

# **OPERATIONAL EVALUATION OF THE FDA HUMAN FOODS PROGRAM**

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December 2022



December 6, 2022

Dear Commissioner Califf,

We, the undersigned, thank you for the opportunity to conduct this independent evaluation of the U.S. Food and Drug Administration's Human Foods Program. We are honored to have been selected for this important task and have worked diligently to review FDA's Human Foods Program culture, structure and leadership, resources, and authorities. We are pleased to provide you our findings, recommendations for your consideration, and rationale as you seek to further strengthen the FDA's Human Foods Program.

We have approached this project with a neutral lens, synthesizing perspectives from a wide array of stakeholders (inside and outside of government). We have applied our own expertise and analysis and kept in mind best management practices. Our aim is to offer both our findings and our recommendations in the most constructive way possible with respect for, and confidence in, the FDA's Human Foods Program's future. We are aware that some of our recommendations will no doubt take time and effort for their benefit to be realized, but we believe that, if implemented, a stronger FDA Human Foods Program will be equipped to greatly benefit the health of the public.

We publicly acknowledge that our work was made possible by the cooperation, insights, and valuable contributions of many external stakeholders, as well as current and former FDA staff who provided comments. We thank them for their time, commitment, and thoughtful insights that benefitted our efforts. Finally, we express our gratitude to the Reagan-Udall Foundation for the FDA and its dedicated staff and Board and to Food Directions for their dedication and hard work in assisting with this project.

We hope these recommendations will be beneficial for your enhancement plans and an additional stimulus for programmatic and operational improvements at FDA.

Sincerely,

Jane E. Henney, MD, Panel Chair

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James Jones

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# Table of Contents

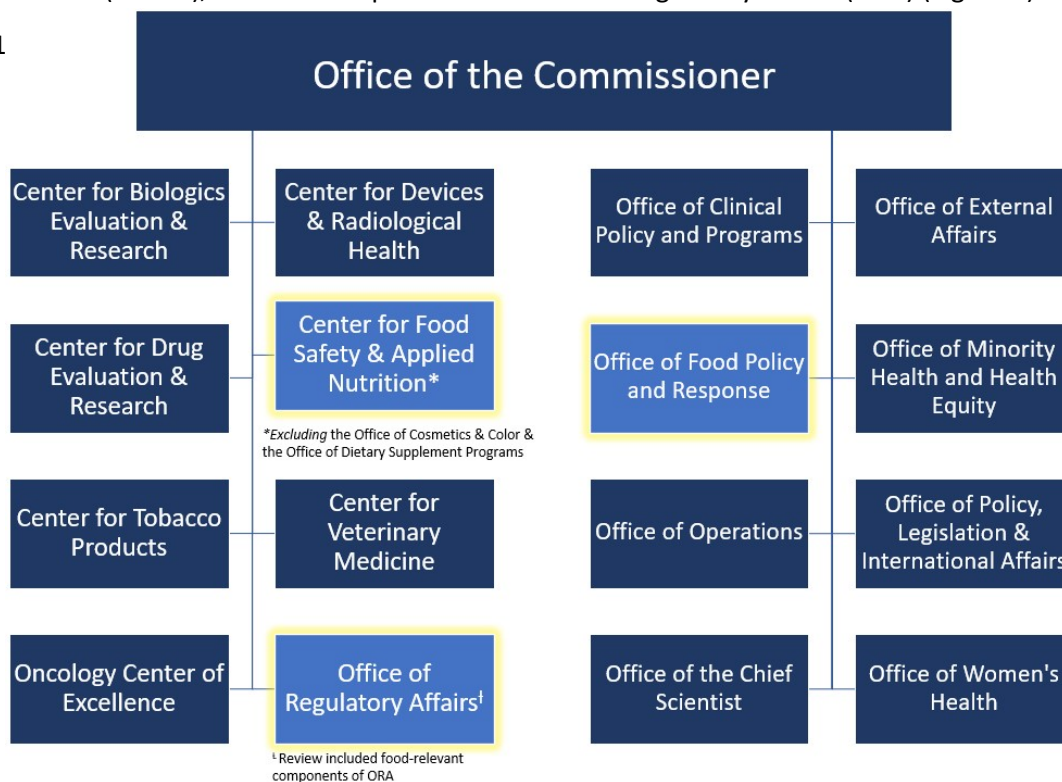
Introduction .....	3
Public Health Impact .....	4
U.S. Food Industry.....	6
Brief History of FDA’s Human Foods Program .....	7
FDA Human Foods Primary Functions .....	8
Attributes of an Agile and Effective Regulator .....	9
Expectations of an Effective Food Regulatory Agency .....	9
Culture .....	11
Recommendations .....	15
Structure .....	17
Recommendations .....	18
Resources .....	26
Recommendations .....	29
Authorities .....	33
Recommendations .....	33
Conclusion.....	38
Appendices.....	39
Appendix A.....	39
Appendix B .....	41
Appendix C .....	43
Appendix D.....	45
Appendix E .....	48

## Introduction

In July 2022, U.S. Food and Drug Administration Commissioner Robert Califf requested that the Reagan-Udall Foundation<sup>1</sup> convene an Independent Expert Panel to conduct a comprehensive evaluation of the FDA Human Foods Program with the aim of strengthening FDA’s food regulatory role. While affirming that Americans generally have access to safe and nutritious foods, Dr. Califf acknowledged that the Agency has “confronted a series of challenges that have tested our regulatory frameworks and stressed the agency’s operations, prompting me to take a closer look at how we do business.” He readily admitted FDA operations “are challenged by our nation’s endlessly complex food systems and supply chain”. Recognizing the urgency of the situation, the Commissioner requested the evaluation be completed within 60 business days.

An Independent Expert Panel (Panel)<sup>2</sup> was convened to evaluate<sup>3</sup> the FDA Human Foods Program and provide recommendations to the Agency in four primary domains: culture, structure and leadership, resources, and authorities. The review and recommendations are meant to help FDA make changes to better carry out its regulatory responsibilities; strengthen its relationships with state, local, tribal, territorial (collectively SLTT), and international governments; and support an abundant, nutritious, safe, and sustainable food supply for the future. For purposes of this evaluation, the Commissioner’s requested scope included the Office of Food Policy and Response (OFPR), the Center for Food Safety and Applied Nutrition (CFSAN), and relevant parts of the Office of Regulatory Affairs (ORA) (Figure 1).

Figure 1



<sup>1</sup> The Reagan-Udall Foundation for the FDA is an independent 501(c)(3) organization created by Congress to advance the mission of the Agency.

<sup>2</sup> Panel Members presented in Appendix 1.

<sup>3</sup> Evaluation methodology presented in Appendix 2.

While this report may reference other components of FDA, the requested scope specifically excluded the Center for Veterinary Medicine (CVM)<sup>4</sup> and two other components of CFSAN: cosmetics and dietary supplements. The Panel is comprised of researchers, former regulators, and process improvement specialists with disciplinary expertise and experience in epidemiology, public health, food science, food safety, microbiology, nutrition, and regulatory operations.

Food and nutrition-related risks affect everyone. FDA is responsible for overseeing the safety of 78% of the U.S. human food supply<sup>5</sup> and all animal feed, in addition to promoting good nutrition. FDA has a broad food safety mandate, including developing and overseeing the enforcement of food safety regulations; detecting and responding to outbreaks of foodborne illness; collaborating with other federal agencies conducting food safety activities; coordinating and supporting state, local, tribal, and territorial food safety activities; conducting and supporting food safety research; and developing and disseminating food safety information to stakeholders. FDA's nutrition mandate is equally important (albeit somewhat less specific) and includes promoting national dietary guidelines through regulations and voluntary guidance documents; collaborating with other federal agencies; conducting nutrition education activities; ensuring the safety of processed food ingredients and that they are used at appropriately safe levels; and overseeing nutrition labeling of most foods.

Never has the role of FDA in food oversight been so important and complex. Passage and implementation of the FDA Food Safety Modernization Act (FSMA), enacted in 2011, was meant to move food safety towards *prevention* rather than *reaction* but making the regulatory paradigm shift envisioned has yet to be realized. The contribution of foods and beverages to the prevalence of diet-related chronic diseases and associated human, social, and healthcare costs is also unacceptably high.<sup>6</sup> FDA needs the expertise and the resources to effectively promote public health by helping to assure the food supply is safe, wholesome, and nutritious.

## Public Health Impact

Protecting the food supply is one of FDA's primary charges, and acute foodborne illness remains a top concern. An estimated 46 million Americans are sickened by foodborne illness each year and, of these, an estimated 128,000 are hospitalized and 3,000 die.<sup>7</sup> While often unrecognized, the medical costs and lost productivity associated with foodborne illness has been estimated to be as high as \$90 billion annually in the U.S.<sup>8</sup>

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<sup>4</sup> Because activities of the Center for Veterinary Medicine affect human food, the Structure section of this report includes CVM although, as noted, the Panel did not evaluate that Center.

<sup>5</sup> Fact Sheet: FDA at a Glance. U.S. Food and Drug Administration. Updated August 17, 2022. Accessed December 2, 2022. <https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance>

<sup>6</sup> Foods and Veterinary Medicine Program's Strategic Plan Fiscal Years 2016-2025. US Food and Drug Administration. Updated September 19, 2018. Accessed December 2, 2022. <https://www.fda.gov/about-fda/office-food-policy-and-response/foods-and-veterinary-medicine-fvm-programs-strategic-plan-fiscal-years-2016-2025>

<sup>7</sup> Estimates of Foodborne Illness in the United States. Center for Disease Control and Prevention. Updated November 5, 2018. Accessed December 2, 2022. <https://www.cdc.gov/foodborneburden/index.html>

<sup>8</sup> Scharff, R. L. 2018. The economic burden of foodborne illness in the United States, p. 123 – 142. In Roberts T. (ed.), *Food safety economics*. Springer Nature, Cham, Switzerland. [Google Scholar](#)

A significant proportion of foodborne illnesses are attributed to FDA-regulated products: in 2019, produce was implicated in 46% of foodborne illness outbreaks.<sup>9</sup> This is not only a considerable food safety concern, but it could also work against recommendations to increase consumption of fruits and vegetables.<sup>10</sup>

Chronic diseases have also been associated with food consumption. National survey data shows that the average American adult is not following dietary recommendations according to the Healthy Eating Index, which shows average scores of  $\leq 60/100$  over the past two decades.<sup>11</sup> Each year, more than a million Americans die from diet-related diseases like cardiovascular disease, diabetes and certain forms of cancers.<sup>12</sup> Nine out of 10 Americans consume too much sodium, which increases risks for high blood pressure, heart disease and stroke.<sup>13</sup> Almost 75% of Americans are overweight or have obesity,<sup>14</sup> which is estimated to be responsible for up to 47% of the total cost of chronic diseases nationwide,<sup>15</sup> underscoring the urgency of more effective nutrition initiatives as part of the FDA's work. And while often overlooked, acute foodborne disease has also been associated with several long-term health outcomes, including irritable bowel syndrome, reactive arthritis, chronic kidney disease and diabetes.<sup>16</sup>

Notably, the American public gains significant value from FDA's food efforts. CFSAN's annual food safety budget in FY 2021 was \$284 million (about 83% of the Center's overall budget) with total public health benefits valued at \$3.1 billion, annually. This equates to an estimated annual return on investment of \$11 in food safety-related public health benefits for every \$1 invested by CFSAN. Between 2011-2020, diet-related disease cost an estimated \$7.6 trillion.<sup>17</sup> The CFSAN nutrition budget was \$24 million in FY 2021 (about 7% of its overall budget)<sup>18</sup> with total public health benefits valued at \$2.8 billion, annually.

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<sup>9</sup> Charts of Note. Economic Research Service, US Department of Agriculture. Updated July 17, 2019. Accessed December 2, 2022. <https://www.ers.usda.gov/data-products/charts-of-note/charts-of-note/?topicId=c8b9267c-b12f-42fe-9e04-80fd2c2510ac#>.

<sup>10</sup> Dietary Guidelines for Americans, 2020-2025, 9<sup>th</sup> Edition. US Department of Agriculture and US Department of Health and Human Services. 2020:30-31. Accessed December 2, 2022. [https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary\\_Guidelines\\_for\\_Americans\\_2020-2025.pdf](https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary_Guidelines_for_Americans_2020-2025.pdf)

<sup>11</sup> Healthy Eating Index. Food and Nutrition Service, US Department of Agriculture. Updated April 27, 2022. Accessed December 2, 2022. <https://www.fns.usda.gov/healthy-eating-index-hei>

<sup>12</sup> Improving nutrition to turn the tide on diet-related chronic disease. *FDA Voices*. US Food and Drug Administration. 2022. Accessed December 2, 2022. <https://www.fda.gov/news-events/fda-voices/improving-nutrition-turn-tide-diet-related-chronic-disease#:~:text=Each%20year%2C%20more%20than%20a,and%20certain%20forms%20of%20cancers>.

<sup>13</sup> Excess Sodium Intake Remains Common in the United States. The Center for Disease Control and Prevention. Updated January 1, 2016. Accessed December 2, 2022. <https://www.cdc.gov/media/releases/2016/p0106-sodium-intake.html>

<sup>14</sup> Fryar C, Carroll M, Afful J. Prevalence of overweight, obesity, and severe obesity among adults aged 20 and over: United States, 1960-1962 through 2017-2018. Revised 2021. Accessed December 2, 2022. <https://www.cdc.gov/nchs/data/hestat/obesity-adult-17-18/obesity-adult.htm>

<sup>15</sup> Milken Institute. October 2018. Accessed December 2, 2022 [https://milkeninstitute.org/sites/default/files/reports-pdf/Mi-Americas-Obesity-Crisis-WEB\\_2.pdf](https://milkeninstitute.org/sites/default/files/reports-pdf/Mi-Americas-Obesity-Crisis-WEB_2.pdf)

<sup>16</sup> Batz M, Henke E, Kowalcyk B. Long-term consequences of foodborne infections. *Infectious Disease Clinics of North America* 2013 Sep; 27(3):599-616.

<sup>17</sup> Hayes T, Asres R. The economic costs of poor nutrition. *American Action Forum*. March 9, 2009. Accessed December 2, 2022. <https://www.americanactionforum.org/research/the-economic-costs-of-poor-nutrition/>

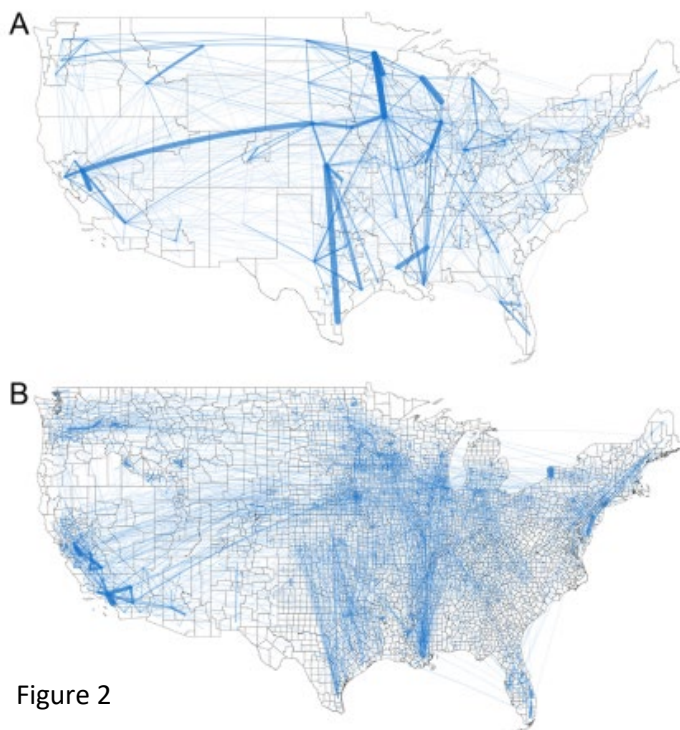
<sup>18</sup> The other 10% of CFSAN's budget supports the Center's other activities, including cosmetics and dietary supplement regulation.

This equates to an estimated annual return on investment of \$119 in nutrition-related public health benefits for every \$1 invested by CFSAN.<sup>19</sup>

## U.S. Food Industry

Today's food industry is estimated to be worth \$1.5 trillion,<sup>20</sup> accounting for approximately one-fifth of the U.S. economy. FDA's regulations cover about 35,000 produce farms, 300,000 restaurant chain establishments, and 10,500 vending machine operators. Its regulated products are manufactured or handled at nearly 275,000 registered facilities, more than half of which are overseas.<sup>5</sup> The food industry is also more global today, with approximately 32% of the fresh vegetables, 55% of fresh fruit, and 94% of seafood that Americans consume annually being imported from other countries.<sup>21</sup>

The supply chain is a source of large-scale complexity. A map depicting 2012 food transportation flow in the U.S.<sup>22</sup>—that is, where food comes from, regional food hubs, and how food travels from place to place—starkly revealed the myriad factors at play in food production and distribution, but also underscored the pressures and responsibility facing the FDA Human Foods Program. (Figure 2)



Each line represents the transportation of all food and feed commodities as well as processed food items, along transit routes, such as roads or railways, with 9.5 million links between counties.

Image: [Environmental Research Letters \(2019\)](#)

The maps depict total food flows in tons for the (A) Freight Analysis Framework (FAF), which includes the flow of coarse food commodity classes, and (B) county scale. Links are shown for all FAF data and for the largest 5% of county links.

Figure 2

<sup>19</sup> The Return on Investment (ROI) estimates are based upon officially published public health benefits noted in CFSAN regulations for food safety and nutrition initiatives. These figures do not capture any realized benefits from guidance or other significant CFSAN actions outside of the rule-making process.

<sup>20</sup> How big is the US food industry? It's worth about \$1.5 trillion. Food Industry. June 2022. Accessed December 2, 2022. <https://www.foodindustry.com/articles/how-big-is-the-u-s-food-industry/>

<sup>21</sup> FDA Strategy for the Safety of Imported Food. US Food and Drug Administration. Updated September 27, 2022. Accessed December 2, 2022. <https://www.fda.gov/food/importing-food-products-united-states/fda-strategy-safety-imported-food#:~:text=American%20consumers%20seek%20a%20safe,of%20its%20overall%20food%20supply>.

<sup>22</sup> Konar M. The first map of America's food supply chain is mind-boggling. The Grainger College of Engineering, University of Illinois. November 11, 2019. Accessed December 2, 2022. <https://cee.illinois.edu/news/first-map-americas-food-supply-chain-mind-boggling>

The COVID-19 pandemic exposed how supply chain gaps can cause havoc for industry, regulators overseeing the food supply, and consumers. These supply chain challenges, specifically the flow of products, were also illuminated during the infant formula crisis that began in late 2021.<sup>23</sup> That crisis demonstrated what can happen when a significant, food-safety related production problem occurs in a food industry sector in which few competitors have the capacity to meet consumer needs. Clearly, change is both necessary and urgently needed to meet the current and future challenges of food oversight.

Environmental impact, multicultural awareness, and food security also affect food production and use. For example, environmental impact is now a more important component of packaging review and regulations. When considering nutritional regulations and recommendations, one must also contemplate how such recommendations will affect different cultures, as well as socio-economic ranges. The future of food regulation demands a holistic view to ensure consumers are protected today and tomorrow, and that food companies participate in solutions.

### **Brief History of FDA's Human Foods Program**

FDA is the oldest comprehensive consumer protection agency in the U.S. federal government. Although it was not known by its present name until 1930, FDA's modern regulatory functions began with the passage of the 1906 Pure Food and Drugs Act that prohibited interstate commerce in adulterated and misbranded food and drugs.

The Bureau of Chemistry became the FDA 24 years later, in 1930. Subsequently, in 1938, Congress passed the Federal Food, Drug and Cosmetic Act, which remains the underlying law authorizing FDA. More consumer-oriented than its 1906 predecessor, the 1938 Federal Food, Drug, and Cosmetic Act represented a significant change in food policy, making food illegal or misbranded if it represented itself as something other than it is.<sup>24</sup>

Since 1938, Congress has passed significant legislation giving FDA more authority over the food supply.<sup>25</sup> Some of the more notable laws include:

- The 1958 Food Additives Amendment required manufacturers to establish the safety of new food additives before going to market;
- The 1980 Infant Formula Act required manufacturers to follow quality, nutrient and stability protocols;
- The 1990 Nutrition Labeling and Education Act required nutrition labels and regulated health and nutrient claims;

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<sup>23</sup> FDA Evaluation of Infant Formula Response. US Food and Drug Administration. September 2022. Accessed December 2, 2022. <https://www.fda.gov/media/161689/download>

<sup>24</sup> FDA History. US Food and Drug Administration. Updated June 29, 2018. Accessed December 2, 2022. <https://www.fda.gov/about-fda/fda-history>

<sup>25</sup> Meadows M. A century of ensuring safe foods and cosmetics. *FDA Consumer magazine*. 2006: 2-11. <https://www.fda.gov/media/110464/download>



- The 1994 Dietary Supplement Health and Education Act created a new regulatory framework for dietary supplements;
- The 2004 Food Allergen Labeling and Consumer Protection Act required food labels to include key allergens, and;
- The FDA Food Safety Modernization Act focused on preventing food safety problems before they occur and recognized the importance of strong foodborne illness and outbreak surveillance systems.

Many of these authority expansions, however, were not accompanied by sustained increases in appropriations. What started as a program with a relatively direct mandate to promote and promulgate purity and truth in labeling grew by one legislative brick at a time. The remit of FDA, and specifically the Human Foods Program, has clearly expanded over time, and its leadership and staff now shoulder greater responsibility for public health, food safety, and nutrition than at its inception. To meet the needs of the 21<sup>st</sup> Century, an adequately resourced FDA Human Foods Program will be required.

### FDA Human Foods Primary Functions

According to the Office of the Commissioner, the current FDA Foods Regulatory Program has nine primary functions.

1. **Standards setting and policy development** for food safety, nutrition, labels, regulatory program frameworks, food defense and other requirements, including development of regulatory methods.
2. **Education, outreach and training** in collaboration with stakeholders in food production, processing, distribution, retail, and regulation related to food safety, as well as public outreach and education on FDA-led nutrition efforts.
3. **Premarket notification and petition review** on issues as varied as food and color additive petitions, infant formula and food packaging amongst others.
4. **Surveillance activities**, including inspections, reviews and sample testing of the domestic and imported food production and food supply for compliance with standards, including surveillance of public nutrition status.
5. **Response** actions when standards are not met or when food safety problems occur, including shortages and outbreaks.
6. **Enforcement**, including civil actions and at times criminal investigations, to protect the public and maintain standards.
7. **Inter- and intra-governmental relations** and cooperation with other government entities involved in food production and regulation, including State, Territorial, Local, Tribal, Federal and International.
8. **Information management**, including compiling, validating, analyzing, and maintaining information related to regulated food entities and products, and their compliance status.
9. **Cross-cutting support activities**, such as governance, planning and strategy development, human resource management, and budgets.

## Attributes of an Agile and Effective Regulator

As the Panel evaluated and considered programmatic recommendations for the FDA Human Foods Program, it also considered the attributes of a high-performing organization (in this case, an agile and effective regulator). The National Academy of Public Administration (NAPA), an independent, non-partisan organization chartered by Congress in 1984 to advance the field of public administration, identified guiding principles for an agile and effective government.<sup>26</sup> These included:

- A laser-focused, crystal clear, easily understood and communicated mission.
- Mission-focused, outcome-based, widely agreed upon, and simple to track metrics.
- Stakeholder behavior and input are critical to any program design, and the stakeholder journey should be embedded in an organization's culture.<sup>27</sup>
- Work environments and culture that celebrate speed, persistence, innovation, and evidence-based solutions.
- Optimized internal teams that are empowered, highly skilled and cross-functional.
- External relationships and networks require attention and affirmation that they are critical to mission success.
- Effective leaders who eliminate roadblocks, aggregate, and assume risks, empower teams, hold people accountable, and reward accomplishments.

These principles can help inform necessary organizational changes and lead to improved policies, regulations, and programs.

## Expectations of an Effective Food Regulatory Agency

With such an array of functions and a critical mission, the FDA Human Foods Program has an opportunity to turn today's challenges into tomorrow's success. However, to fully accomplish its public health mission as an effective food regulatory agency, FDA requires adequate resources, sufficient authority, and a structure and culture that breeds success. An approach that is primarily focused on identifying and reacting to acute outbreaks of foodborne illness and death is unacceptable, and, after FSMA, such an approach is inconsistent with the goals of the statutory framework. Relying solely on food labeling and consumer education to drive the needed changes in the food supply is also an unacceptable strategy for reducing diet-related chronic diseases. In both cases, cures may come too late to prevent illness and deaths.

To strengthen the FDA Human Foods Program as a premier public health regulator, necessary resources must be provided to ensure the Agency has the best technology, expert staff, and unrivaled infrastructure to advance its mission. Sufficient authority to fulfill its mission effectively is required. Leadership must embrace a proactive, prevention-driven strategy that is action-oriented and fosters effective and efficient decision-making. Leaders must also make their support clear to staff as they make decisions. Each staff member should operate in a culture with a preference for action, where they are

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<sup>26</sup> National Academy of Public Administration. Accessed December 2, 2022. <https://napawash.org/>

<sup>27</sup> For the FDA Human Foods Program, stakeholders include regulated industry, additional stakeholders in the food supply chain, partner federal and state regulators, foreign government food safety agencies, nongovernmental organizations, and American consumers.

empowered to respond quickly to challenges as they arise. Lastly, an effective FDA Foods Program cannot operate in a vacuum: collaboration across the federal government, with states and state government, international regulatory bodies, and with the many food stakeholders is crucial to leveraging best practices, eliminating redundancy, and optimizing efficiencies.

## Culture

Organizational culture, defined here to be the shared values and beliefs that govern how individuals behave in an organization, directly affects the ability of an organization to execute its mission and strongly influences how decisions are made throughout an organization. An enabling and effective organizational culture is one that encourages transparency, inspires and rewards collaboration, expects decisiveness, and generates a preference for action. Such a culture is necessary for the success of any organization, including the FDA Human Foods Program.

Input from internal and external stakeholders, including FDA staff, illustrated components of the culture of the FDA Human Foods Program for the Panel. The Panel was briefed by FDA on high-level results of a limited survey the Agency had commissioned to explore the culture of the Human Foods Program, which were largely consistent with stakeholder input. According to the briefing, the evaluation included cultural components such as courage, commitment, inclusion, shared beliefs, risk and governance, and external orientation. While the sample size was not disclosed, the survey exposed several challenges in collaborating (both internally and externally), making decisions in risk-filled environments,<sup>28</sup> and remaining adaptable in a risk-filled environment. Like the Panel's direct findings, the survey identified the strong commitment to the Human Foods Program work as a positive cultural component.

### **Key Findings**

*FDA has dedicated staff who are committed to protecting public health, but the current culture of the FDA Human Foods Program is inhibiting its ability to effectively accomplish this goal.* The dedication to public service and loyalty to the Agency's mission contribute positively to the culture of the Human Foods Program. Most FDA employees understand the immense responsibility of the Agency's Human Foods Program, appreciate the importance of their work, and share a common value of striving to protect public health. However, the current culture, structure, and governance model detract from the Program's effectiveness.

There are several factors contributing to this culture, including the lack of a clear vision and mission; a disparate structure and a consensus governance model; competing priorities; and the lack of a strong, supportive leader and, when the situation requires, an ultimate decision-maker, who is responsible for the Human Foods Program. The lack of a clear overarching leader of the Human Foods Program has contributed to a culture of indecisiveness and inaction and created disincentives for collaboration. The potential to overcome these issues was foremost among the Panel's considerations when making recommendations for potential structural changes (explored in the Structure section of this report), recognizing that a definitive and facilitative structure is necessary, but not sufficient, for addressing cultural problems. In addition, as outlined below, there are several actions that could be taken to make the culture of the FDA Human Foods Program more enabling and effective.

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<sup>28</sup> External risks facing the Human Foods Program range from significant public health ramifications of failing to respond to an outbreak of foodborne illness in a timely manner, to the risk of being sued for regulatory action, and to the less significant, but still impactful, risk of being perceived by the public as too biased toward (or against) regulated industry. Internal risks include, for example, a recommendation being rejected or criticized.

*While the Human Foods Program has specified functions, a clear unifying vision and mission for the entire program is not apparent.* FDA should articulate the vision and mission that drive the Human Foods Program. The absence of a unifying vision and mission is exacerbated by a lack of definition regarding what components of the Agency make up the Human Foods Program. Without an internally shared identity for the program, developing and enabling an effective overarching program culture is difficult. Most often, it is assumed that the FDA Human Foods Program consists of CFSAN, OFPR, portions of CVM,<sup>4</sup> and portions of ORA. As reported by FDA staff,<sup>29</sup> this collection of offices yields a ‘Human Foods Program’ that is an abstract concept with little substantive meaning in the scope of their day-to-day work. Most individuals who are, by virtue of an organizational chart, part of the Human Foods Program identify themselves as being part of an office or center but not necessarily as part of a ‘Human Foods Program’ team. It appears that staff are not actively encouraged to broaden their thinking and work with individuals outside of their division, office, or center. Such a narrow range of engagement can inhibit staff from identifying or embracing the over-arching goals of the Program.

In the absence of a clear vision, mission or definition, or broader identification and engagement with the Human Foods Program, FDA staff often operate in silos within the organizations or subcultures where they feel most valued and comfortable. For example, during the aforementioned infant formula foodborne-illness outbreak and subsequent product shortage, a review of events indicates that lack of communication and engagement across the Agency accounted, in part, for missteps.<sup>23</sup> While it appears that staff at all levels sought to follow the rules and procedures within their division, there was little motivation, and apparently no requirement, to share information and interact across the Agency to facilitate critical thinking and proactive decision-making. This is especially problematic in a crisis, where decisions should be made quickly and be vetted properly.

*The lack of a single clearly identified person to lead the Human Foods Program has adversely impacted the organizational culture and led to overlapping roles and competing priorities that result in what is perceived as constant turmoil.* Strong leadership is essential to an effective and enabling organizational culture. Strong and supportive leadership articulates, fosters, and models the desired organizational culture, and ensures organizational engagement by clearly defining roles and responsibilities and articulating how these advance the mission of the organization. Good leadership and management should occur at all levels and is necessary for creating an environment where people can work effectively and thrive, individually and as part of a team. It is also important that the leaders and managers of the Human Foods Program have the skills necessary to advance the Agency’s public health mission around food. As senior leaders are considered for the Human Foods Program, an ideal leadership skill set should include:

- Expertise and knowledge in food safety and/or nutrition
- Ability to make decisions in a complex regulatory environment
- Ability to lead in a complex work environment
- Strong demonstrated management capability
- Superb communication skills
- Ability to identify and nurture talent

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<sup>29</sup> This comment came through the online stakeholder portal which was open to gather public input from September 16 to October 7, 2022.

- Commitment to collaboration, not isolation
- Capable of breaking down silos
- Proven abilities to lead, support, and incent teamwork
- Ability to support initiatives that increase staff professionalism and performance
- Commitment to joint staff development and other activities by the collective parts of the Human Foods Program

Clear lines of authority are also essential in establishing and enabling an effective organizational culture. The lack of clarity in authority lines across and within the components of the Human Foods Program leads to frustration and substantial confusion among both staff and leadership. For example, the similar food safety responsibilities of OFPR and CFSAN create an environment where work may be duplicated. The structure also reinforces confusion or conflict, as a “decision” made in CFSAN may or may not be sustained or may be second-guessed in OFPR. Staff are unsure whom to speak with when a question or problem of this type arises. This confusion can extend outside the Agency to other government entities sharing responsibility for fostering nutrition and food safety, limiting the FDA’s impact.

The ambiguity about leadership and the subsequent lack of clarity also results in a lack of communication, particularly around the context for decisions and the “big picture” of Human Foods Program priorities, such as the transition to a prevention mindset envisioned in FSMA. Insufficient communication erodes confidence, generates frustration, and may result in loss of staff who move to different roles or organizations at FDA or elsewhere in the government or private sector.

*The Human Foods Program approach of relying on consensus has significant drawbacks for making decisions about taking regulatory action. FDA’s culture should foster collaboration and give high priority to finding the best solution over yielding unanimous agreement. While striving for consensus can be beneficial in innovating and gaining better insight on issues, ultimately leading to greater “buy in,” it can also lead to agreement around the lowest common denominator if consensus is not driven by an underlying spirit of resolute decision-making, collaboration, and trust. Lack of clarity in the decision-making structure further compromises reaching consensus. Decision-making under the Human Foods Program Governance Board<sup>30</sup> appears to generate cross-Center inertia, where the Board may be used more often to stop an initiative than to advance it. For more operational, and program-specific decisions, collections of individuals from various offices contribute, but may not be unified in their priorities nor have a clear articulation of the final decision, or the process used to generate a final decision. In the absence of a collaborative, problem-solving posture enabled by a clear process supporting timely decisions, the scales can be tipped in favor of inaction, minimizing risk, and maintaining the status quo. This culture creates an environment where decision-making is unacceptably slow. From an external perspective, the Human Foods Program can be left appearing sluggish and non-responsive to public health concerns.*

*A culture of cooperation and accountability in the Human Foods Program’s field operations needs to be reestablished to fulfill the potential of program alignment and to optimize the performance of the Human Foods Program. The goal of the program alignment initiative was to modernize and strengthen*

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<sup>30</sup> FDA Human Foods Program Governance Board Charter, Oct 2019

the Agency's ability to improve its public health response in a way that keeps pace with the acceleration of scientific innovation, global expansion of markets, and new legislative and programmatic mandates like the passage of FSMA. To achieve this goal there was an expectation that some longstanding processes, approaches to performing work, and cultural practices would be modified to ensure that the prevention focus of FSMA would be adopted and implemented by ORA. In its Program Alignment fact sheet,<sup>31</sup> ORA notes that commodity-based restructuring and specialization of staff will better position the organization to implement FSMA and create a new food safety system that emphasizes prevention and accountability; to implement the new FSMA authorities in a manner that results in more uniformity in both process and policy across ORA; and more seamlessly coordinate interactions within FDA, between the field and the Centers, with other federal agencies, and with state, regulatory, and public health departments, especially in the consistent application of FDA's inspectional approach to regulating preventive controls. ORA made some important structural changes, and its staff has become more specialized — and these changes are significant improvements; however, based on what the Panel heard from internal and external food program stakeholders, it appears that fully embracing a culture of cooperation and accountability, in particular as it relates to fully embracing the prevention ethic of FSMA, has not yet happened.

This shortcoming has prevented the program alignment goals from being fully realized in FDA's Human Foods Program. For example, the Human Foods Program portion is the largest portion of ORA's budget, representing 62% of total FY 2021 ORA funding. However, this budget allocation to ORA is neither accompanied by clear, collaborative decision-making with CFSAN nor transparency regarding use of funds. The Panel heard of disconnects between the field and CFSAN's policy priorities, and resource allocation being determined independently, without a full accounting as to how these resources are used. Taken collectively, these cultural issues need to be addressed to optimize the performance of the Human Foods Program, to complete the implementation and enforcement of FSMA, and to fulfill FDA's public health mission.

*The Human Foods Program culture appears to foster an aversion to risk that undercuts its ability to meet its public health mandate. FDA's culture should foster both incremental and far-reaching innovation and encourage responsible and well informed risk-taking. Oversight of a global and constantly changing food system requires a willingness to take novel, precedent-setting, and/or aggressive enforcement actions in the name of public health. Such actions are inherently risky but necessary for effectively addressing the food challenges of the 21<sup>st</sup> Century and beyond. The FDA Human Foods Program's aversion to risk compromises the Agency's willingness to act in enforcement or policy development, to collaborate within the Agency and across government, and to discuss novel and innovative approaches to policy and science as part of meaningful stakeholder dialogue. For example, FDA's Human Foods Program has at times appeared to be reluctant to take enforcement action unless they feel that, with certainty, the action could withstand legal challenges. This risk-averse culture also emerges in internal rules of governance intended to protect against possible negative outcomes – a not-surprising development in a*

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<sup>31</sup> Program Alignment and ORA. U.S. Food and Drug Administration. Updated April 29, 2019. Accessed December 2, 2022. <https://www.fda.gov/about-fda/ora-program-areas/program-alignment-and-ora>

program subject to significant external criticism. Finally, without the confidence to engage routinely, and transparently, with the external community, the FDA’s Human Foods Program loses the opportunity to understand more fully the industry it regulates. External stakeholders observe that the Agency is often in “listen-only” (or in “talk-only”) mode rather than having a constructive dialogue that could yield better and more informed decisions.

## **Recommendations**

The Panel appreciates the Agency’s desire to strengthen its culture and its ongoing efforts to do so. These efforts show promise, as shown in the recently announced strategy outline to help prevent future illnesses linked to consumption of powdered infant formula, particularly the elements related to improving stakeholder collaboration, strengthening regulatory activities, and working with federal, state, and local partners.<sup>32</sup> Additional, and more deliberate, actions of this type are needed.

To move the Human Foods Program toward a more enabling and effective culture, the Panel recommends FDA leadership consider the following:

- *Identify, communicate, embrace, and promote a clear and compelling vision, mission, and value statement for the Human Foods Program.* [[Recommendation/Culture1](#)]
- *Establish an organizational structure with a clear leader and ensure that there is a clear articulation of roles and responsibilities within the Human Foods Program and a culture that is well-equipped to survive (inevitable) leadership transitions.* [[Recommendation/Culture2](#)(Also in Structure)]
- *Develop and nurture a culture where regulatory decision-making is rooted in scientific evidence and FDA’s legal framework.* [[Recommendation/Culture3](#)]
- *Commit to transparency, timeliness, and predictability in decision-making, with a preference towards action.* [[Recommendation/Culture4](#)]
- *Commit to an on-going process of culture change from the highest levels of FDA leadership.* [[Recommendation/Culture5](#)]
- *Develop and implement a change management strategy that not only manages change, but also effectively improves and monitors the environment for cultural change.* [[Recommendation/Culture6](#)]
- *Build expectations and incentives into the system to embrace a positive, collaborative culture that expects, values, and rewards teamwork.* [[Recommendation/Culture7](#)]
- *Create a culture of feedback and authenticity where continuous, honest, and constructive feedback is given and received.* [[Recommendation/Culture8](#)]
- *Nurture current staff and recruit, hire, and promote top quality staff, including strong managers.* [[Recommendation/Culture9](#)]

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<sup>32</sup> Outline of FDA’s Strategy to Help Prevent Cronobacter sakazakii Illness Associated with Consumption of Powdered Infant Formula. US Food and Drug Administration. Updated November 15, 2022. Accessed December 2, 2022. [https://www.fda.gov/food/new-era-smarter-food-safety/outline-fdas-strategy-help-prevent-cronobacter-sakazakii-illnesses-associated-consumption-powdered?utm\\_medium=email&utm\\_source=govdelivery](https://www.fda.gov/food/new-era-smarter-food-safety/outline-fdas-strategy-help-prevent-cronobacter-sakazakii-illnesses-associated-consumption-powdered?utm_medium=email&utm_source=govdelivery).

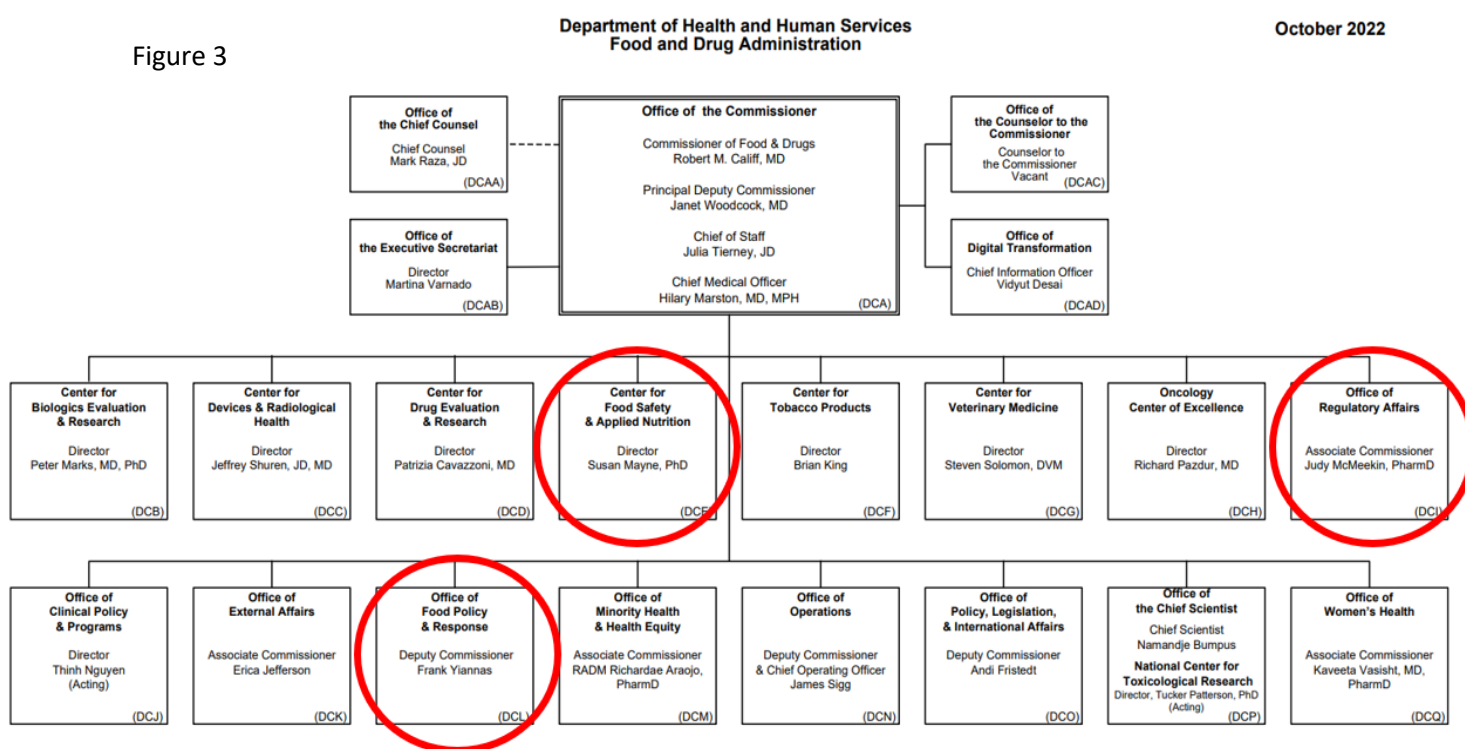


Even with the best structure and most dedicated staff, culture change is difficult and requires buy-in and resolute commitment of senior leadership to 1) participate personally, 2) encourage and expect participation of all others, and 3) communicate regularly about the importance of the process. The turmoil experienced by many within the Human Foods Program creates a challenging environment for implementing these culture changes. Nevertheless, such culture change should be pursued. Culture transformation efforts should include developing processes (e.g., onboarding, training, incentives, standard operating procedures) to incorporate, embed, and operationalize the values that articulate expected behaviors throughout the organization – from field staff to laboratory scientists, administrative assistants to senior executives and everyone in between. These steps can help empower staff, improve employee retention, and facilitate top-talent recruitment.

## Structure

Although there is no formal definition of the FDA Human Foods Program, for the purposes of this review, it is assumed to include CFSAN, OFPR, and portions of ORA and of CVM, although the latter was not included in the charge to the Panel nor was CVM evaluated by the Panel. As noted in the Culture section of this report, the current structure of the FDA Human Foods Program reinforces duplicative or competing roles and responsibilities, siloed work, and inadequate internal and external engagement. This reality impedes the Human Foods Program move toward a prevention paradigm. While a change in structure cannot address all the challenges identified through this Human Foods Program review, changing the current organizational configuration will assist the Agency in advancing its mission.

As can be seen in FDA’s current organizational structure (Figure 3), CFSAN, OFPR and ORA (each circled in red) each report to the Commissioner and are independent of one another.



Legend:  
--- Direct report to DHHS General Counsel

There is no clear Human Foods Program leader or decision-maker, outside of the Commissioner. Although the missions of CFSAN and OFPR have differences on paper, staff are often left wondering which program is responsible for decision-making. As mentioned previously, a Governance Board was established in 2014 (and updated in 2019) to address this need for coordinated decision-making. However, this concept has not effectively addressed the structural challenges.

Compounding the issue, as noted in other sections of this report, the implementation of policies and field work done by ORA is largely independent of CFSAN, the organization that is responsible for developing and writing the policies that are then discharged with a majority of ORA’s funding. With this

structure and the absence of a Concept of Operations document outlining how the two should work together, neither CFSAN nor ORA has a direct stake in ensuring that their work and perspective align.

Another area of concern with the current structure is the broad remit of CFSAN, which requires balancing the limited time, attention, and resources across two missions critical to public health (in addition to its responsibilities for cosmetic and dietary supplement regulation). Food safety and nutrition activities are both critically important to the health and wellbeing of our nation—albeit in different ways—and each should be recognized and given high priority within FDA. However, CFSAN’s nutrition-related responsibilities are not clearly articulated and are often not referenced in general discussions about the Human Foods Program; generally, nutrition is not recognized at the level implied by the national reliance on the FDA for essential public health nutrition policy. The FDA has a key role within a broader, whole-of-government approach to help reduce the burden of chronic diseases and advance health equity by helping to improve dietary patterns in the U.S.<sup>33</sup>—the “applied nutrition” functions of CFSAN.

Along with the leadership attributes addressed in the Culture section of this report, good management is critical to a successful FDA’s Human Foods Program. As leaders set the direction, build a vision, and adapt as circumstances require, managers are responsible for executing programs and responsibilities, as well as motivating, encouraging, and generally instilling confidence in staff to perform at their highest level. Decision-making is a significant component of management. Understanding the relevant information and making the best decision available, particularly in an environment of imperfect or incomplete information, is a fundamental management skill. Good leadership and management should occur at all levels, not just among those who work in defined “leadership positions”. High quality managers and leaders should be identified and nurtured (and recruited, where necessary), regardless of the structure.

Identifying an organizational configuration that unifies the Human Foods Program can also help the Agency better meet its mission. The right organizational structure will better support leaders in:

- Setting the strategic direction and successful operations of the Human Foods Program
- Communicating to internal and external stakeholders about who oversees the various facets of the Program
- Facilitating timely and predictable decision-making, with a preference for action
- Recruiting qualified internal and external candidates into senior management positions

## **Recommendations**

The Panel strongly supports some sort of structural change to address the challenges facing the Human Foods Program. As the Panel discussed different alternatives, a set of cross-cutting themes emerged. The Panel agreed that the following recommendations should inform the structure of the Program.

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<sup>33</sup> FDA’s Nutrition Initiatives. US Food and Drug Administration. Updated September 28, 2022. Accessed December 2, 2022. <https://www.fda.gov/food/food-labeling-nutrition/fdas-nutrition-initiatives>

*FDA should increase the visibility and prominence of the Human Foods Program.*

[[Recommendation/Structure1](#)] Given the economic impact that foodborne illness and diet-related chronic disease have on Americans and the federal budget, it is imperative that the Human Foods Program become more prominent. When compared to the medical products programs within FDA, the Human Foods Program continuously struggles for visibility and prominence. A component of this elevation of the Human Foods Program is strong advocacy to advance the Human Foods Program at all levels of the government, especially at the Department of Health and Human Services (HHS) and the White House, including the Office of Management and Budget.

*The Human Foods Program should have clear lines of authority.* [[Recommendation/Structure2](#)] As articulated in the Culture section of this report, the current organizational structure lacks a clear leader and decision maker; this has reinforced and exacerbated many of the challenges the Human Foods Program experiences. The current structure allows for substantial, counterproductive ambiguity, and each of the proposed structures attempts to eliminate, or at least limit, that ambiguity. Consequently, the current OFPR is subsumed in the various approaches and thus does not appear in any of the proposed alternatives. The “Smarter Era for Food Safety” responsibility would be transferred to CFSAN (or its subsequent iteration) in each model.

*Within the Human Foods Program, the importance of nutrition should be elevated.*

[[Recommendation/Structure3](#)] Each structure includes a longer-term goal of creating a new Center for Nutrition. This will require addressing the interdependence of nutrition and food safety activities in what is now CFSAN, as well as ensuring that nutrition-related activities in CVM are appropriately linked. A new Center for Nutrition will require dedicated resources and leadership and may require Congressional action.

*The foods portfolio of ORA should be integrated directly with the other elements of FDA’s Human Foods Program.* [[Recommendation/Structure4](#)] Each structure includes a longer-term goal of separating out at least some portions of ORA’s foods program (i.e., inspectional and compliance activities) to ensure that field work aligns with the foods program policies, with an intent to facilitate the transformation of the inspectional service to the prevention model envisioned in FSMA and to bolster and support the cooperative and harmonization efforts of inspectors at the state, local, territorial, and international level. Other components of ORA that merit consideration for transfer to the Human Foods Program include relevant portions of laboratories, imports, and training. For elements that stay with ORA, a transparent shared services budget should be developed.

*The food-relevant work of CVM should be integrated with the overall FDA Human Foods Program.*

[[Recommendation/Structure5](#)] Although the Panel did not evaluate CVM, in keeping with One Health,<sup>34</sup> each structure includes recommendations for the location of CVM because of its role in food safety and nutrition.

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<sup>34</sup> One Health is a concept that embraces a multisectoral and transdisciplinary approach to solving health problems by recognizing the interconnection between humans, animals, and their shared environment. <https://www.fda.gov/science-research/fda-grand-rounds/pandemic-and-call-action-one-health-fda-one-health-initiative-06112020-06112020>

A new Foods Advisory Committee, at the Commissioner-level, should be established to strengthen external input to Human Foods Program activities. [Recommendation/Structure6] Advisory committees are an important method to deliver external information, insight, and expertise from outside of the Agency. CFSAN’s former Food Advisory Committee was disbanded in 2017; establishing a new Committee to advise the Commissioner reinstates, and elevates, this input.






Structure changes should be implemented with cultural transformation efforts.

[Recommendation/Structure7/(Also in Culture)] It will take time to institute any structural change and over that time there will be leadership changes. Change is not easy for organizations, and the Human Foods Program has experienced many reorganizations in a relatively short period of time. It will be important for the Commissioner to include a strong change management component for success and position such change management to persist through likely leadership (or Administration) changes. The consistent turmoil experienced by many within the Human Foods Program creates a challenging environment for implementing changes. Nevertheless, change should be pursued.

The Panel proposes several potential structures that would, as described or with variations, elevate and support an effective Human Foods Program. The above recommendations served as a backdrop for the proposed structures. Each proposed structure has its own considerations that should be carefully weighed.

Figure 4 illustrates elements of the various options.<sup>35</sup> In the subsequent organizational charts presenting Options A through E, green boxes indicate a change, blue boxes indicate areas that are unchanged and gray boxes indicate areas that were not addressed. Options are not presented in any particular order.

Figure 4

Structure Options	Elevates Human Foods Program	Creates a Separate Center for Nutrition	Integrates foods portion of ORA with Foods Program Centers	Authority for change resides largely within FDA/HHS	Creates a separate Human Foods Program budget	Relative time and effort to implement*
Option A: Separate Food Administration	Within HHS	✓	✓		✓	 Likely requires the most time
Option B: Separate Medical Products and Foods within FDA	Within FDA	✓	✓	✓		
Option C: Establish CFSAN as Overall Lead for the Foods Program	Within FDA	✓	✓	✓		
Option D: Separate CFSAN and ORA	Within FDA	✓	✓	✓		
Option E: Deputy Commissioner for Foods	Within FDA	✓	✓	✓		

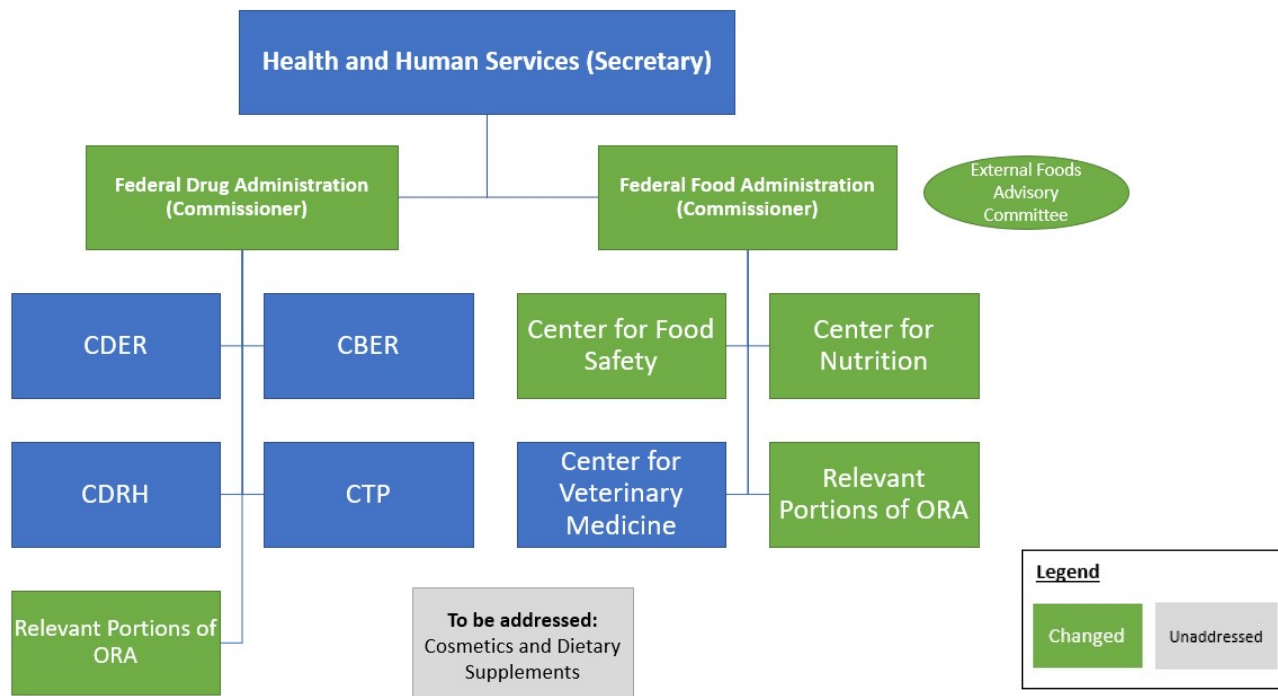
\*Icon illustrates the time to implement in relative terms; it is not intended to provide a quantitative comparison

<sup>35</sup> This evaluation did not include all elements of CFSAN (specifically cosmetics and dietary supplements). The Panel recommends that the functions of these two areas be reviewed and subsequently aligned with the most applicable Center or Office. In the structure options, cosmetics and dietary supplements are indicated via a gray box to reflect the recommendation for subsequent review and alignment.

## Option A: Create Separate Food and Drug Administrations within HHS

### Key Changes from Current Structure:

- Creates a new operating division within the HHS: a Federal Food Administration that is separate from a Federal Drug Administration, each with a Commissioner reporting directly to the HHS Secretary



**Considerations:** This structure elevates the visibility of the FDA Human Foods Program within HHS, creates a separate budget structure for the Human Foods program, and signals the desire for a significant cultural shift to occur within the agency. The Commissioner challenged the Panel to “think big”. Thus, this structure offers an option that changes the way the HHS Secretary would manage foods and medical products, independent of one another, including separate budgets.

A new Federal Foods Administration will require HHS engagement and support; creating another HHS Operating Division will likely require statutory change. This is a longer-term option and includes a risk that the uncertainties and challenges that exist today will continue during that transition time. This model would likely disrupt information exchange between foods and medical products personnel. To address the latter, each Commissioner could establish a liaison to drive collaboration between the new operating divisions, although this liaison role will not replicate the current level of interaction among the Centers.

There is also a possibility that the new Federal Foods Administration will be challenged to compete for visibility, budget, and policy engagement resources with the larger and well-established operating divisions within HHS (e.g., the National Institutes of Health, the Centers for Disease Control and Prevention). There is also the risk that the new Federal Foods Administration could become an easy political target resulting in weaker food oversight than the current structure.

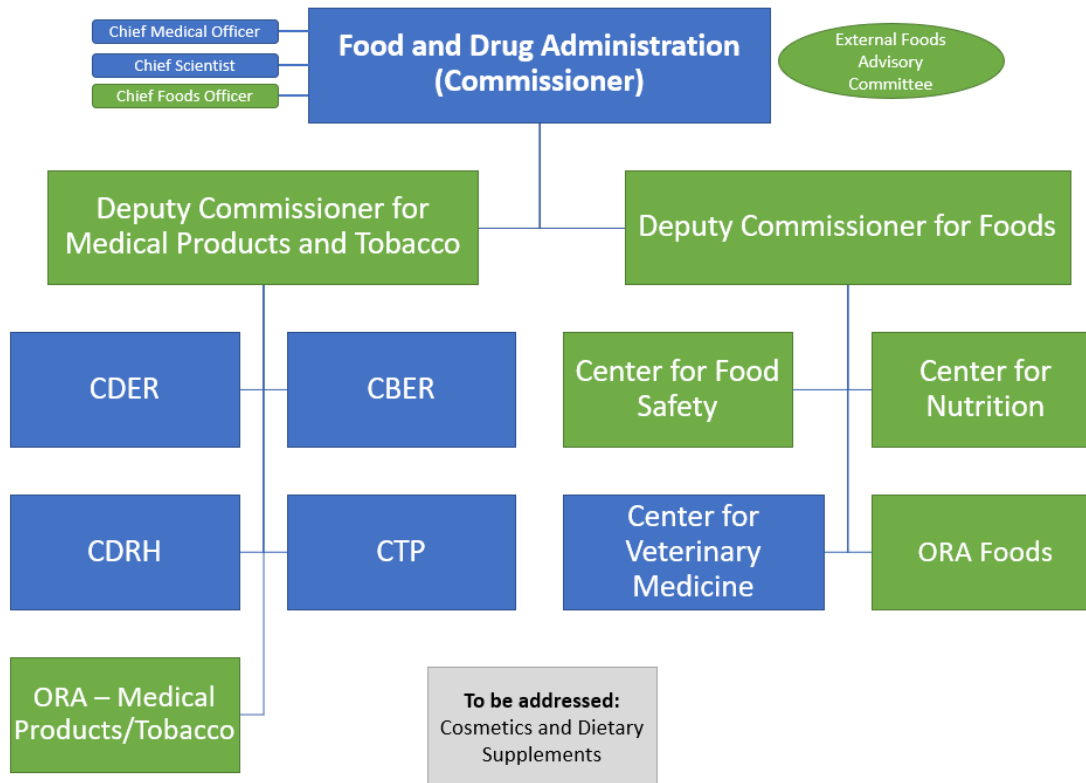
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**Option B: Separate Medical Products and Foods within FDA**

**Key Changes from Current Structure:**

- Creates both a Deputy Commissioner of Foods and a Deputy Commissioner for Medical Products and Tobacco, each with line authority over respective Centers
- Establishes a Chief Foods Officer within the Office of the Commissioner



**Considerations:** This structure elevates the visibility of the FDA Human Foods Program within FDA and re-establishes the Deputy Commissioner structure within FDA. It reduces the direct reports to the FDA Commissioner, and includes a designated leader for Foods (and, separately, Medical Products and Tobacco) efforts. (Notably, this structure deviates from the prior Deputy Commissioner structure by including relevant food portions of ORA within the line authority of the position.) The parallel Deputy Commissioner structure is intended to indicate the equal importance of the foods and medical products mandates within FDA, although it addresses components of the Agency outside of the Panel’s charge and the Panel did not evaluate the need for a second Deputy Commissioner. The proposed Chief Foods Officer would serve, similar to the Chief Medical Officer and Chief Scientist, as an agency-wide advocate and spokesperson for the Human Foods Program, but without an operational role.

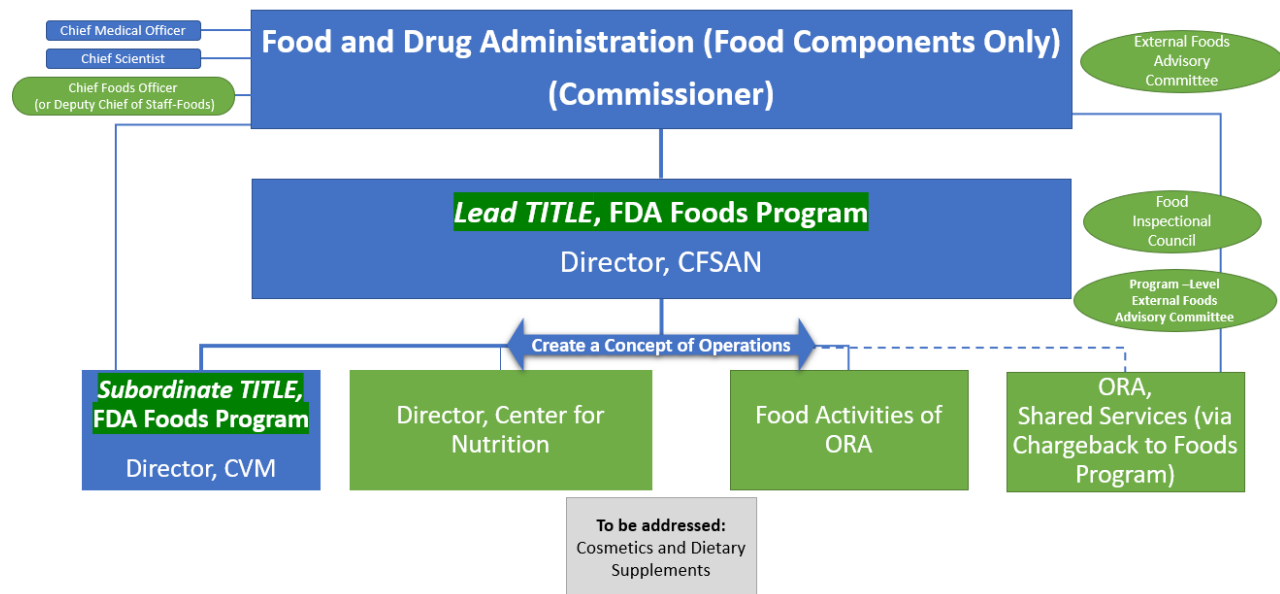
This approach would take time to implement but may not require explicit Congressional approval; it will likely require Congressional notification. To the extent that long-term leadership can provide program stability, the structure may be limited by the relatively short tenures of Commissioners and Deputy Commissioners, when compared with the typically-longer tenure of Center Directors. Adding a Deputy Commissioner between the Commissioner and Center Directors may create challenges in retaining (and recruiting) Center Directors across the Agency due to a perceived lower stature.

Legend	
Changed	Unaddressed

**Option C: Establish CFSAN as the Overall Lead for the FDA Human Foods Program**

**Key Changes from Current Structure:**

- Creates a dual-role for the CFSAN Director as the overall lead for the FDA Human Foods Program
- Creates a dual-role and dual-reporting relationship for the CVM Director, with a dual-role as the deputy within the FDA Human Foods Program (reporting to the CFSAN Director/Foods Program lead) and reporting to the Commissioner for non-food-related responsibilities
- Establishes a Chief Foods Officer (or Deputy Chief of Staff/Foods) within the Office of the Commissioner



**Considerations:** This structure elevates the visibility of the FDA Human Foods Program within FDA and adds a political appointee as the Chief Foods Officer (or Deputy Chief of Staff-Foods) to advocate for the Human Foods Program within the Commissioner’s office as well as work with CDC, HHS, USDA, and OMB’s Office of Information and Regulatory Affairs to expedite and streamline processes critical for public health. With the Chief Scientist and Chief Medical Officer, the Chief Foods Officer would coordinate response to outbreaks and cross-Agency food issues, medical foods, biotech, etc. and serve as the lead for cross-Government food-related activities. The CFSAN Director would serve as the “Lead” for the Human Foods Program and cross-Agency food-related matters. The structure includes establishing a Human Food Program Inspectional Council with representation from heads of Compliance for CFSAN and CVM, from ORA, and from SLTT agencies and international regulators, to help bring together the field and policy operations of FDA Human Foods Program and strengthen partnerships. This structure option refers to ‘CFSAN’, with an understanding that the creation of a new Center for Nutrition would likely result in a subsequent change to the current ‘CFSAN’ name (and role).

This approach would take time to implement but may not require explicit Congressional approval; it will likely require Congressional notification. Having the food components of ORA shift to report to the Head of the Human Foods Program (who is also the Center Director) creates a lack of parity for other portions of ORA which still report to the Commissioner.



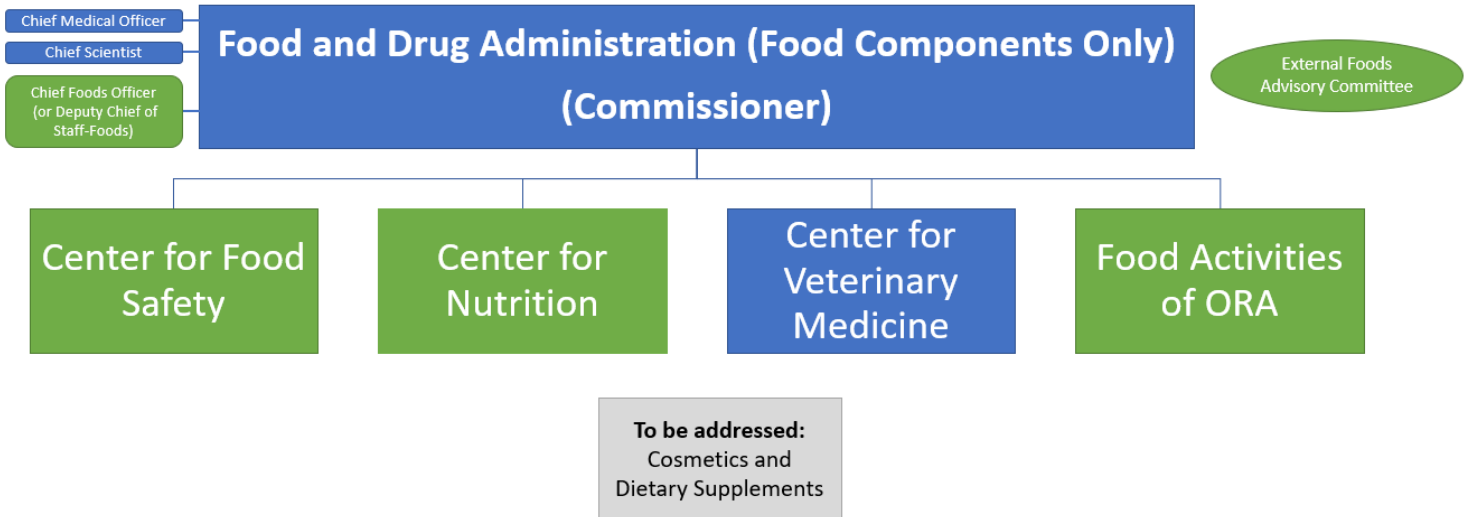
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**Option D: Commissioner Leads Foods Program; CFSAN and ORA are Separated**

**Key Changes from Current Structure:**

- Challenges the Commissioner to actively engage in and embrace the Human Foods Program responsibilities, serving as the Agency lead for food-related topics
- Establishes a Chief Foods Officer (or Deputy Chief of Staff/Foods) within the Office of the Commissioner



**Considerations:** This structure elevates the visibility of the Human Foods Program within FDA by having the Commissioner—personally—engage as the leader of the Program. The structure maintains the direct line of reporting of the Center Directors to the Commissioner. It adds two direct reports for the Commissioner: the head of the new Center for Nutrition (when established) and head of the Food Activities of ORA. In this structure, programmatic issues and managing responsibilities such as inspections, imports, and emergency response operational issues fall under the Centers, but with engagement and leadership from the Commissioner and the Office of the Commissioner.

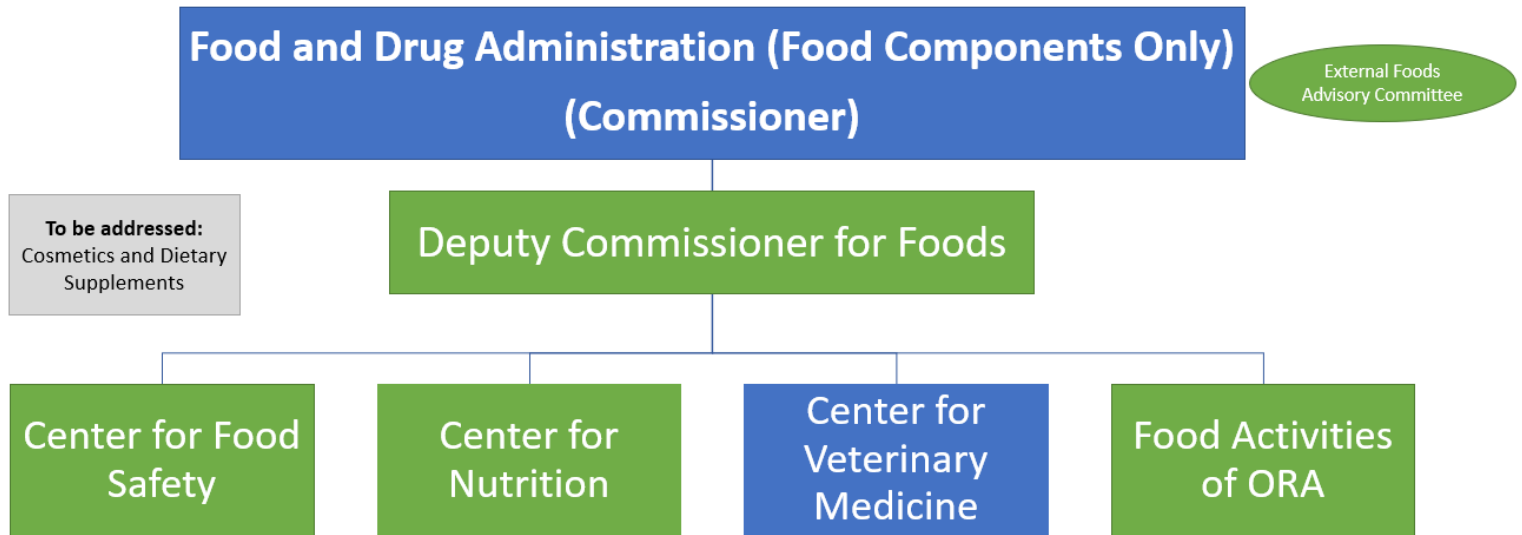
This approach could be a transitional structure; it likely will not require explicit Congressional approval; it may require Congressional notification. The structure requires the Commissioner to serve as the single leader for the Human Foods Program, which may prove challenging given the many other responsibilities of that role and may not improve the decision-making process. Leadership would be vulnerable to changes in the Commissioner and Chief Foods Officer/Deputy Chief of Staff positions.

Legend	
Changed	Unaddressed

**Option E: Create a Deputy Commissioner for Foods**

**Key Changes from Current Structure:**

- Creates a Deputy Commissioner for Foods with line authority over the Human Foods Program



**Considerations:** This structure elevates the visibility of the Human Foods Program within FDA and provides a single leader for the Human Foods Program. It decreases direct reports to the Commissioner. The Deputy Commissioner for Foods would serve as the primary advocate for the Human Foods Program both internally and externally.

This approach would take time to implement but may not require explicit Congressional approval; it will likely require Congressional notification. This structure does not include the creation of a Deputy Commissioner for Medical Products and Tobacco, which may create a perception of lack of parity with other Center Directors who report directly to the Commissioner.

## Resources

The expectations of the FDA Human Foods Program and its impact on public health and our nation’s economy are immense. However, relatively modest increases in federal budget authority, flat staffing levels, and lack of sustained and sufficient commitment to upgrading information technology (IT)—contrasting with a rapidly changing food industry— have constricted the ability of the Human Foods Program to carry out its mission efficiently and effectively. In addition to aforementioned cultural and structural changes, the FDA’s Human Foods Program urgently needs additional personnel, financial, and IT resources to perform its Congressional mandate more effectively.

The FDA’s Human Foods Program is significantly under-resourced and additional resources, in conjunction with other changes, are critical to future success. In FY21, FDA allocated approximately \$1B to the Human Foods Program across CFSAN, OFPR, and ORA. (Figure 5) As discussed in this section, staffing numbers and funding have increased in the Human Foods Program, but this growth is insufficient and, notably, at the slowest pace of any component of the Agency except the Office of the Commissioner and the National Center for Toxicological Research. (Figure 6) In inflation adjusted terms, CFSAN’s budget, for example, has remained relatively flat for more than a decade. CFSAN’s total funding increased from \$260M in FY 2011 to \$381M in FY 2022, an increase of 46%. However, approximately \$90M of this +\$121M increase was needed to keep pace with inflation, resulting in a net increase of only \$31M since FY 2011. By comparison, the Human Drugs Program total funding grew 121% over the same period. Resource infusions are necessary and will need to be sustained.

Figure 5

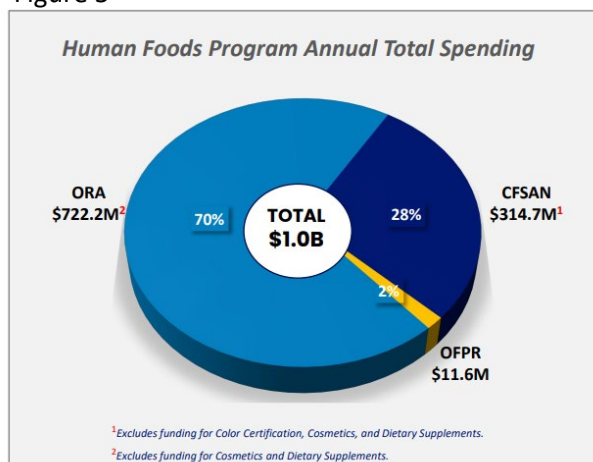
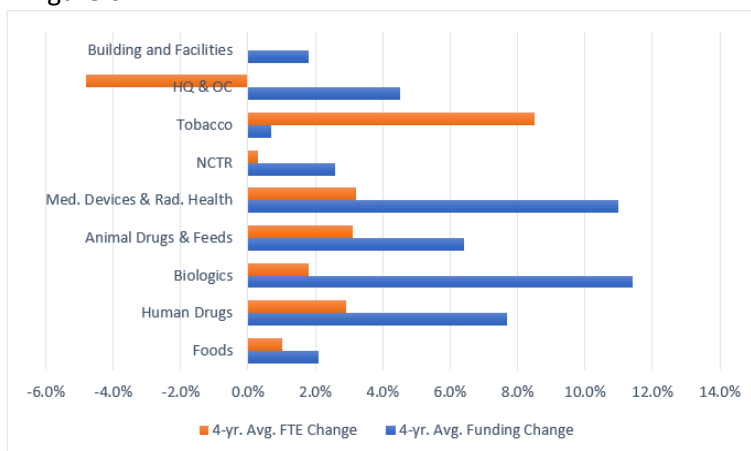


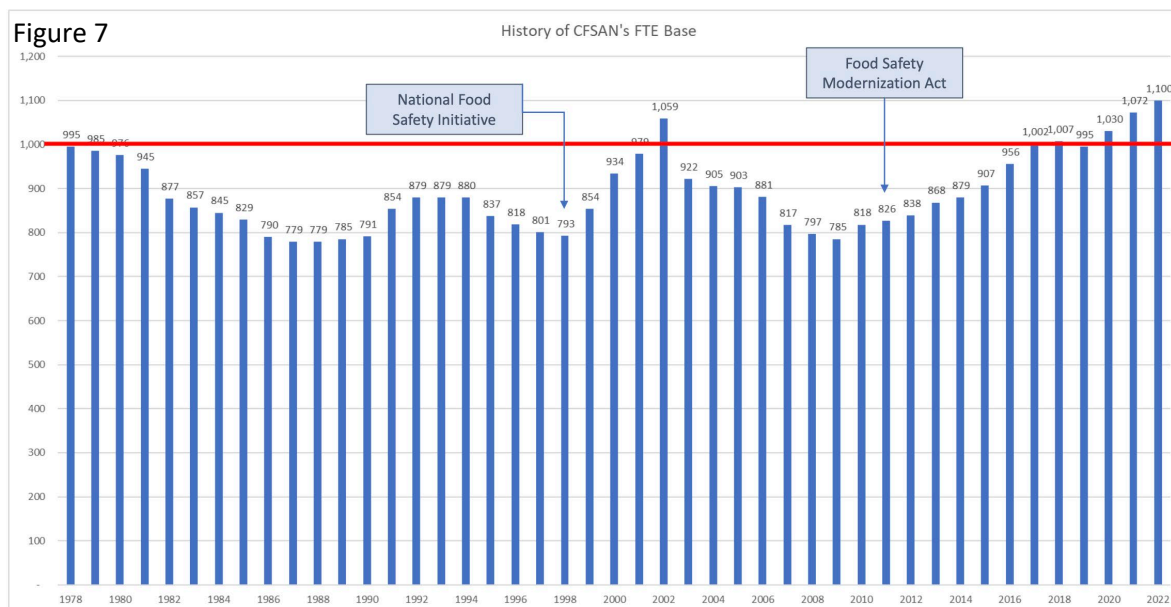
Figure 6



## Personnel

It is helpful to view FDA’s budget through staffing because budget levels must reflect the cost of inflation, salary step and other compensation increases, and other government-mandated costs for personnel. People are the FDA Human Foods Program most valuable resource—both those employed by the Agency and those deployed through contracts or cooperative agreements with the States. In FY21, CFSAN had approximately 1071 full-time employees (FTEs) (including seven Senior Executive Service and 36 Title 42 staff), and 91% or 971 were in the Human Foods Program. As illustrated in Figure 7, staffing for CFSAN has remained relatively flat since 1978. In the same time period, Congress increased CFSAN’s responsibilities, including the dramatic expansion and reorientation captured in FSMA (the biggest

overhaul of the Nation’s food safety laws in more than 70 years).<sup>36</sup> Of note, while Congress was considering enacting FSMA, the Congressional Budget Office estimated that implementation of the then-proposed Act would increase spending by approximately \$1.4 billion over the 2011-2015 time period.<sup>37</sup>



The ability to recruit, hire and retain scientists is imperative to meeting FDA’s public health mission around food. Securing 21<sup>st</sup> Century Cures Act hiring agility and salary flexibility authority could address some of the lack of parity between the Human Foods Program and other FDA Centers. Specifically, Section 714A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379d-3a), as added by the 21<sup>st</sup> Century Cures Act, and referred to as “Title 21”, gives the Commissioner the authority to hire directly and set the annual rate of pay for outstanding and qualified candidates to scientific, technical, or professional positions that support the development, review, and regulation of medical products.

Further, Office of Personal Management (OPM) qualifications for professionals often do not match Human Foods Program needs, which complicates the ability of the Human Foods Program to hire qualified individuals specific to the needs of the program. The newly OPM-issued Data Scientist qualification, for example, requires specific degrees. FDA has found that most highly qualified candidates for Data Scientist positions have critical, relevant experience, but because the field is so new, they may not have gained the designated degree.

### Financial Resources

Congressional appropriations, the primary source of funding for the Human Foods Program, have not kept pace with the needs of the Human Foods Program. This is further exacerbated by the imbalanced availability of user fee programs across the Agency. While other FDA programs effectively utilize industry user fee funding, there is a near absence of such funding for the Foods Program. Agency-wide,

<sup>36</sup> Additional detail regarding expansion of authority is provided in the Introduction.

<sup>37</sup> Congressional Budget Office Cost Estimate, S. 510 Food Safety Modernization Act, August 12, 2010. [S. 510 \(cbo.gov\)](https://www.cbo.gov/publications/2010/08/s510).

industry user fees account for 46% of FDA’s overall budget. The Foods Program receives about 1% of its budget in user fees, in contrast to other FDA programs such as tobacco (at 100%) and human drugs (66% of budget is user fee funded).<sup>5</sup>

Most FDA user fee programs include a legislatively required level (a so-called “trigger”) of baseline appropriations as part of their statutory authorization. A required level of appropriations assures that user fees are additive to, rather than replacing, appropriations funding. This means that user fees cannot be collected in any given year if the established trigger-level of, or baseline, appropriations is not met. The Foods Program has some trigger protection, as FSMA-related fees must be refunded unless FDA’s Food Safety Appropriation is equal to or greater than the FY 2009 level, exclusive of user fees, and adjusted for increases as required by the statute. There is, however, significant confusion both inside FDA and in the stakeholder community about the impact (or lack thereof) related to the appropriation triggers in the user fee programs. The Panel recommends that FDA bring greater transparency, both internally and externally, to the facts related to the impact of the trigger language associated with user fees on the Human Foods Program. The lack of a common understanding on this issue leads to a lack of trust and a distraction from more productive activity.

Historically, Human Foods Program user fees have not been implemented and prior efforts to establish substantial user fee structures for the Human Foods Program have been unsuccessful. Much of the Agency’s regulatory authority for foods is positioned in a post-market structure (i.e., most food products do not involve any sort of pre-market approval). Comparatively, many other FDA programs (e.g., drugs, biologics, medical devices) have pre-market authority review. This post-market-predominant structure is less aligned with industry-based user fees that (typically) support market-entrance services, such as human and animal drug, biologic or medical device review. There is also significant skepticism in the public interest community about the potential for “industry capture” of the Human Foods Program if FDA is overly reliant on industry fees. Efforts to establish structures to secure additional industry funding, such as enhanced registration fees, may address these concerns. While the Panel acknowledges these concerns, the Panel recommends that FDA explore whether common ground can be found on this issue.

### **Information Technology**

Additional funding would help FDA bolster its information technology. Modern information technology is an important tool that allows for the access and exchange of data in real time to all the people involved in a response or action. Common or shared agency activities, such as IT, have received considerable attention in recent years. Initiatives such as the Technology Modernization Action Plan (2019), Digital Modernization Action Plan (2021) and Enterprise Modernization Plan (2022) are supposed to provide a framework to integrate all aspects of FDA operations. However, without an overarching plan and adequate resources, this vision has not been realized. For example, there are multiple systems for the public and other stakeholders to submit product safety and quality complaints and the disconnect between these systems contributed, in part, to FDA’s delayed response to the outbreak of illness from infant formula.<sup>23</sup>

Without sufficient personnel, financial, and IT resources, a number of critical food safety and nutrition activities have slowed or even stalled, including FSMA implementation (and accompanying inspection

mandates) as well as nutrition labeling, food additive, and Generally Recognized As Safe-designation (GRAS) reviews. Critical staff have departed the FDA Human Foods Program because of pay disparity, and recruiting challenges continue; food safety issues divert scarce resources from nutrition and other human foods program activities.

## **Recommendations**

### **Personnel and Workforce Resources**

*FDA should secure the agile hiring authorities and salary flexibility of the 21<sup>st</sup> Century Cures Act to improve its ability to recruit, hire, and retain personnel with the needed skills to effectively meet its public health mandate around food. FDA should also work with OPM to develop solutions to facilitate hiring professionals matching the Human Foods Program's needs. [Recommendation/Resources1/(Also in Authorities)]* This authority has provided the incentives and process improvements necessary to attract highly qualified candidates and has even encouraged some in the Human Foods Program to move into the medical product area. Given ongoing advancements in science and technology, the Human Foods Program urgently needs these hiring and salary authorities.

*To further expand its utilization of state capabilities, FDA should move to a stronger, more cooperative relationship with states and other local authorities. [Recommendation/Resources2]* Field operations are the responsibility of ORA, and approximately half of the human food inspections are done by states through contracts and cooperative agreements. In FY 2022, FDA and state partners conducted 13,190 human food inspections. In that same fiscal year, over \$100 million<sup>38</sup> of ORA's approximately \$722 million food-related budget was provided to SLTTs to fund FDA inspections and sample collection/analysis, as well as build SLTT regulatory infrastructure, capacity, and capabilities. This partnership is critical to the success of FDA's food safety program. While this should be a strong partnership, the Panel heard tension and frustration regarding the lack of data sharing and a sense of being something less than true partners. Further, SLTT programs often compete with FDA for funding. When budget cycles are shortened due to lack of Congressional action, SLTT programs are sometimes used as a budget balancer where funds might be suddenly added when they cannot be spent elsewhere or reduced when other spending priorities are identified. These sudden changes are disruptive to SLTT partners. Moving from a competitive to a cooperative environment should help address these budgetary challenges and allow FDA to view SLTTs as additive staff to support the Agency in accomplishing its food safety mission.

*To help Agency staff keep pace with scientific advancements and industry innovation, FDA should expand staff engagement in outside conferences. [Recommendation/Resources3]* Directives<sup>39</sup> from OMB significantly reduced travel expenses and established new policies and practices for conference sponsorship, hosting, and attendance. These directives have reduced government employee participation in scientific conferences, which has 1) resulted in a disconnect between federal agencies and their stakeholders, and 2) impeded the ability of federal scientific agencies to recruit and retain

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<sup>38</sup> FDA Human Foods Program (ORA)

<sup>39</sup> OMB Guidance. Accessed December 2, 2022. <https://www.govinfo.gov/content/pkg/CFR-2015-title2-vol1/pdf/CFR-2015-title2-vol1-sec200-474.pdf>

highly qualified scientists. Several entities, including the FDA Science Board, have called for increased participation of FDA employees in scientific and technical conferences. Such attendance would facilitate Human Foods Program staff (in policy and inspectional roles) to maintain their scientific expertise, keep pace with innovation and changes, interact formally and informally with peers and stakeholders regarding the Human Food Program's goals and priorities, and recruit new talent.

*To develop a workforce pipeline of future FDA Human Foods Program staff and improve scientific engagement, FDA should develop and implement a strategic plan for a robust competitive external research structure.* [Recommendation/Resources4] As stated previously, FDA struggles to recruit, hire and retain a trained workforce with the skills needed to fulfill FDA's food safety and nutrition missions. One factor contributing to this is the lack of trained individuals coming through the academic pipeline. In academia, research and training funding greatly influences the development of the workforce pipeline but such funding opportunities are limited for food safety and, to a lesser degree, nutrition. For example, the National Institutes for Health have not traditionally funded food safety research, viewing that as the purview of USDA, which focuses in a slightly different direction on improving food, agricultural and natural resource systems. To expand the Human Foods Program workforce pipeline, FDA should develop a strategic plan for external research and training needs and implement cooperative agreements with academia and/or partner with research funding agencies to address these needs. The Human Foods Program should also explore how research programs of other areas of FDA, such as the Orphan Products Grants Program and the Center for Tobacco Products, might be mirrored in the Human Foods Program.

*FDA should develop and adequately resource an internal Human Foods Program research strategy.* [Recommendation/Resources5] The Human Foods Program requires a strong research approach that links regulatory actions, particularly when controversial, to evidence from in-house or credible external research findings. A strength of the Human Foods Program and the basis of its regulations are its foundations in science. A competitive Federal research structure for food safety and nutrition--keeping pace with innovation and industry advancements--is challenging but needed.

## Financial Resources

*FDA should give the highest priority to the formulation of an appropriations strategy that begins with a well-defined agenda and a clear case for why increased Program funding is necessary.*

[Recommendation/Resources6] FDA, with support from the HHS Secretary, should develop a two-prong strategy to increase funding for the Human Foods Program, with increasing Congressional funding as the first prong. This strategy should include, at a minimum, enhancements to the nutrition program, chemical safety work (e.g., food additives, review of Generally Recognized as Safe list), implementation of FSMA, and resources for SLTT partners – all of which have widespread stakeholder support for greater resources. This strategic agenda should clearly articulate the activities FDA will be able to undertake, the staff and facilities needed to support its mission and the public health benefits that will be achieved. FDA will need to build support within HHS, and then more broadly within the Administration. With HHS support, FDA should work with the stakeholder community and then Congress to see this ambition realized. In formulating this strategy, the Panel urges FDA to heed the House

Appropriations Committee concerns as noted in the FY 2023 report and then work with Congress to ensure needs are appropriately and effectively communicated.<sup>40</sup>

*Separately, FDA should more fully implement the industry fee authorities provided by FSMA. In addition, while the Panel recognizes that prior efforts have been unsuccessful, FDA should actively engage stakeholders to explore additional mechanisms for industry support of the Human Foods Program.*

[[Recommendation/Resources7](#) (Also in Authorities)] Due to long-standing opposition to industry fees to finance the Human Foods Program, this pathway faces longer odds than the appropriations pathway. However, states have a long history of assessing annual fees to facilities registered in their states. Such an approach may be feasible at the federal level. FDA is encouraged to invest some finite time to seriously explore whether a consensus can be reached in the stakeholder community for industry fees as a funding source for the Human Foods Program.

*Internally, FDA should do more to support the Human Foods Program budget.*

[[Recommendation/Resources8](#)] The FDA Office of the Commissioner should utilize its limited budget flexibility, particularly within the Office of the Commissioner, to allocate some funding to the FDA Human Foods Program. Only a small amount of the total Agency budget supports the FDA Human Foods Program, and the Panel encourages the Commissioner to identify additional funding, such as:

- Commissioner-level activity, such as the Foods Advisory Committee recommended in the Structure section of this report, could be funded by the Office of the Commissioner.
- The Office of the Commissioner budget may also be a source of funding, for a limited time, for more administrative needs, such as Human Resources, IT, and Communications, which would conserve Human Foods Program funding for programmatic efforts.
- Retaining within the Program any efficiencies gained in Human Foods Program re-organization.

The Human Foods Program also warrants more support because of the competitive advantage provided to most user-fee-funded activity of other centers. FDA should use these requested improvements to augment its staff with a range of personnel, including epidemiologists, physicians and nurses, toxicologists, nutritionists, data scientists, statisticians, investigatory and import staff, milk safety specialists, retail food specialists, shellfish specialists, food technologists, consumer safety officers, and project managers.

## Information Technology

*FDA should invest and adequately resource its Enterprise Modernization initiative, particularly the Human Foods Program components.* [[Recommendation/Resources9](#)] FDA needs considerable resources to build a cohesive system that replaces the various independent information collection systems that do not interact with each other. However, the lack of resources and other challenges have made it difficult for the Agency to achieve this goal and establish an effective system. FDA's Enterprise Modernization

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<sup>40</sup> That Appropriations report stated: "The FDA budget document has become unwieldy, running around 400 pages and providing a lot of information that is not directly relevant to the budget ... The Committee directs FDA to radically revise its budget presentation...". <https://www.congress.gov/117/crpt/hrpt392/CRPT-117hrpt392.pdf>



Action Plan is designed to provide a framework to integrate all aspects of FDA's operations in support of cross-Agency initiatives to optimize common and essential business processes and enhance operational efficiency while strengthening the alignment between Agency-wide strategic objectives and investments. FDA should consider the feasibility, resource requirements, and potential benefits of connecting existing IT systems or developing a single system to receive, track, and process information and ensure timely notification of appropriate personnel of potential signals of significant public health threats.

The Panel stresses the importance of involving the users of the IT systems in the planning process. Without the insights from FDA staff and SLTT partners, new or enhanced systems may fail to include key components and opportunities for connections. FDA should review its systems and processes for receiving information from external parties, including industry, consumers, other federal agencies, and SLTT and international regulators regarding product safety and quality, adverse events, and manufacturing. Among other benefits, a robust IT system could consolidate emergency notifications from stakeholders and alert appropriate personnel in a timely manner and efficiently communicate with states and across the Human Foods Program enterprise. Additionally, it is critical to focus on IT to protect against cybersecurity breaches.

## Authorities

Since the inception of FDA, and as acknowledged in the Introduction, the remit of the Agency in food oversight has grown significantly.<sup>41</sup> Congress has tasked FDA with performing a wide range of standard-setting and oversight activities involving food and chemical safety, nutrition labels and fortification, and dietary supplement oversight. Through the course of its work, the Panel identified important, and in some cases, urgent areas where additional authority should be considered and areas where the Agency could be bolder—both in policy development and enforcement—in exercising its existing authority. The Panel also identified a list of potential new authorities to strengthen the Human Foods Program.

### Proposed New Authorities

#### **Personnel and Workforce-Related (Urgent)**

*FDA should secure the agile hiring authorities and salary flexibility of the 21<sup>st</sup> Century Cures Act for the Human Foods Program to improve its ability to recruit, hire, and retain personnel with the expertise and skills that can support the Agency's efforts to effectively meet its public health mandate around food.*

[[Recommendation/Authorities1](#) (Also in Resources)]

The Human Foods Program is challenged in recruiting, hiring, and retaining managers and staff. Food innovation and science advancements are happening across all food product categories and the Agency must be appropriately staffed to protect public health today and in the future. Innovation in food and regulatory science is increasing exponentially, and FDA needs the agility to compete with industry and technology companies for the right expertise and staff. The ability to recruit, hire and retain scientists is imperative to meeting FDA's public health mission regarding food. The Human Foods Program currently<sup>41</sup> has 237 vacancies and is seeking to hire scientific experts in a highly competitive market. To fully address current and future staffing gaps, the Human Foods Program needs both modern hiring and compensation tools to employ the right expertise and compete in a highly competitive job market. Through Title 21 CURES Authority, the Commissioner has the authority, in specified programs only, to hire and set the annual rate of pay for outstanding and qualified candidates to scientific, technical, or professional positions that support the development, review, and regulation of medical products. Given the advancements in science and technology that are occurring in the food industry, the Human Foods Program also needs these hiring and salary authorities. While the hiring authorities are critical, without adequate resources, the values of this authority will not be fully realized.

#### **Data Reporting and Data Sharing Authority (Urgent)**

*FDA should seek to amend the Federal Food, Drug, and Cosmetic Act, specifically, section 708 (21 U.S.C. 379), to allow for disclosure of non-public information to state, local, and U.S. territorial government agencies with counterpart functions related to FDA-regulated products by preempting related state, local, or territorial disclosure laws.* [[Recommendation/Authorities2](#)]

SLTTs play an important role in the protection of public health, particularly as FDA partners in the regulation of products, helping to ensure the safety and integrity of the supply chain, and assisting in enforcement against unlawful products. Information sharing, for example, during joint responses to emergencies and outbreaks, inspection and investigatory initiatives and recalls, may be delayed or

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<sup>41</sup> As of November 28, 2022.

limited because of the boundaries placed on FDA's authority to disclose non-public information. These limits on information sharing compromise regulatory collaboration and may increase public health risks. This amendment would allow FDA to work more closely with their regulatory partners and more effectively leverage the oversight capabilities and resources of those partners. It should allow for increased mutual reliance related activities and other partnerships by expanding and expediting information sharing.

*FDA should seek authority to:*

- *Request records from food manufacturers in advance of or in lieu of an inspection, with a reasonable timeframe, within reasonable limits, and in a reasonable manner, and either in electronic or physical form.*
- *Be notified when designated food categories, such as medical foods/infant formula, are likely to experience shortages or when supply chain disruptions are anticipated.*

[Recommendation/Authorities3]

Given the size and complexity of today's food supply, the number of foreign and domestic establishments that require inspection, and the need to maintain continuity in the food supply, it is important that FDA and industry have a process to ensure the collection of and access to critical information. Currently, FDA's Human Foods Program relies on physical presence to inspect facilities and confirm establishments have and are adhering to a food safety plan. Similarly, the Human Foods Program relies on intermittent communications with industry to learn about potential supply chain challenges. Both the recent infant formula crisis and COVID-19 illuminated more about the information needed to protect and sustain the food supply. FDA needs access to appropriate information to be able to work with industry to address food supply challenges and when in-person inspections are not possible. Additionally, the ability to request records for remote assessment would help FDA have a better real-time view into industry compliance with FSMA. Information sharing between FDA and industry should be strengthened to provide alternate tools for oversight of food products and establishments. These authorities would allow FDA to request records in advance or in lieu of an inspection and industry's compliance would be mandatory. This would help the Human Foods Program gain "remote access" to inspection records and test results and to obtain information on significant toxicological data associated with new chemicals.

### **Funding (Urgent)**

*FDA should seek a substantial amount of 'no-year' funding for Human Foods Program, particularly for funding infusions intended to address longer term challenges (such as IT) and engagement with SLTT partners for inspectional activity. [Recommendation/Authorities4]*

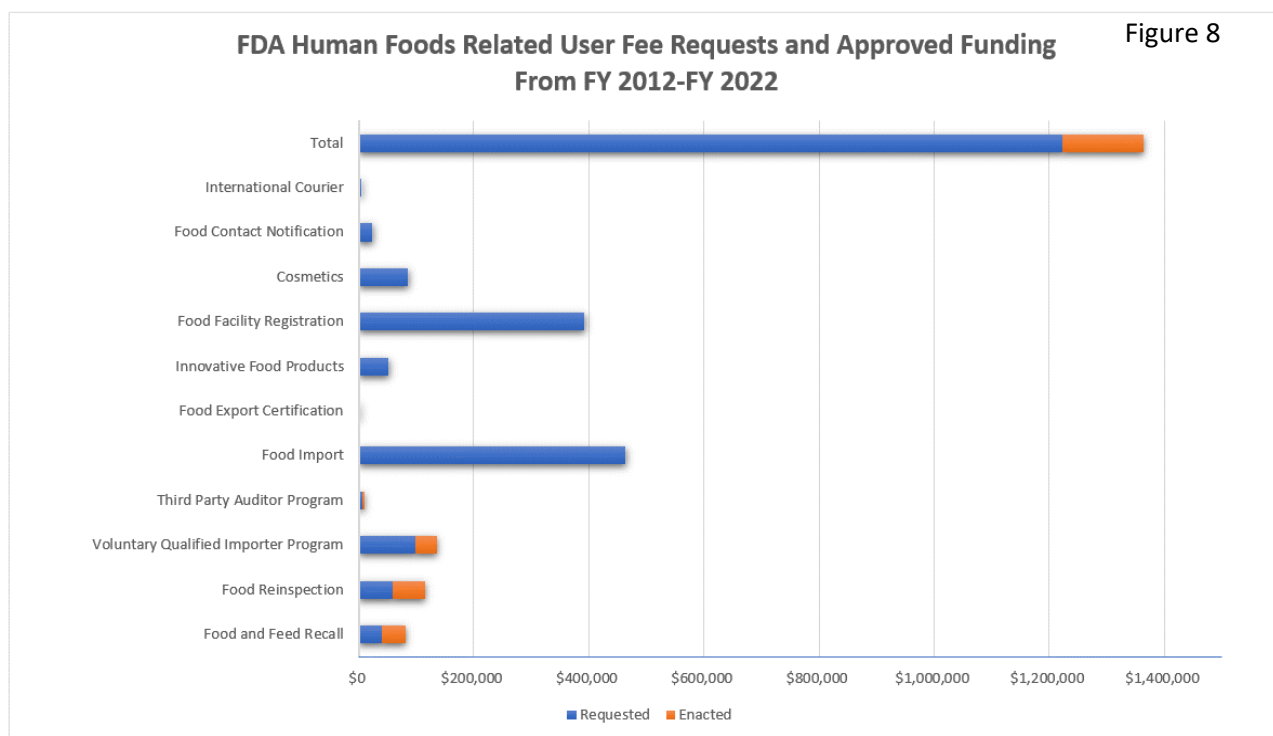
As described in the Resources section of this Report, short budget cycles have compromised the Human Foods Program implementation of funding increases and have reportedly yielded situations where a significant portion of the Foods budget was not awarded as planned. Providing more than the typical 12-month funding cycle to expend appropriated funds would allow the Human Foods Program to deploy resources more strategically and efficiently. When working with SLTT partners for inspectional or other activities, no-year funding could facilitate longer agreements with those partners and provide greater stability to the partners and to the FDA.

### Industry Fees (Important, but longer term)

*FDA should actively engage stakeholders to explore industry financial support, such as user or registration fees, to increase financial resources for the Human Foods Program.*

[Recommendations/Authorities5 (Also in Resources)]

The Human Foods Program is substantially under-funded; industry financial support could supplement increased federal funding. Due to long standing opposition by industry to such fees and public interest community concern regarding the potential for under industry influence of the Human Foods Program, prior attempts to establish significant industry user fees have not been successful (Figure 8 depicts prior use fee requests to Congress and those enacted). This pathway faces longer odds than the appropriations pathway, so it should be explored independently of the appropriations approach discussed in the Resources section of this report. However, states have a long history of assessing annual fees to facilities registered in their states. Such an approach may be feasible at the federal level. FDA is encouraged to invest a finite period to seriously explore whether a consensus can be reached in the stakeholder community for industry fees for both domestic and foreign firms as a funding source.



### Preventive Controls (Important, but longer term)

*FDA should seek authority to align the consequences for violations of the Preventive Controls rule requirements with the violations of FDA's food safety Hazard Analysis Critical Control Point (HACCP) requirements.* [Recommendation/ Authorities6]

FDA's existing requirements for Preventive Controls should be strengthened. Just as the lack of a HACCP plan or an inadequate plan renders the food from that processor adulterated under FDA's seafood and juice HACCP regulations, it should also render food adulterated under the Preventive Controls regulation.

## **Bolder Use of Existing Authorities**

The Panel recommends FDA be bolder in exercising its existing authority in the following areas:

### **Budget**

*FDA should strengthen its implementation and use of existing FSMA authority to collect user fees.*

[[Recommendation/Authorities7a](#) (also in Resources)]

FDA has limited existing user fee authorities that are currently not being used, but, if implemented, could provide additional funding. For example, under FSMA, FDA has authority to, but has not, collected domestic and foreign facility reinspection fees nor mandatory recall fees.

### **Generally Recognized as Safe (GRAS)**

*FDA should work with stakeholders to better structure the approach to the GRAS designation, including exploring a routine assessment of what qualifies for GRAS designation.* [[Recommendation/Authorities7b](#)]

*FDA should explore efforts to routinely review, either through an internal or a National Academies process, current and recent FDA practices related to GRAS implementation in light of current U.S. Dietary Guidelines and the evolution of modern manufacturing practices.* [[Recommendation/Authorities7c](#)]

The review would include an examination of how the authority is being used, and whether the full authority for GRAS exceptions is being appropriately and adequately utilized. An examination would also identify tradeoffs and feasibility issues for potential changes in practices overall and with respect to specific types of ingredients, as well as recommendations related to the most pressing public health nutrition issues.

### **Data Sharing**

*In addition to seeking new authority regarding data sharing and records access, FDA should explore applying existing authority that infant formula manufacturers must retain microbiological testing records—and that those records “shall be made available . . . for review and duplication upon request” by FDA— to require real time disclosure of final product testing results from infant formula manufacturers.*

[[Recommendation/Authorities7d](#)]

### **Mandatory Recall**

*FDA should use its mandatory recall authority more frequently, recognizing that a process should be in place to assure that accommodations are made for life-sustaining products that are the only source of nutrition for certain populations (e.g., infant formula).* [[Recommendation/Authorities7e](#)]

### **Nutrition Labeling**

*FDA should identify opportunities to monitor both industry and consumer behavior, to better understand industry implementation and consumer response to FDA’s nutrition initiatives.* [[Recommendation Authorities7f](#)]

For example, CFSAN’s recent finalization of voluntary sodium guidance is a positive step, but sufficient monitoring needs to take place to ensure the industry is indeed lowering sodium in the food supply. Simultaneously, it is critical to understand consumer acceptance of such changes.

*FDA should maintain the forward progress on “healthy” associated with the September 2022 White House Conference on Hunger, Nutrition and Health to lead to a timely approval and to establish a program for rigorous assessment and monitoring of the impacts of “healthy” on consumer and industry behavior. [Recommendation/Authorities 7g]*

### **New Authorities Raised for Consideration**

During the Panel’s work, several ideas for strengthening existing authorities were shared. The evaluation time was not sufficient for exploration of each of these ideas; the following ideas are included, in no particular order, for consideration by the Agency to explore, pending further stakeholder input, increased resources, or matters of priority.

- Expand the criteria for suspension of registration for food facilities
- Strengthen authority to destroy product after an administrative review or allow detention of product for a longer period to allow more time to pursue other remedies (e.g., a seizure action)
- Invoke Civil Money Penalties for various violations, like a failure to register
- Administrative authorities that allow FDA to use a progressive enforcement strategy that does not require a Serious Adverse Health Consequences or Death to Humans or Animals determination
- Ensure adequate time to review a new infant formula before the marketing of such new infant formula
- Strengthen authority addressing medical foods
- Update to application of the Delaney Clause as it relates to food additives to incorporate the application of modern toxicology approaches
- Clarify authority on how to regulate pharmacologically active extracts (e.g., Cannabis-derived products) used in the food supply
- Seek prior approval (pre-market) label approval authority
- Clarify FDA’s jurisdiction to access, investigate, and collect samples on property where food-producing animals are raised or graze (e.g., grazing lands and commercial animal operations) that are adjacent to or nearby produce farms or water sources to facilitate FDA’s investigation of foodborne illness outbreaks
- Ability to monitor industry and consumer behavior to improve food safety efforts

## Conclusion

As noted in the correspondence at the beginning of this report, the Panel is honored to have been selected for this important task and has worked diligently to review FDA's Human Foods Program culture, structure and leadership, resources, and authorities. FDA's work in food safety and nutrition affects every consumer in the nation, and our hope is to provide options to improve, strengthen, and expand current activity. We recognize that it will take time to consider this input and determine next steps. We look forward to the output of the Agency's deliberations and subsequent efforts to move the Human Foods Program toward a more enabling and effective culture, to change the organizational configuration in a way that will advance the FDA's foods-related mission, and to secure the additional personnel, financial, and IT resources to perform its Congressional mandate more effectively.

The FDA Human Foods Program has the opportunity to turn today's challenges into tomorrow's success; the Panel hopes this work will contribute to that success.

#### FDA STATEMENT

# FDA Conducting Evaluation of Key Agency Activities to Strengthen Operations

#### For Immediate Release:

July 19, 2022

#### Statement From:

Robert M. Califf, M.D., MACC  
Commissioner of Food and Drugs - Food and Drug Administration

In February 2022, I rejoined the U.S. Food and Drug Administration as Commissioner of Food and Drugs, having served in the role five years earlier. Since my return, the agency has taken many significant actions that benefit the public health. Yet at the same time, the agency has confronted a series of challenges that have tested our regulatory frameworks and stressed the agency's operations, prompting me to take a closer look at how we do business.

As a result, for two of the agency's key programs, I have commissioned external agency experts to conduct a comprehensive evaluation for:

**The agency's Human Foods Program, including the Office of Food Response and Policy (OFPR), Center for Food Safety and Applied Nutrition (CFSAN), as well as relevant parts of the Office of Regulatory Affairs (ORA)**

While America's food supply is safe, and our Foods program experts have significantly contributed to the availability of more nutritious food options for consumers, the program has been stressed by the increasing diversity and complexity of the nation's food systems and supply chain. Fundamental questions about the structure, function, funding and leadership need to be addressed. The agency's inspectional activities related to the program also need to be evaluated, particularly in light of stresses related to the COVID-19 pandemic.

**The Center for Tobacco Products (CTP)**

Just over 13 years ago, Congress tasked the FDA with regulating tobacco products. In the ensuing years, we have made important progress and reached regulatory decisions on a broad array of millions of products. But even greater challenges lie ahead as we determine how the agency will navigate complex policy issues and determine enforcement activities for an increasing number of novel products that could potentially have significant consequences for public health. CTP will continue its important work during the evaluation, including review pending applications and take enforcement actions as needed.



I have discussed this evaluation with the relevant leadership of these centers and offices, all of whom welcome the opportunity to work towards organizational excellence. Each of these areas are full of hardworking and talented individuals who have dedicated their careers to working across a variety of scientific, policy, legal and administrative activities. FDA employees deserve the best support possible so they can fulfill their strong commitment to public health – and the American public that we serve.

**The Reagan-Udall Foundation**, an independent partner organization for the agency, will be working with an external group of experts on the evaluation. The Foundation will report its findings, including an initial assessment of the processes and procedures, resourcing, and organizational structure for the Foods program and CTP, to the agency within 60 business days of initiation. It may take some time to implement any recommended changes, but I am committed to addressing them and communicating them to the public in a timely manner. It is my belief that this effort will continue strengthening the FDA and better position the agency to deal with the many immediate public health issues we are facing, while preparing for the many scientific challenges and fascinating opportunities of the future.

###

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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## Inquiries

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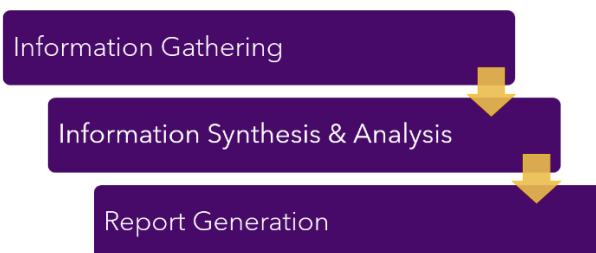
## Appendix B

### FDA Evaluation Methodology

On July 19, 2022, FDA Commissioner Robert M. Califf asked the Reagan-Udall Foundation to facilitate, via two Independent Expert Panels, operational and programmatic evaluations of FDA’s human foods and tobacco programs.

The Human Foods Program Panel was established and announced on August 17, 2022, comprised of researchers, former regulators, and process improvement specialists with disciplinary expertise and experience in epidemiology, food science and safety, microbiology, nutrition, and regulatory operations. Former Commissioner of Food and Drugs Jane E. Henney, MD, chaired the Panel which was comprised of Francisco Diez-Gonzalez, PhD; James Jones; Barbara Kowalczyk, PhD; Shiriki Kumanyika, PhD, MS, MPH; and John Taylor, JD.

The Panel used a three-phase evaluation protocol focused on structure/leadership, authority, resources, and culture, spanning 60-business-days between September 8, 2022, and December 6, 2022. (The scope of the requested review excluded FDA’s Center for Veterinary Medicine and cosmetic and dietary supplement responsibilities.) The evaluation process consisted of (1) Information Gathering; (2) Information Synthesis and Analysis; and (3) Report Generation.



#### Information Gathering

The Panel gathered information, perspectives, and experiences from numerous sources, including an online Stakeholder Portal, in-person stakeholder meetings, and one-on-one interviews with FDA officials and stakeholders.

*In-Person Stakeholder Meeting:* The Panel heard from 38 stakeholders during two days of in-person meetings on Thursday, September 29, 2022, and Friday, September 30, 2022. The meetings, held at the PATH offices in Washington DC, allowed stakeholders to share insights and interact directly with the Panel. Each session had a single moderator and a cross-section of up to six panelists who were each given up to 5 minutes of remarks followed by a question-and-answer period with the Panel. Topics included: nutrition programs, food safety, intra-federal relations, state/federal relationships, resources, and innovation. The meetings were open to the public and live audio was made available online via Zoom webcast; more than 140 people attended either virtually or in-person.

*Stakeholder Portal:* The Stakeholder Portal, which was announced via [press release](#), allowed stakeholders to share their insights about what is working in FDA’s human foods program, the challenges it faces, and suggestions to improve program operations. The Stakeholder Portal remained open from noon (eastern) on September 16, 2022, until 11:59 p.m. (eastern) on October 7, 2022, and receiving 274 public comments in total. Commenters were asked to self-identify their stakeholder group from among the following options: Academia, Advocacy, Association/Organization, Consultant, Consumer/Consumer Advocate, FDA Staff, Producer, Public Health/Medical, State/Local/Tribal Territorial Government, and Other. The comments were shared with and closely reviewed by the Panel charged with generating the recommendations for FDA. Commenters were provided the option to remain anonymous; the details of those who included their contact information were shared with the Panel along with their comment. Most of the comments were available publicly while the Portal was open, except those that identified individuals by name or by current government position, which were shared only with the Panel.

*One-on-One Interviews:* More than 20 additional subject matter experts, current FDA staff, and former FDA leaders were engaged for interviews with the Panel to complete the Information Gathering phase of the operational and programmatic evaluation.

### **Information Synthesis and Analysis**

Following the Information Gathering phase, the Panel compiled, reviewed, synthesized, and analyzed the various sources of information, including all comments received online or in-person. This process included multiple days of in-depth, in-person work by the Panel. The Panel identified key findings and possible recommendations and began outlining the report.

### **Report Generation**

Building on the outline developed during the Information Synthesis and Analysis phase, the Panel aligned recommendations for the final report presenting more than one option where possible. Those recommendations and accompanying rationale were detailed to produce the final report for consideration by the Commissioner.

The Panel was supported by food and nutrition experts at [Food Directions, LLC](#) and Reagan-Udall Foundation staff.

## Appendix C

### Panelist Biographies

#### **Jane Henney, MD (Chair)**

Jane Henney, MD, was Commissioner of Food and Drugs at the U.S. Food and Drug Administration from November 1998-2001. She previously served as the Agency's Deputy Commissioner for Operations, and held multiple posts, including Deputy Director, at the National Cancer Institute of the National Institutes of Health and senior leadership positions at three academic health sciences centers (the University of Kansas Medical Center, University of New Mexico Health Sciences Center and the University of Cincinnati Health Sciences Center). She is a member and former elected officer of the National Academy of Medicine.

#### **Francisco Diez-Gonzalez, PhD**

##### **Director and Professor, Center for Food Safety, University of Georgia**

Francisco Diez-Gonzalez, PhD, a food safety microbiologist, is Director of the Center for Food Safety and a Professor in the Department of Food Science and Technology at the University of Georgia's College of Agricultural and Environmental Sciences. He conducts research aimed to control foodborne pathogens and is a member of the USDA's National Advisory Committee on Microbiological Criteria for Foods.

#### **James Jones**

##### **President, JJones Environmental**

James Jones is President of JJones Environmental, following a 30-year career at the U.S. Environmental Protection Agency. His posts at EPA included five years as the Assistant Administrator, and his accomplishments include leading the agency's effort to significantly reduce pesticides in food and navigating a years-long backlog of pesticide registrations and tolerances as well as leading the Obama Administration's efforts to reform the Toxic Substances Control Act.

#### **Barbara Kowalcyk, PhD, MA**

##### **Director, Center for Foodborne Illness Research and Prevention**

##### **Associate Professor, Department of Food Science and Technology**

##### **Core Faculty, Translational Data Analytics Institute**

##### **The Ohio State University**

Barbara Kowalcyk, PhD, directs the Center for Foodborne Illness Research and Prevention at The Ohio State University's College of Food, Agricultural, and Environmental Sciences and is Associate Professor of Food Safety and Public Health in the Department of Food Science and Technology. She is a well-respected epidemiologist and biostatistician, and a nearly ten-year member of the FDA Science Board, which she currently chairs.

**Shiriki Kumanyika PhD, MS, MPH**

**Research Professor, Community Health and Prevention, Drexel University**

Shiriki Kumanyika, PhD, MS (Social Work), MPH, is Research Professor in the Department of Community Health and Prevention at Drexel University's Dornsife School of Public Health. She is also Emeritus Professor of Epidemiology at the Perelman School of Medicine, University of Pennsylvania. Dr. Kumanyika has applied her interdisciplinary background and extensive research experience in numerous roles related to nutrition policy. She is a member of the National Academy of Medicine and currently chairs the National Academies Food and Nutrition Board.

**John Taylor, JD**

**President and Principal, Compliance and Regulatory Affairs, Greenleaf Health**

John Taylor, JD, is President and Principal, Compliance and Regulatory Affairs, at Greenleaf Health. He spent more than 20 years at FDA, holding posts that included Counselor to the Commissioner, Acting Deputy Principal Commissioner, Acting Deputy Commissioner for Global Regulatory Operations and Policy, and Associate Commissioner for Regulatory Affairs.

## Appendix D



### Independent Expert Panel FDA Human Foods Program (Public Stakeholder Meeting)

455 Massachusetts Avenue NW, 10<sup>th</sup> Floor

Washington, DC

September 29 & 30, 2022

#### AGENDA

##### DAY ONE

##### 10 a.m. Welcome

*Speaker:* Susan C. Winckler, RPh, Esq., CEO, Reagan-Udall Foundation for the FDA

##### 10:05 a.m. Meeting Overview

*Speaker:* Jane Henney, MD, Panel Chair and 18<sup>th</sup> Commissioner of Food and Drugs

##### 10:15 a.m. Session One: Nutrition Initiatives

*Moderator:* Jerold Mande, MPH

CEO of *Nourish Science*, Adjunct Professor of Nutrition, Harvard T.H. Chan School of Public Health, and a Visiting Fellow, Tufts University

*Speakers:*

- Emily Broad Leib, JD, Harvard Law School
- Kevin Hall, PhD, National Institute of Diabetes & Digestive & Kidney Diseases
- Barry Popkin, PhD, UNC Gillings School of Global Public Health
- Barbara Schneeman, PhD, UC Davis Department of Nutrition
- Nicole Nice, JD, Mars, Incorporated
- Sally Greenberg, JD, National Consumers League

##### 11:45 a.m. Session Two: Food Safety

*Moderator:* Georges C. Benjamin, MD

CEO, American Public Health Association

Board Member, Reagan-Udall Foundation for the FDA

*Speakers:*

- Bill Marler, JD, Marler Clark LLP, PS
- Mitzi Baum, MS, Stop Foodborne Illness
- Scott Faber, Environmental Working Group
- Jennifer McEntire, PhD, International Fresh Produce Association

- [Caroline Smith DeWaal, JD](#), EatSafe at GAIN
- [David Goldman, MD, MPH](#), formerly of FDA's Office of Food Policy and Response

**1:10 p.m. LUNCH**

**2:10 p.m. Session Three: Intra-Federal Relations**

*Moderator:* [Dale Morse, MD, MS](#)

Adjunct Professor, Emory University, Rollins School of Public Health  
Former Associate Director for Food Safety in the Division of Foodborne, Waterborne and Environmental Diseases, CDC

*Speakers:*

- [Stephen Ostroff, MD](#), Ostroff Consulting
- [Steve Sundlof, DVM, PhD](#), formerly of the U.S Food and Drug Administration
- [Roberta Wagner](#), Consumer Brands Association
- [Brian Ronholm](#), Consumer Reports
- [John Besser, PhD](#), formerly of the U.S. Centers for Disease Control and Prevention

**3:35 p.m. Adjourn Day One**

**DAY TWO**

**10 a.m. Welcome & Brief Overview**

*Speaker:* [Susan C. Winckler, RPh, Esq](#), CEO, Reagan-Udall Foundation for the FDA

**10:05 a.m. Session Four: Federal/State Relationships**

*Moderator:* [Shari Shea, MHS, MT \(ASCP\)](#)

Director, Food Safety Programs  
Association of Public Health Laboratories

*Speakers:*

- [De Ann Davis, PhD](#), Western Growers
- [Carlota Medus, PhD, MPH](#), Minnesota Department of Health
- [Steven Mandernach](#), Association of Food and Drug Officials
- [Joseph Reardon](#), National Association of State Departments of Agriculture
- [Ellen Morrison](#), formerly of the U.S. Food and Drug Administration

**11:35 a.m. Session Five: Resources**

*Moderator:* [Steven Grossman, JD](#)

Executive Director, Alliance for a Stronger FDA

*Speakers:*

- [Jessica Schulken](#), The Russell Group, Inc.

- [Maureen Holohan](#), Avise Solutions
- [Carolyn Brickey, JD](#), formerly of the U.S. Food and Drug Administration
- [Thomas Gremillion](#), Consumer Federation of America
- [Donna Garren, PhD](#), American Frozen Food Institute

**1 p.m. LUNCH**

**2 p.m. Session Six: Positioning FDA for the Future: Understanding the Changing Food Supply (Sustainability, Supply Chain Dynamics, Climate Change, Emerging Food Preferences)**

*Moderator:* [Molly Fogarty](#)

Head of Corporate & Government Affairs, Nestlé

Board Member, Reagan-Udall Foundation for the FDA

*Speakers:*

- [J. Glenn Morris, MD](#), University of Florida's Emerging Pathogens Institute
- [Lee-Ann Jaykus, PhD](#), NC State University's Department of Food
- [Sharon Natanblut](#), Natanblut Strategies
- [Sarah Sorscher, JD, MPH](#), Center for Science in the Public Interest
- [Hilary Thesmar, PhD, RD, CFS](#), The Food Industry Association
- [Cindy Jiang](#), McDonald's

**3:25 p.m. Adjourn Meeting**



## Appendix E

# Stakeholders

*The online Stakeholder Portal received 274 comments.*

*The following stakeholders provided input to the Independent Expert Panel outside of the Portal.*

### Individuals

Acheson, David	Medus, Carlota
Barfell, Glenda	Mettler, Erik
Baum, Mitzi	Miles, Pamela
Beckerman, Peter	Montalbano, Angela
Benjamin, Georges	Morris, JG
Besser, John	Morrison, Ellen
Brackett, Robert	Morse, Dale
Brickey, Carolyn	Musser, Steven
Broad Leib, Emily	Natanblut, Sharon
Buckner, Rebecca	Nice, Nicole
Califf, Robert	Ostroff, Stephen
Christin, Charlotte	Oxenham, Ann
Cohen, Caitlin	Pillsbury, Laura
Colonus, Tristan	Plaisier, Melinda
Davis, De Ann	Popkin, Barry
Dutcher, Michael	Raza, Mark
Eschmeyer, Debra	Reardon, Joseph
Faber, Scott	Reikes, Peter
Fogarty, Molly	Rogers, Michael
Fristedt, Andi	Ronholm, Brian
Garren, Donna	Roth, Lauren
Goldman, David	Sauer, Don
Greenberg, Sally	Schneeman, Barbara
Gremillion, Thomas	Schulken, Jessica
Grossman, Steven	Shea, Shari
Hall, Kevin	Simon, Katherine
Holohan, Maureen	Sklamberg, Howard
Jaykus, Lee-Ann	Smith DeWaal, Caroline
Jiang, Cindy	Solomon, Steven
Kux, Leslie	Sorscher, Sarah
Landa, Michael	Sundlof, Steve
Levitt, Joe	Tauxe, Robert
Lynch, Kara	Taylor, Michael
Mande, Jerold	Thesmar, Hilary
Mandernach, Steven	Tierney, Julia
Marler, Bill	Wagner, Roberta
Mayl, Sharon	Walter, Elaine
Mayne, Susan	Wirsing, Elizabeth
McEntire, Jennifer	Woodcock, Janet
McMeekin, Judith	Yiannas, Frank

## **Organizations**

American Bakers Association  
American Frozen Food Institute  
Antibiotic Resistance Action Center  
Association of Food and Drug Officials  
Center for Biological Diversity  
Center for Food Safety  
Center for Science in the Public Interest  
Consumer Brands Association  
Consumer Federation of America  
Consumer Reports  
Corn Refiners Association  
Environmental Defense Fund  
Environmental Working Group  
The Food Industry Association  
Friends of the Earth  
Global Cold Chain Alliance  
Healthy Babies Bright Futures  
International Fresh Produce Association  
Johns Hopkins Center for a Livable Future  
National Confectioners Association  
National Consumers League  
National Fisheries Institute  
National Grocers Association  
National Pasta Association  
National Restaurant Association  
National Seasoning Manufacturers Association  
Natural Resources Defense Council  
North American Millers' Association  
Peanut and Tree Nut Processors Association  
Refrigerated Foods Association  
SNAC International  
STOP Foodborne Illness  
Western Growers



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