

October 7, 2022

## **IDFA Comments to the Reagan-Udall Foundation Food Expert Panel**

### **Greatest Strengths of the FDA Program**

The FDA has many skilled, knowledgeable, and dedicated staff, as well as leaders. FDA has shown its ability to adapt and recognized the importance of working with industry to effectively respond to crises, as demonstrated during the CoVID-19 pandemic. Prior to the pandemic, the agency rarely collaborated with outside stakeholders to address food related issues. More recently, the FDA has been proactive in seeking more reliance on state regulatory partners, for example, through the ongoing work to develop a pilot program to enhance the efficiency of inspections of facilities that make both Grade “A” milk products and other non-Grade “A” foods. IDFA sees such collaboration as critical to making the much-needed changes to make the FDA a credible and authoritative food regulatory agency!

### **Greatest Challenges of the FDA Program**

FDA should undertake a comprehensive assessment of the Agency’s food related priorities and then assess the personnel skills and functions currently available. A thorough review will highlight resource gaps needed to accomplish the strategic priorities of the Agency. FDA should establish the Agency’s strategic priorities, assess resourcing, and reorganize the leadership to bring focus, accountability, and transparency to begin the progress of reestablishing the Agency’s credibility.

Projects within the foods program are siloed with a lack of internal and external communication and collaboration. There is a total lack of transparency in terms of the process or the status of the many initiatives or regulatory reviews. The FDA regulatory responsibilities must be prioritized, aligned with other departments/agencies, and focused on truly public health-related issues; however, there are other, non-public health oriented, consumer interest areas under FDA’s purview that are important and deserving of the same prioritization and alignment. The dairy industry has many issues that are non-public health oriented that the FDA needs to act on—or in some cases defer to states—in ways that do not unnecessarily delay progress nor harm the industry’s abilities to meet consumer and marketplace demands, especially when FDA cannot point to specific downsides and there is no public opposition.

The agency is woefully behind in issuing guidance documents that are instrumental in helping the food industry meet FSMA requirements. Failures in basic, foundation level food safety practices are often at the root of many food safety problems. Therefore, FDA policy development, industry guidance and outreach should be focused on basic, foundation level food safety practices in collaboration with industry experts. FDA's resources should be focused primarily on finalizing important pending work rather than introducing new streams of work.

## **Recommendations for Improvement**

Establish a deputy commissioner for foods to ensure the Center for Food Safety and Applied Nutrition (CFSAN), Center for Veterinary Medicine (CVM), and the food personnel of the Office of Regulatory Affairs (ORA) have aligned strategic direction, clear priorities, sound resource management, and internal accountability. It is important for the new leadership to establish a culture that encourages collaboration with their state partners and seeks industry input to ensure Agency personnel are up to date on the technology and innovation used by industry to meet consumer needs.

To foster a culture of continuous learning, the Agency must proactively leverage input from industry and academic experts. FDA should: 1) reinvigorate the use of advisory committees and expert panels composed of individuals drawn from academia, industry and consumer groups; 2) rely on outside bodies to conduct research that will form the foundation for regulation and guidance (e.g., CDC, NIH, USDA); 3) further leverage state regulatory agencies to enhance efficiency and reduce duplication of inspection activities; and 4) utilize the HHS Food/Ag Sector Coordinating Council to prepare for future critical supply chain crises.

The lack of transparency and collaboration with industry are major concerns for IDFA, which are illustrated by the agency's work on food standards. In many cases, standards have not been updated in decades and are overly prescriptive and restrictive. FDA should be encouraged to allow for innovation, changing consumer trends and needs, and explore more efficient and cooperative ways to issue rules and respond to petitions. IDFA has long advocated for such reforms yet, due to the lack of transparency and lack of outreach to industry, after a delay of nearly 40 years and submissions of multiple industry comments, IDFA had to formally object to the 2021 yogurt standard of identity final rule, as it would have been impossible to continue making many yogurts based on this rule.

## **Other Comments**

There are US Government Agencies that embody many of the principles we have described. We would strongly encourage FDA to review the model used by the Federal Aviation Administration — an agency that is focused on investigation, enforcement and prevention and shares learnings with industry after events occur — as part of its outbreak investigation and follow-up work. Cultivating within FDA a food safety culture of prevention through continuous

improvement and collaboration with academic experts, partners in state regulatory agencies, and industry is critical, and such a model can help in this regard.

Respectfully submitted,

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