risks of pathogen contamination.
- We collected romaine lettuce samples at commercial coolers in the Yuma, Arizona, and Imperial Valley, California, growing regions through April 2019. A total of 120 samples were collected, with each sample containing 10 subsets for a total of 1,200 assays. No strains of pathogenic *E. coli* or *Salmonella* of public health significance were found in the samples, and we are working expeditiously to finalize and make public the findings of this sampling assignment.
- We are preparing to collaborate with the University of Arizona and the Yuma leafy greens industry on a multi-year study focused on the environment in the Yuma agricultural region. The goal is to identify potential risks in the environment and develop possible mitigation strategies.

- CBD

As you also know, there is a growing interest in products made from cannabis. We have a cross-agency working group within FDA that works on cannabis issues, including policy, enforcement, outreach, and interagency coordination. This group continues to evaluate new information and the ever-changing landscape around this issue.

The Agriculture Improvement Act of 2018, which was signed into law in December, removed hemp -- defined as cannabis and cannabis derivatives with extremely low concentrations of the psychoactive compound THC -- from the definition of marijuana under the Controlled Substances Act. However, the bill specifically preserved FDA's authorities to regulate products containing cannabis or cannabis-derived compounds. What that means is that cannabis and cannabis-derived products are subject to the same authorities and requirements as FDA-regulated products containing any other substance.

In the foods area, it remains unlawful under the Federal Food, Drug and Cosmetic Act (FD&C Act) to add cannabidiol, also known as CBD, or the psychoactive compound THC to foods, or to market CBD or THC products as dietary supplements, because these substances are active ingredients in FDA-approved drugs and the subject of substantial clinical investigations that have been made public.

We are taking new steps to evaluate whether we should pursue establishing a regulatory framework to allow some such products to be lawfully marketed. We would only consider doing so if we were able to determine that all other requirements in the FD&C Act are met, including those required for food additives or new dietary ingredients.

[We held a public hearing on May 31 for stakeholders to share their experiences and challenges with these products, including information and views related to safety](#), and a docket remains open until July 2 for additional stakeholder input.

And we have developed a web page entitled "[FDA Regulation of Cannabis and Cannabis-Derived Products](#)" that goes into greater detail about the legal provisions mentioned above and many other issues surrounding FDA's regulation of these products.

- Animal Cell Culture for Food Production

This technology is gaining interest among food companies that see potential for using cell culture to grow animal tissues for food. We recognize that our stakeholders want clarity on how we will move forward with a regulatory regime to ensure the safety and proper labeling of these cell-cultured food products while continuing to encourage innovation.

That is why FDA and USDA's Food Safety and Inspection Service on March 7 announced a [formal agreement to jointly oversee the production of human food products derived from the cells of livestock and poultry](#).

Collaboration between USDA and FDA will allow us to draw upon the unique expertise of each agency in addressing the many important technical and regulatory considerations. Workgroups with representatives of both agencies will focus on key aspects of implementing the formal agreement.

NUTRITION

- Standards of Identity

Our Center for Food Safety and Applied Nutrition is leading the [Nutrition Innovation Strategy](#) for the Agency, and in doing so, it continues its work on modernizing standards of identity and addressing naming issues for certain products. FDA wants to make sure that food standards are not barriers to product innovation while also ensuring that foods meet consumer expectations.

As part of that commitment, we are considering approaches that could provide flexibility across multiple standards, as well as continuing our work to modernize certain standards, such as the standard of identity for yogurt, which we announced in the [Spring Unified Agenda](#). To guide our overall approach, we are planning a public meeting to discuss approaches to modernizing standards of identity for this fall. Additional information will be forthcoming.

We are studying the use of dairy food names like “milk,” “cheese,” or “yogurt” in the labeling of plant-based foods and beverages marketed as dairy alternatives. Last fall, FDA issued a “request for information” to solicit feedback from our stakeholders and the comment period for that request ended in late January. CFSAN is currently reviewing the thousands of comments received to inform how we may move forward to clarify such labeling.

I’m looking forward to our continued work together and am looking forward to our meeting with NASDA’s Food Regulations Committee in June. FDA is committed to continuing the progress we have made together in recent years to share information and jointly address the challenges and opportunities we see for strengthening food safety.

Sincerely,

A handwritten signature in black ink, appearing to read 'F. Yiannas', with a long horizontal line extending to the right.

Frank Yiannas
Deputy Commissioner
Food Policy and Response