



SAFE FOOD COALITION

Dear Dr. Woodcock,

The undersigned organizations, representing the food industry, consumers, and state and local food safety regulators, write to express our support for FDA's compliance with the Food Safety Modernization Act (FSMA) domestic inspection frequency mandates, and to propose a collaborative approach to addressing the inspection challenges and opportunities outlined in your recent report "Resiliency Roadmap for FDA Inspectional Oversight" (hereafter "Inspection Roadmap").

This year marks the 10th anniversary of FSMA's enactment. The regulatory framework is largely in place, but your Inspection Roadmap report is a reminder that much work remains to achieve a modernized inspection program – one that makes the best use of all available resources and fulfills the law's vision of risk-based prevention, comprehensive accountability, and consumer confidence in the safety of the food supply. We propose that FDA build on its Inspection Roadmap and New Era initiatives by leading a stakeholder engagement process to explore ways to meet the domestic inspection frequency mandates in FSMA and better protect public health through modernizing inspections. The undersigned stakeholders specifically request a seat at the table to discuss inspection modernization with FDA and how to most effectively leverage technology and state regulatory resources.

The **Consumer Brands Association** (Consumer Brands) champions the industry whose products Americans depend on every day, representing more than 1,700 iconic brands. From household and personal care to food and beverage products, the consumer-packaged goods industry plays a vital role in powering the U.S. economy, contributing \$2 trillion to the U.S. GDP, and supporting more than 20 million American jobs. Consumer Brands advocates for smart, uniform regulatory frameworks that are risk-based, founded on the most current science and that promote choice and build consumer trust across the sectors we represent. We also support modernized regulatory oversight approaches that ensure the production of safe products while facilitating the efficient and effective use of both regulatory and industry resources.

The Safe Food Coalition (SFC) brings together consumer, public health, and labor organizations to advocate for improvements to the food safety system. Coordinated by Consumer Federation of America, the Coalition has played a pivotal role in ushering in changes to the food inspection systems at USDA and FDA since 1986.

The Association of Food and Drug Officials (AFDO) was formed in 1896 as a forum for education, discussion, debate, and problem resolution among local, state and federal regulatory officials. The organization's historic motto "Uniformity through Cooperation and Communication," has fostered open debate, discussion, problem-solving and consensus-building

among state, local and federal regulatory programs. AFDO is currently engaged with the Partnership for Food Protection, Seafood HACCP Alliance (SHA), Food Safety Preventive Controls Alliance (FSPCA), Produce Safety Alliance (PSA), and in collaborative efforts to advance development of a nationally integrated food safety system, including assisting FDA in meeting the mandates of FSMA.

We all embrace the goals of reducing foodborne illness and strengthening consumer confidence in the safety of the American food supply. We also share a deep and abiding commitment to the successful implementation of FSMA, which provides the legal and regulatory framework for achieving these goals.

We understand how challenging COVID-19 has been for all of FDA's inspection activities, including the FSMA-mandated food safety inspections. We admire the dedication of FDA's leadership and field staff to do the best they can under very difficult circumstances. We also applaud FDA's innovative approaches to providing oversight of food facilities during the pandemic and the focus on inspection modernization in "New Era of Smarter Food Safety – FDA's Blueprint for the Future."

We are concerned, however, by FDA's suggestion in the Inspection Roadmap document that Congress should revisit and possibly modify or repeal the FSMA inspection frequency mandate for domestic food facilities.¹ We support having a risk-based inspection strategy, but we see no conflict between such a strategy and the FSMA domestic inspection mandate, which establishes a baseline frequency of domestic facility inspection and gives FDA broad discretion to tier inspections based on the agency's assessment of risk. Indeed, we see the inspection mandate as a critical component of managing foodborne illness risk, and for that reason, oppose weakening this important provision of FSMA.

Further, the FSMA frequencies are *minimum* inspection frequencies, not mere goals and not ceilings. They must be treated as such. ORA has been reducing the number of inspections under contract with many States routinely over the last several years. We believe this is the wrong approach, as States provide additional inspection capacity and often can do inspections at a lower cost. FDA should leverage States that can perform FDA-audited equivalent inspections and expand the FDA workforce in those areas where states do not have the needed capacity. It is important for State personnel to be appropriately trained as a prerequisite to conducting inspections under FDA contracts and that FDA provide oversight to ensure consistent, quality inspections are conducted by State contractors. With better work planning and inventory coordination between the FDA and state agencies, FDA and the states can ensure that FDA is not only meeting but exceeding the domestic inspectional frequency mandates of FSMA. To that end, the FDA-supported Partnership for Food Protection's vision of "mutual reliance for a safer food supply" provides a sound framework for a truly integrated national food safety system.

¹ Inspection Roadmap at 11 ("FDA is ready to work with Congress on changes that would allow the agency to conduct inspections of human and animal food facilities at a more risk-based frequency determined by a data-driven, analytical approach to deploying available resources. In the agency's experience, such an approach would result in inspectional resources going to where they can optimize public health impacts.")

In considering inspection modernization, it is important to recall that the frequency mandates served as a cornerstone to the agreements that led to the enactment of FSMA. In addition to serving the goal of risk-based prevention of illness, these mandates were intended to be a basic element of accountability for FDA to maintain an adequate inspection program and for the food industry to comply with FSMA's new requirements. These mandates also provide an assurance to consumers that there will be at least some direct oversight of facilities that produce and handle food. If FDA lacks the resources to fulfill the FSMA domestic inspection frequency mandate, we urge the agency and the administration to request the necessary funds from Congress – a request that we will strongly support.

As a first step toward a collaborative approach to food inspection modernization, we urge FDA to engage in dialogue with us and other stakeholders to improve understanding of the data and analysis underlying the Inspection Roadmap report. We acknowledge that changes may be warranted for FSMA's foreign inspection mandate, which previous administrations and Congress have not adequately funded, and which FDA has never come close to meeting. Like domestic food facility inspections, foreign inspections are important, and should be more frequent than they are today. However, they are one of several tools that FDA has for verifying compliance of foreign firms with the requirements of FSMA.

In summary, FDA's food inspection program serves a vital role in protecting consumers from foodborne illness and supporting confidence in the food supply. We are eager to collaborate with FDA in a process to modernize and support the program for future success. We encourage FDA to engage with its stakeholders, including the signatories to this letter, as it considers inspection and compliance modernization going forward.



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