

Statement by

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**Before the Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies
Committee on Appropriations, U.S. Senate**

Chair Baldwin, Ranking Member Hoeven, and Members of the Subcommittee, thank you for the opportunity to appear before you today to discuss FDA's Foods Program.

The ongoing situation with infant formula has brought needed attention to the critical nature of our food safety and nutrition work. I look forward to discussing the long-term efforts the Agency is making within the program to try to keep pace with the massive transformations that have occurred over the last two decades in the industries that this program regulates, and the even more dramatic changes we foresee happening across the food industry in the years ahead.

FDA's Foods Program regulates approximately 80% of foods consumed by Americans, including those bought in grocery stores, restaurants, and cafeterias, as well food consumed in other venues, such as on airlines. While much of our discussion today will focus on food safety work, which includes mitigating the risk of potential exposure to a wide variety of hazards such as microbial, certain chemicals, toxic elements, and allergens, the program also drives public health policy and education work to improve the nutrition of all Americans and reduce the burden of diet-related chronic disease. With the exception of products regulated by the U.S. Department of Agriculture, such as meat, poultry, and pork, FDA's Foods Program regulates nearly all of the nation's food supply, including all of the ingredients used in foods and all of the

substances that come in contact with those foods throughout the production cycle, from the farmers' fields through harvest, processing, manufacture, distribution, packaging, and delivery to the consumer. Additionally, the program regulates animal foods for all species of animals including animals kept in zoos and exhibits, the pets that are part of most American families, and the animals that make or will become human food and other products like leather and fiber. Further, the Foods Program regulates cosmetics, dietary supplements, and, as we are all acutely aware, infant formula and medical foods industries.

Regulating this volume and diversity of products and facilities, as well as addressing the diversity of hazards that can enter the food supply, is an immense undertaking with serious consequences for American consumers when the regulated entities fail to control the hazards that could impact the safety of their products.

In a perfect world, consumers would not need to know how the safety of these industries is secured – they would correctly assume that the products they purchase will not harm them or their loved ones. Millions of products are purchased and safely consumed every day, evidence of the robustness of our food safety system, which includes an industry shift to a prevention-oriented framework and the dedication and diligence of the public servants tirelessly working in FDA's Foods Program from our entry level employees on up through the leaders who accompany me today.

While food contamination and recall events capture the headlines, a far greater threat to public health is the morbidity resulting from American dietary and nutritional trends. Our Center for Food Safety and Applied Nutrition (CFSAN) takes a leading role in federal efforts to drive reformulation of foods to cut back on sodium and *trans*-fat, promote transparency in labeling, and allow consumers to make informed dietary choices. The results of this work go largely unseen, only becoming evident through health data over generations, yet this is one of the most critical and resource intensive public health efforts across government because of the potential to impact every American.

The Foods Program is not without challenges. Some, like the rapid pace of change and the breadth of the work, are inherent in our mission. Others, like hiring and retention, organizational structure, and the lack of authority to access some essential information, can be more readily tackled. I appreciate your partnership in identifying and implementing lasting solutions.

I. FSMA

Today's global food system depends on an increasingly complex and fluid supply chain, which cannot be adequately regulated by a surveillance and response framework alone. To address this, the FDA Food Safety Modernization Act (FSMA) of 2011 transformed FDA's food safety program and, in turn, the Nation's food safety system. FSMA instituted a preventive model for protecting food safety to replace the responsive model that previously prevailed.

With the support of Congress, FDA has made significant progress in implementing the landmark law and modernizing our food safety capabilities by promulgating and largely implementing eight "foundational rules," including preventive controls for human and animal food, produce safety, foreign supplier verification for importers, intentional adulteration, and sanitary transportation. To facilitate the food industry's shift to a prevention-oriented safety and compliance paradigm, FDA has also published more than 50 draft and final guidances. As the food industry continues to change, implementing FSMA will be an ongoing process. As such, we have staff continuing the work needed to further implement FSMA through additional rulemakings (such as for food traceability recordkeeping requirements), guidance development, training, inspections, and other activities.

As with any complex, scientific undertaking, FSMA rulemakings require research, analysis of data, and, in certain cases, engagement with the scientific community to inform decision-making and adjustments when new science emerges. Stakeholder input also is essential to ensure that requirements we promulgate are feasible.

For example, in late 2021, FDA proposed new requirements for pre-harvest agricultural water for covered produce other than sprouts. The new proposal takes a comprehensive, systems-based approach to identifying and addressing hazards in pre-harvest agricultural water that we believe, when implemented, will be a game-changer for public health protection. FDA issued this proposal after stakeholder concerns were raised about the complexity and practical implementation of the pre-harvest agricultural water testing requirements in the 2015 Produce Safety Rule. These concerns led the Agency to pursue a rigorous and thorough process for engaging with stakeholders. FDA experts participated in hundreds of farm visits, listening sessions and meetings with industry, consumer groups, academia, and regulatory partners to better understand the diversity of uses of agricultural water. The Agency believes this was time well spent to ensure that the proposed approach is feasible while also being protective of public

health, deeply rooted in the most current science, and adaptable to future advancements in agricultural water quality science.

Among the highest FSMA-related priorities is finalizing a rule on food traceability, including the food traceability list, which outlines foods for which additional recordkeeping requirements will apply, to help FDA rapidly and effectively identify recipients of foods to prevent or mitigate foodborne illness outbreaks.

Additionally, FDA is continuing to implement the Laboratory Accreditation for Analysis of Foods Rule. The portal for Accreditation Bodies to apply to participate in the program opened in February 2022, and 6 entities have been approved to date. Implementation of the Preventive Controls for Animal Food rule is also continuing. This rule has faced challenges because in some cases the animal food industry and our state, local, and tribal regulatory partners lack the infrastructure and expertise needed to meet and monitor compliance with FSMA requirements, and the resources dedicated to this sector lag behind those for human food.

II. New Era of Smarter Food Safety

FDA is committed to building on the work of FSMA while taking a modernized approach to food safety that leverages technology and other tools to create a safer and more digital, traceable food system. This approach, which we call the New Era of Smarter Food Safety, aims to bend the curve of foodborne illness in this country by reducing the number of illnesses attributed to FDA-regulated foods.

We are in the midst of a food revolution—including how foods are produced, delivered, and handled. Many of the changes which were already underway have been accelerated by the pandemic as we acclimate to a new normal in all aspects of life. Through the New Era initiative, we are identifying technologies, data streams, and approaches that will greatly reduce the time it takes to trace the origin of a contaminated human or animal food.

In July 2020, we published the New Era for Smarter Food Safety blueprint, which identified four Core Elements that we see as critical to this work. These include:

- **Tech-Enabled Traceability:** technologies, data streams, and approaches that will greatly reduce the time it takes to trace the origin of a human or animal food of public health concern.

- Smarter Tools and Approaches for Prevention and Outbreak Response: adapting and incorporating new data, information, and approaches to respond to outbreaks and prevent them from happening again.
- New Business Models and Retail Modernization: advancing the safety of food produced and sold by both new and traditional business models for retail food safety.
- Food Safety Culture: strengthening FDA’s approach to recognizing the critical importance of food safety culture and behavioral change in the Agency’s work processes, promoting food safety culture throughout the food system, and developing smarter food safety consumer education.

Together, these Core Elements will enable the change necessary for FDA and the entire food industry to adapt to the future. We have had a number of recent accomplishments in this area, including publishing a Foodborne Outbreak Response Improvement Plan, working toward finalization of the proposed Food Traceability Rule, completing the second phase of an artificial intelligence/machine learning pilot to enhance the Agency’s ability to quickly and efficiently identify imported seafood products that may pose a threat to public health, signing five domestic mutual reliance agreements with California, Florida, Utah, Wisconsin, and Minnesota which enhance FDA’s use of state agencies to strengthen oversight of the food supply, and holding a three-day e-commerce summit to help the Agency improve its understanding of how human and animal foods are sold through business-to-consumer e-commerce models across the U.S. and globally.

I thank the Committee for its commitment to food safety by providing us funds in recent years to support our New Era of Smarter Food Safety initiative. In FY 2023, we plan to take our efforts modernizing America’s food safety regulatory framework to another level and are requesting a total of \$43 million across the Foods Program. In a rapidly changing world, this funding will allow the Agency to continue to leverage new and emerging technologies, enhance implementation of traceability, and adapt oversight to new production and business models. This is work that will have an immediate impact on food safety in this country while also preparing the Agency to be more adaptable to changes across the food system in the future.

III. Challenges

As I have explained, the food system has been growing ever more complex and is undergoing rapid change unlike anything seen in a century. This growth has created new challenges in both keeping up with and attempting to get ahead of industry innovation. Unfortunately, we have found that there are barriers which make it difficult to keep pace.

For example, on-site food facility inspections remain an important oversight tool for FDA. However, given the very large number of foreign and domestic food facilities to be inspected, and the level of existing FDA resources for this work, fully meeting the FSMA requirement to inspect all domestic facilities at least once every five years—every three years for high-risk facilities—has sometimes been unattainable since the requirement went into effect in 2011. As a result, we are exploring the use of other tools to enhance our oversight. This includes use of new data streams, technologies, and tools to better prioritize oversight activities and respond nimbly to newly identified or changing risks. While in-person inspections will remain the foundation of our oversight of these facilities, authorities around remote regulatory assessments as requested by the Administration would also greatly assist in our ability to more efficiently evaluate food facilities.

Hiring and retaining Foods Program staff has long been a challenge. Many state and local health and agriculture departments across the nation express concern about the food safety system's decades-long shortage of qualified personnel. In FDA's Office of Regulatory Affairs, direct-hire authority proved very helpful in making strides towards closing the hiring gap in its investigative and compliance staff, but this authority expired in October 2021 and ORA, along with other offices within the Agency including CFSAN, the Office of Food Policy and Response, and the foods-related portions of the Center for Veterinary Medicine continue to have great difficulty recruiting and hiring critical experts with the agility and speed needed to rival the private sector without similar authorities granted to the medical products centers under the 21st Century Cures Act. Our Foods Program's need for mission-critical skill sets and keeping up with the pace of industry innovation is no less critical than the Medical Products Program, which has hiring authorities under the 21st Century Cures Act. We believe the hiring flexibilities provided in the user fee reauthorization bill will give FDA agile and competitive hiring tools in the foods program to get the right staff we need and to get them quickly.

Failures of the supply chain throughout the pandemic, and particularly the recent crisis, have shown the importance of new additional authorities to anticipate and respond to supply shortages, particularly for infant formula and medical foods. No law requires manufacturers of these products to notify FDA when they become aware of a circumstance that could lead to a shortage of these products. Without this information, the Agency may have little or no insight as to when a major shortage may occur, preventing us from taking potential mitigation efforts until a crisis becomes apparent. This is why early in the pandemic (March 2020) we began work on a legislative proposal seeking authority to require firms producing infant formula and medical foods to notify FDA of anticipated significant interruptions in the supply. The proposal has appeared in the FY 22 and FY 23 budgets and would ensure that FDA routinely receives timely and accurate information about likely or confirmed shortages and can take steps to promote the continued availability of these essential foods. The proposal also provides for infant formula and medical food manufacturers to develop and make available to FDA supply redundancy/risk management plans. In addition, we are seeking authority to require firms to provide shortage notification for other FDA-designated categories of food during a declared public health emergency. In future situations where supply chain disruptions are likely, this would help address some of the shortage issues like those we witnessed early in the pandemic and are currently witnessing in the wake of the Abbott Nutrition recall.

Although we greatly appreciate the Committee's work to fund our foods safety work, it is important to understand that our resources in this area have not kept up with inflation and the growing and ever-changing foods industry. Prior to passage of the first Prescription Drug User Fee Act in 1992, our Center for Drug Evaluation and Research (CDER) and CFSAN were comparably sized. Now, CDER is approximately five times the size of CFSAN, which receives 97 percent of its funding through budget authority. This amounts to only about six percent of the Agency's total budget and has prevented the center from performing the food safety and nutrition work that Americans expect. This is a long-term challenge and our budget request this year is intended to begin the process of closing the capability gap.

As products, manufacturing processes, and supply chains have become increasingly complex, the potential for hazards to impact the safety of these products has multiplied. FDA is continually examining the industry and our existing policies and practices to anticipate and adapt

to the changing landscape and still strike the right balance between regulatory oversight and affordable, available products.

FDA has been seeking to make gains in balancing the ongoing efforts of providing safe food with a renewed emphasis on encouraging the increased availability in the marketplace of healthy food options. To meet this goal, FDA needs better data, tools, and greater capacity to generate and analyze real-time information on the food supply's evolving composition.

Leveraging foundational data and building these tools and capacity would enable FDA to better understand and address population exposure to various food components—both those that are helping consumers reduce their risk to diet-related chronic disease and also those that may be leading to exposures that have chronic health risks. In that regard, reducing people's exposure to chemicals known to be harmful in foods to the greatest extent possible is essential to protecting long-term human health and ensuring consumer confidence in the safety of the foods they eat.

We recognize that our pre-market programs are challenged to keep pace with increasing innovation by industry and advances in science, and our post-market oversight and our capacity to mitigate risk due to chemical hazards across our products have been especially under-resourced and falling behind in their ability to keep pace with increasing numbers of signals of possible concerns about chemical hazards in foods. We are working to modernize and streamline our regulatory frameworks, including by acquiring new tools that leverage new and evolving toxicity data sources to support pre-market safety evaluations and to prioritize our post-market efforts in a scientific and risk-based way.

Finally, the Office of the Commissioner is actively evaluating changes to ensure the foods program is best organized, resourced, and has the right authorities and modern data systems to be effective for the next decade of challenges in food policy, systems, and regulation. An optimal foods program organization must take into account that FDA's product areas and centers are not silos, but a matrix of interdependent information and operations encompassing product and regulatory organizations and enterprise-wide support organizations. I look forward to continuing the conversation beyond today as my evaluation wraps up.

IV. Conclusion

We are in an unprecedented time; our food has never been safer, yet the challenges remain significant, and we strive to do better. We must remain vigilant and adaptable. We look forward to working with you to continue to ensure Americans' access to safe, nutritious food.