

Dear Dr. Califf,

The FDA Foods Program is different. The food system and food safety are complex, but the core of FDA's food safety role and congressional mandate is straightforward. FDA establishes standards and guidance for industry and engages with industry and regulatory partners in multiple ways to assure compliance with those standards. The Foods Program mission is fundamentally different from Google or a hospital.

As logical as matrix management may sound, it is a prescription for continued failure of the FDA to live up to the vision and mandates of the Food Safety Modernization Act (FSMA).

As representatives of the food industry and consumers, and state food regulators who have worked directly for many years with all levels of the Foods Program and share an abiding commitment to FDA's food safety success, we offer the following:

1. **Culture Change Requires Central Leadership.** FDA's food safety success depends on headquarters and field inspection, laboratory and import units working seamlessly with a common vision, sense of mission, and priorities. The change needed will not be achieved solely by defining decision rights in a matrix management system. It's about culture change, and it's about leadership that can transform the field units from their entrenched react and enforce culture to one of public health prevention and collaboration to achieve food safety, supported by enforcement when necessary.
2. **Previous Attempts at Matrix Management Have Failed.** Beginning with a partially empowered Deputy Commissioner for Foods and Veterinary Medicine from 2010-2018 and Commissioner Hamburg's Program Alignment, matrix management for FSMA implementation has been tried for over a decade in multiple formulations and has glaringly failed. We see no basis for believing it will succeed now.
3. **The Need for a Single Empowered Leader is Well Documented.** The failure of matrix management in the Food Program was documented thoroughly by the Reagan-Udall Foundation Independent Expert Panel. On that basis, the panel recommended that all elements of the Food Program be unified under a single leader with full line management authority to lead its essential culture change and program modernization. Thus far, there has been no convincing explanation to rebut this recommendation.
4. **Food Safety Requires an Integrated Food Program.** For FDA to succeed on food safety, its large frontline workforce needs to think of itself as, and become, an integral part of the Food Program, not remain a separate organization that protects its independence and its outdated culture of insularity and reaction to food safety problems.
5. **Integrating the Field Force Does Not Undermine Efficiencies.** Desirable efficiencies in logistical and administrative support to the Food Program's field activities can be achieved through shared services with medical product programs, rather than holding onto the fragmented ORA Food Program structure that blocks food safety progress.

We urge you to reconsider your plan to rely on a failed matrix management approach to leading and transforming the Foods Program. We recognize that major organizational change often encounters internal questions and resistance. These need to be considered but the stakes are too high to let bureaucratic issues block progress that is so vital to America's health and to public confidence in FDA's oversight of food safety.

Food safety success requires and deserves better.

STOP Foodborne Illness

Consumer Reports

Consumer Brands Association

Association of Food and Drug Officials