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This Teachable Moment: How COVID-19 Provides Lessons from FDA's Past and Present That Will Benefit Its Future Preparedness
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2. Agencies Unbound: How COVID-19 Prompted Regulatory Flexibility and How to Build on it for the Future

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The COVID-19 crisis has called for governmental responses of unprecedented scale, scope, and speed. COVID-19 has stressed not only medical infrastructure, supply chains, and financial systems, but also the very regulatory apparatus the government must use to react. Regulatory agencies have had to respond nimbly, with at times imperfect information, and in at times unfamiliar territory beyond their core mission areas. Agencies accustomed to following deliberate administrative processes have had to take action and make significant policy decisions in mere days. Agencies have had to balance important competing concerns, such as keeping critical infrastructure operating while curtailing virus transmission, requiring cross-agency collaboration. And regulatory agencies found great value in collaboration with industry and other stakeholders. Flexible regulatory approaches emerged by necessity to allow FDA and USDA to respond to the public's need for access to food, personal protective equipment, and other critical items. Designated "critical infrastructure sectors," key industries required decisive shifts in how these agencies traditionally go about the business of regulation to protect public welfare during the growing pandemic.

This article explores the various approaches taken by regulatory agencies to respond to the COVID-19 crisis through the lens of the food and agriculture sector. A diverse sector regulated by multiple federal agencies, the food industry is considered critical infrastructure under federal and state emergency orders. As a result, the food industry continued operations while managing myriad challenges including supply chain disruption, ingredient shortages, worker and customer safety concerns, access to labor, coordinating with public health departments, and navigating state and local lockdown orders and the Defense Production Act.

These challenges have required federal regulatory agencies to respond with unprecedented speed and agility but have also pointed to significant regulatory challenges and potential new ways for regulatory agencies to operate both during and after this crisis. For example, the COVID-19 crisis response saw FDA leverage newly created guidance documents and exercises of enforcement discretion among other tools that were implemented at an unprecedented pace and scope. At the same time, regulatory agencies had to develop new communication channels with the regulated industry and to some extent had to step outside their normal regulatory mindset to understand and address effectively the ability of the food industry to meet the needs of the public. By acting promptly and creating and adapting regulatory policies on the fly, the agencies demonstrated that they can, when necessary, operate flexibly and responsively to urgent needs. These actions also showcase shortcomings in a regulatory system often not designed for speed as well as complications that can arise when agencies are forced to act through nonbinding guidance. It also highlights opportunities for better future collaboration between regulatory agencies and industry stakeholders.

This article analyzes the key regulatory strategies used by FDA, USDA, CDC, and sister agencies, identifies key learnings from how those strategies were used in the initial phase of the COVID-19 crisis, and explores ways for regulatory agencies to build on those processes, both for future crisis response and day-to-day regulatory activities.