



Food Evaluation Independent Expert Panel Stakeholder Meeting

October 14, 2022

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The Center for Science in the Public Interest (CSPI), “Your Food and Health Watchdog,” is grateful for this opportunity to submit written comments on the Reagan-Udall Foundation’s operational evaluation of the FDA foods program.

For over 50 years, CSPI has been a leading voice for consumers in the food system. As an independent organization, we do not take gifts from industry or grants from government, and we are uniquely positioned to comment on the agency’s foods program, as much of our work over the years has been in advocating for the FDA policies that shape our food system, from food labeling to food safety.

This testimony focuses on 10 core areas where innovation is needed to position FDA for the future. These are: Leadership, Communication, Culture, Funding, Transparency, Technology, Public health-based priority setting, Legislation, Enhanced Scientific Capacity, and Assessment.

1. Leadership

Perhaps the most important challenge before the agency is ensuring strong leadership with clear divisions of responsibility and lines of authority. Regardless of what structure the Foundation recommends, these principles are paramount. It is clear that the current structure, with a Deputy Commissioner and a Center Director both reporting to the Commissioner, has produced confusion, inefficiency, and poor communication.

A clear chain of command is essential to ensure the agency is responsive and effective in its day-to-day work, but is particularly necessary for swift action in a time of crisis, as demonstrated most recently during the FDA’s response to the Abbott infant formula outbreak. As stated in the FDA Evaluation of Infant Formula Response published by Center for Veterinary Medicine Director Steven Solomon in September 2022 “[t]he emergency response to this food safety incident lacked clarity of roles between programmatic and incident command standard operating procedures.”¹ These issues could be resolved more easily and effectively under more streamlined leadership.

Strengthening the Center for Food Safety and Applied Nutrition’s (CFSAN’s) relationship with the Office of Regulatory Affairs (ORA) is critical. Following ORA realignment in the 2010s, the Center for Drug Evaluation and Research (CDER) developed a Concept of Operations that governed relations between the two entities in an effort to establish clear lines of authority and

¹ Solomon S. FDA Evaluation of Infant Formula Response, September 2022. <https://www.fda.gov/media/161689/download>. Accessed October 14, 2022.

improve communications.² A similar structure is worthy of consideration in the foods area as well.

Leadership is also needed at a higher level to foster cross-agency coordination. As the U.S. Government Accountability Office (GAO) has noted, “federal agencies have not developed a national plan or strategy for food safety.”³ The recent infant formula outbreak involved the Departments of Justice, Agriculture, Health and Human Services, and the Centers for Disease Control and Prevention, among others.⁴ Similarly, a recent Government Accountability Office report identified 21 federal agencies involved in efforts related to diet.⁵ To coordinate these efforts in food and nutrition, CSPI has recently recommended the creation of a working group to lead cross-agency efforts in food and nutrition, led by a White House Deputy Assistant.⁶ A similar intra-governmental structure was assembled in order to develop the recently released National Strategy on Hunger, Nutrition, and Health.

2. *Communication*

CFSAN has authority over a wide array of products beyond conventional foods: infant formula, medical foods, food and color additives, dietary supplements, and cosmetics. And it must protect against both acute (e.g., pathogens, allergens) and chronic diseases (e.g., diet-related diseases). But, across this wide range of responsibilities, agency leaders can be reticent to exhibit bold leadership. The FDA lacks adequate communication and coordination across the agency’s many siloed teams. Here, new leadership could play a role in developing an organizational plan to identify and enhance the processes and touchpoints by which teams coordinate.

Priority areas where teams should focus include ensuring that FDA’s outbreak investigation unit, Coordinated Outbreak Response and Evaluation (CORE), holds regular touchpoints with inspectional staff at FDA’s Office of Regulatory Affairs (ORA). The goal of these touchpoints would be to leverage information from inspections and outbreaks, and develop operational protocols, as suggested above, for swiftly directing inspectional resources in response to requests from CFSAN. This would ensure, for example, that inspections are scheduled in a timely manner to investigate outbreaks and conduct root-cause analyses, and that routine inspections are scheduled and carried out in a manner that reflects the policy priorities of the agency.

The agency should also ensure that all staff engaged in collecting information from the public are trained in identifying and elevating whistleblower complaints.

² Brown, NA, Sklamberg HR, FDA Implements a New Concept of Operations for Drug Inspections. September 5, 2017. <https://www.akingump.com/en/news-insights/fda-implements-a-new-concept-of-operations-for-drug-inspections.html>. Accessed October 14, 2022.

³ U.S. Government Accountability Office. Improving Federal Oversight of Food Safety. <https://www.gao.gov/highrisk/improving-federal-oversight-food-safety>. Accessed October 14, 2022.

⁴ *Ibid.*

⁵ Government Accountability Office. Chronic Health Conditions: Federal Strategy Needed to Coordinate Diet-Related Efforts. August 2021. <https://www.gao.gov/products/gao-21-593>. Accessed October 14, 2022.

⁶ Lurie P. Letter to President Joe Biden and Ambassador Susan Rice. May 26, 2022. <https://www.cspinet.org/resource/cspi-letter-white-house-re-conference-hunger-nutrition-and-health>. Accessed October 14, 2022.

3. Culture

FDA's administrative culture is also plagued by a slow pace and lack of accountability in developing new policies, and the agency often fails to take advantage of FDA's full authority to implement policy change. CSPI and other consumer groups have frequently been compelled to resort to litigation to advance policy at the FDA. For example, the agency delayed over a decade in responding to a 2005 CSPI petition to promote sodium reduction, leading CSPI to sue the agency to compel a response. FDA finally issued draft voluntary targets in 2016, which were only finalized in 2021.⁷ Similarly, the agency waited 6 years to respond to a straightforward CSPI petition requesting that sesame be labeled as an allergen in foods, eventually issuing only draft voluntary guidance on the subject.⁸ (Sesame labeling has since been required through an Act of Congress⁹).

The agency also fails to meet its own, internally established targets. For example, the agency's Closer to Zero Initiative Action Plan promised draft action levels for lead in categories of foods consumed by infants and young children by April 2022,¹⁰ but, as of October 2022, this guidance still remains pending on the agency's list of Foods Program Guidance Under Development.¹¹

Creating an organizational culture that is more responsive and accountable, that is has a clear public health focus, rather than a narrower technocratic focus, and that prioritizes the needs of the public, rather than those of the food industry, must be a key priority for culture reform.

4. Funding

Congress must create a sustainable source of funding for FDA's human foods program. In 2020, CFSAN employed about 1,200 full time equivalent (FTE) positions,¹² an amount that has barely moved since 1978, when the agency employed approximately 1,000 FTEs.¹³ In the meantime, the food system has changed dramatically, and FDA has been given new statutory responsibilities to fulfill, including transformative changes under the Food Safety Modernization Act. To respond to these responsibilities without new staffing, FDA is forced to cannibalize existing food programs, leading to unacceptable trade-offs. To avoid this and ensure the successful operation of the foods program, a secure source of funding must be identified.

⁷ Center for Science in the Public Interest, FDA issues voluntary sodium reduction targets. June 1, 2016. <https://www.cspinet.org/news/fda-issues-voluntary-sodium-reduction-targets-20160601>. Accessed October 12, 2022.

⁸ Center for Science in the Public Interest, Comment to FDA re: Voluntary disclosure as sesame as an allergen. March 1, 2021. <https://www.cspinet.org/resource/comment-fda-re-voluntary-disclosure-sesame-allergen>. Accessed October 14, 2022.

⁹ Center for Science in the Public Interest. CSPI celebrates passage of the FASTER Act making sesame a major food allergen. April 15, 2021. <https://www.cspinet.org/news/cspi-celebrates-passage-faster-act-making-sesame-major-food-allergen-20210415-0>. Accessed October 14, 2022.

¹⁰ U.S. Food and Drug Administration. Closer to Zero: Action Plan for Baby Foods. October 6, 2022. <https://www.fda.gov/food/metals-and-your-food/closer-zero-action-plan-baby-foods>. Accessed October 14, 2022.

¹¹ U.S. Food and Drug Administration. Foods Program Guidance Under Development. Content current as of 09/06/2022. <https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/foods-program-guidance-under-development>. Accessed October 12, 2022.

¹² Food and Drug Administration. Detail of Full-Time Equivalents. <https://www.fda.gov/media/132813/download>. Accessed October 14, 2022.

¹³ Levitt, JA et al. Joint Letter to Reagan-Udall Foundation Review Panel on Strengthening FDA's Human Foods Program. September 27, 2022.

CSPI also supports amending the FDA’s existing user fee legislation to ensure that user fees may not be collected unless base funding is maintained in the food program. This is a protection that currently exists for drugs and medical devices, but not foods, resulting in an untenable situation where any cuts to the overall agency budget are inevitably pulled disproportionately from the foods program.

5. *Transparency*

The agency should reform how it allocates resources and makes policy decisions, to make these processes more transparent.

One major challenge is how the agency communicates its annual budget to Congress and the public. Each year, the FDA develops a narrative theme for the budget cycle and organizes its reporting around that theme, as opposed to consistently reporting a breakdown of expenses within the foods program from year to year. This makes it impossible to understand how much the agency spends on dietary supplements, infant formula, or other offices within the foods program. Notably, the FDA budget format is structured this way across all products categories, so steps to modify this approach must be taken at the Commissioner level.

Issues with this approach to budget reporting were recently highlighted in the FY 2023 report of the House Appropriations Committee, which noted that the FDA budget narrative was not clear in communicating needs to allocators.¹⁴ That report stated:

*“FDA Budget Document.—*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 request itself. The 2023 budget for Foods, for example, contains 24 pages of “accomplishments” before the budget presentation. The budget presentation must always be the first item under each budget topic. The Committee directs FDA to radically revise its budget presentation so that it follows the same format as USDA agency budgets. The Committee will work with FDA on this during the year”

Committee members also pointed out that critical needs in infant formula were not communicated via the budget, stating:

[The infant formula] crisis revealed the FDA had only nine people in the office that regulates infant formula. This raises a concern about how many other key offices at the agency are also severely understaffed. The Committee will be in dialogue with the agency throughout the year about critical staffing needs.

The same principles of transparency should apply to FDA’s approach to regulation. For example, CSPI recently engaged in litigation with the FDA over regulations finalized in 2016 that allow food companies to self-certify ingredients as “Generally Recognized as Safe” without notifying

¹⁴ Report of the Committee on Appropriations accompanying the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2023. <https://docs.house.gov/meetings/AP/AP00/20220623/114947/HMKP-117-AP00-20220623-SD002.pdf>. Accessed October 6, 2022.

the FDA or publishing the basis for their determination.¹⁵ Regulations like this are antithetical to transparency and should be reconsidered. The judge, in denying CSPI's pursuit of a regulatory remedy, pointed us to the Congress. Rather than defend a secretive process that denies consumers, competing companies, and even the agency itself basic information, the agency should appeal to the Congress for fundamental GRAS reform.

An additional opportunity for transparency and collaboration would involve ensuring that cooperative agreements between FDA and the states/local agencies contain an agreement by each party to share information from consumer complaints, inspections, and outbreak investigations and other information, without redaction. This will require legal review to verify that data shared under the agreements will remain confidential under state and federal sunshine/freedom of information disclosure rules.

FDA remains one of the most misunderstood of federal agencies. Boosting targeted outreach to stakeholders, including members of Congress and their staff, state and federal agencies, and stakeholders to share updates on agency activities is critical.

6. *Technology*

The agency's data systems are not optimized to take advantage of the latest technology, both within each system, and in communication across systems. FDA has published a Data Modernization Action plan,¹⁶ but it remains rudimentary, lacking in details on means to prioritize and update the agency's many data systems related to food. FDA should develop a more detailed and comprehensive plan for modernizing data collection and analysis in its foods program, modeled after the Data Modernization Initiative of the Centers for Disease Control and Prevention (CDC).¹⁷

The data modernization plan should detail:

- Plans for moving current pilot projects to full implementation. This includes, for example, a description of how and when the agency will integrate findings from the artificial intelligence seafood pilot program, which has now been in progress since 2019,¹⁸ into wider FDA import inspection operations.
- Goals and priorities for updating and integrating data systems. For example, FDA should identify and prioritize plans to update the facilities inventory for inspections conducted pursuant to the Food Safety Modernization Act, to ensure that inspectional resources are leveraged effectively.
- Plans for creating a more consumer-friendly adverse event reporting portal for foods. The agency has been privately promising consumer groups it will soon launch a new

¹⁵ Center for Science in the Public Interest. Secret GRAS rule. October 8, 2021. <https://www.cspinet.org/case/secret-gras-rule>. Accessed October 14, 2022.

¹⁶ Food and Drug Administration. Data Modernization Action Plan. Content current as of: 03/03/2021. <https://www.fda.gov/about-fda/reports/data-modernization-action-plan>. Accessed October 12, 2022.

¹⁷ U.S. Centers for Disease Control and Prevention. Data Modernization Initiative. Page last reviewed: May 10, 2022 <https://www.cdc.gov/surveillance/data-modernization/index.html>. Accessed October 14, 2022.

¹⁸ U.S. Food and Drug Administration. The FDA Moves into Third Phase of Artificial Intelligence Imported Seafood Pilot Program. August 22, 2022. <https://www.fda.gov/food/cfsan-constituent-updates/fda-moves-third-phase-artificial-intelligence-imported-seafood-pilot-program>. Accessed October 14, 2022.

consumer-friendly interface for reporting food adverse events – promises made since as early as 2018.¹⁹ But FDA has never published a strategy for this update, nor has the agency published a plan describing how events collected under the new system will be analyzed and translated into regulatory action.

- Plans for modernizing adverse event collection and analysis. CSPI has recently co-authored 3 peer-reviewed studies^{20,21,22} demonstrating how food adverse events are dramatically under-reported in CAERS. FDA should explore innovative approaches to collecting and analyzing adverse events, such as registries, hospital records, internet search engines, electronic health records, claims databases, wearables, and meal-tracking apps, ongoing longitudinal studies, and social media.

7. *Priority Setting Reflecting Public Health Need*

Chronic disease, often preventable through improved nutrition, dwarfs other causes of death in the United States. The leading cause of death in the United States is heart disease, and it has been estimated that 80 percent of heart disease deaths could be prevented through lifestyle changes that include improved diet (as well as physical activity, and not smoking).²³

Yet, of the \$1.1 billion devoted to foods at FDA, \$766 million, or two-thirds of the budget, goes to field activities at ORA.²⁴ CFSAN, the agency handling nutrition work, takes home only a third, about \$345 million.²⁵ Within that third, only 7 percent of CFSAN’s budget, or \$23.5 million, is dedicated to nutrition activities.²⁶ This means, effectively, that only 2 cents of every dollar spent on food programs at the FDA goes towards nutrition policy work.

Nutrition should be a key focus as FDA attempts to keep pace with a changing food system. We were heartened to see the White House announce this week a new commitment by the FDA to develop a standardized front-of-package labeling system.²⁷ The agency is also looking beyond food labeling to focus on promising initiatives to reduce sodium and added sugars in the food supply.

¹⁹ Email communication between Kari Barrett and Sarah Sorscher, September 21, 2018. On file with author.

²⁰ Nguyen K, Greenthal E, Sorscher S, Lurie P, Spergel JM, Kennedy K. Adverse events and labeling issues related to suspected sesame allergy reported in an online survey. *Ann Allergy Asthma Immunol.* 2021;S1081-1206(21)01303-X.

²¹ Greenthal E, Lurie P, Doyon S. Opioid exposure associated with poppy consumption reported to poison control centers and the U.S. Food and Drug Administration. *Clin Toxicol.* 2021;59(8):746-755.

²² Markon AO, Jones OE, Punzalan CM, Lurie P, Wolpert B. Caffeinated energy drinks: adverse event reports to the US Food and Drug Administration and the National Poison Data System, 2008 to 2015. *Public Health Nutr.* 2019;22(14):2531-2542.

²³ Stampfer MJ, Hu FB, Manson JE, Rimm EB, Willett WC. Primary prevention of coronary heart disease in women through diet and lifestyle. *N Engl J Med.* 2000;343:16-22.

²⁴ Department of Health and Human Services Fiscal Year 2023 Food and Drug Administration Justifications of Estimates for Appropriations Committees. <https://www.fda.gov/media/157192/download>. Accessed October 14, 2023.

²⁵ *Ibid.*

²⁶ First, B, Adams JM, Mande J, Commissioner Califf needs to put the F back in FDA, *STAT News*, March 14, 2022. <https://www.statnews.com/2022/03/14/commissioner-califf-needs-to-put-the-f-back-in-fda/>, Accessed October 14, 2022.

²⁷ Biden-Harris Administration National Strategy on Hunger, Nutrition, and Health. September 2022. <https://www.whitehouse.gov/wp-content/uploads/2022/09/White-House-National-Strategy-on-Hunger-Nutrition-and-Health-FINAL.pdf>. Accessed October 14, 2022.

8. *Authorizing Legislation*

At least some of the changes needed to bring FDA into the future must come from Congress. The agency outlined in its FY 2023 budget several new authorities that are needed for the foods program.²⁸ Three of these priorities gained bipartisan support from members of Congress, and were included in the Food and Drug Administration Safety and Landmark Advancements Act of 2022, although they were ultimately stripped from the legislation prior to final passage:

- Enhanced dietary supplements regulation to require individual products to be listed in a database and to facilitate enforcement against unlawfully marketed products.
- New authority to identify and mitigate supply chain risks for infant formula and other essential foods.
- Updated legislative authorities to modernize and enhance the FDA Cosmetic Safety Program.

Congress should also consider additional reforms, including:

- Statutory authority to impose civil penalties through administrative proceedings against facilities that do not voluntarily comply with statutory and regulatory requirements.
- Enhanced authority to require online retailers to make food labeling information available to consumers at the online point of sale.
- A ban on the use of PFAS, a class of chemicals associated with health risks, in food packaging.
- As noted above, reforming the FDA's "generally recognized as safe" regulations to ensure new food additives are assessed by the FDA using a public process.

9. *Enhanced Scientific Capacity*

The broad range of products regulated by CFSAN require ongoing institutional learning to stay abreast of the rapidly evolving science. Struggles with recruitment of highly trained staff are an ongoing problem at the agency, as is the ability to obtain external scientific input at the highest level. The termination of the Food Advisory Committee seems to have been ill-advised. Moreover, FDA's regulatory documents are sometimes not updated for years. For example, the FDA has developed guidelines, known as the "Redbook 2000" to provide guidance on conducting safety studies of new food additive products requiring premarket approval. This guidance should be revised continuously to reflect contemporary scientific methods, but it has not undergone a comprehensive update in more than 20 years.²⁹

10. *Assessment*

FDA's programs are often reviewed in response to a crisis, and many of these reviews identify similar problems. For example, following the repeated outbreaks associated with leafy greens in

²⁸ Department of Health and Human Services Fiscal Year 2023 Food and Drug Administration Justifications of Estimates for Appropriations Committees. <https://www.fda.gov/media/157192/download>. Accessed October 14, 2023.

²⁹ U.S. Food and Drug Administration. Guidance for Industry and Other Stakeholders: Redbook 2000. July 2007. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-and-other-stakeholders-redbook-2000>. Accessed October 14, 2022.

2018, the agency contracted with the University of Minnesota’s School of Public Health to assess its outbreak response and develop an independent report.³⁰ That report identified suboptimal coordination across teams within FDA and with state/local partners, the need for technological and operational innovation, and resource constraints. Many of these themes echo in this testimony and are likely to be featured in the Foundation’s report.

The HHS Office of Inspector General (OIG) and GAO have also produced multiple investigative reports that identify operational improvements for the agency in line with the findings that we expect the Foundation will likely highlight. Many of these issues have festered at FDA for years. Indeed, the GAO added federal oversight of food safety to its High Risk List in 2007.³¹ While GAO has identified progress by the agency in the intervening years, as has the HHS OIG,³² much work remains to be done.

³⁰ Hedberg CW, An Independent Review of FDA’s Foodborne Outbreak Response Processes. August 23, 2021. <https://www.fda.gov/media/154484/download>. Accessed October 14, 2022.

³¹ U.S. Government Accountability Office. Improving Federal Oversight of Food Safety. <https://www.gao.gov/highrisk/improving-federal-oversight-food-safety>. Accessed October 14, 2022.

³² U.S. Department of Health and Human Services Office of Inspector General. OIG’s Top Unimplemented Recommendations: Solutions to Reduce Fraud, Waste, and Abuse in HHS Programs. 2021 <https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2021.pdf>. Accessed October 14, 2022.