Agencies Unbound: How COVID-19 Prompted Regulatory Flexibility and What it May Mean for the Future

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ABSTRACT

The COVID-19 crisis called for governmental responses of unprecedented scale, scope, and speed. COVID-19 stressed not only medical infrastructure, supply chains, and financial systems, but also the very regulatory apparatus the government must use to react. Regulatory agencies had to respond nimbly, with at times imperfect information and in unfamiliar territory beyond their core mission areas. Agencies accustomed to following deliberate administrative processes had to act and make significant policy decisions in mere days, balancing important competing concerns, such as keeping critical infrastructure operating while curtailing virus transmission, requiring cross-agency partnership. 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 evolving pandemic.

Viewing agency actions through the lens of the food industry, this Article analyzes the key regulatory strategies used by FDA and USDA (in conjunction with CDC and other agencies), identifies key learnings from how those strategies worked 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.

I. INTRODUCTION

The COVID-19 crisis called for a governmental response of unprecedented scale, scope, and speed. COVID-19 has stressed not only medical infrastructure, supply chains, and financial systems, but also the regulatory apparatus the federal government must use to react to national emergencies. Regulatory agencies have had to respond nimbly, often in unfamiliar territory beyond their core mission areas. Agencies accustomed to following deliberate administrative processes have had to act and make and execute significant policy decisions in mere days, while balancing important competing concerns, such as keeping critical infrastructure operating while curtailing virus transmission.

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This Article shows that these challenges were especially acute for the nation's regulatory agencies charged with overseeing the food supply—the Food and Drug Administration (FDA) and the United States Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS). As a "critical infrastructure sector," it was imperative that the food supply chain continue to function throughout the COVID-19 crisis. While traditionally charged with overseeing food safety, FDA and FSIS were charged with overseeing food supply chain continuity during the height of the crisis and suddenly became responsible for keeping a large economic sector running. Overseeing food supply continuity, however, is very different than regulating food safety, and many of the traditional regulatory tools, processes, and techniques available to FDA and FSIS were ill-suited to the task. Rulemaking, for example, was out of the question. FDA and FSIS therefore had to adopt flexible regulatory approaches to address the exigency of the COVID-19 situation while still performing their regulatory oversight missions, drawing heavily on different forms of informal guidance and enforcement discretion to keep food on the table.

The challenges facing the food supply during the early days of the COVID-19 crisis were real, varied, and extremely significant. Maintaining continuity through the supply chain was of paramount importance. The food supply is built on a complex and interconnected web of suppliers, manufacturers, distributors, and retailers. Disruption to a key ingredient supply or distribution network—such as a mass quarantine or a poorly tailored shelter in place order—could compromise the entire system. At the same time, as food service all but collapsed overnight, the food industry had to find a way to redirect specially prepared and specially labeled product into retail channels. And in the early days of the COVID-19 crisis, there was public concern over whether the food itself was a potential transmission vector. Moreover, as a critical infrastructure sector, the food industry faced the dual challenge of maintaining continuity of operations to feed the country while also trying to protect food workers. FDA and FSIS were charged with facilitating resolution of these issues, all the while also trying to find ways to continue their core mission of protecting the public health through the crisis.

Addressing these issues required swift action, action that typical regulatory tools are not conducive to. Fundamentally, FDA and USDA did not try to use these more traditional, plodding regulatory processes, such as agency rulemaking.[1] Nor, however, did the agencies draw heavily on emergency authorities such as the Defense Production Act. Instead, FDA and USDA relied heavily on informal statements, agency guidance materials, and exercises of enforcement discretion to help address these and other challenges facing the food supply. In one sense, these actions reflected a continuation of regulatory trends prior to COVID-19, in which rulemaking was increasingly difficult and time consuming and agencies appeared to prefer issuing guidance and policy statements, coupled with enforcement, to drive change. With the benefit of hindsight, it may not be a surprise that FDA and FSIS grabbed the most

[1] The rich literature addressing the complexity, costs, and barriers to conducting rulemaking in the modern age is beyond the scope of this Article. Suffice to say that the authors, as administrative law practitioners, lend their support to the notion that modern rulemaking is rarely a swift process. *See, e.g.*, Stephen M. Johnson, *Junking the "Junk Science" Law: Reforming the Information Quality Act*, 58 ADMIN. L. REV. 37, 61 (2006) (stating that "Over the past few decades, Congress, the courts, and the executive branch have layered so many significant procedural requirements on notice and comment rulemaking that most academics and policymakers agree that the process has become ossified and inefficient.") (citations omitted).

expedient and flexible tools in their regulatory toolboxes. Viewed in the context of the rapidly developing initial weeks and months of the COVID-19 pandemic, though, that approach was far from certain. And with that hindsight, the agencies' response to COVID-19 highlighted both benefits and challenges with the agencies' tools to respond to a crisis of the scope of COVID-19. The agencies undoubtedly will learn from their responses in ways that could influence future agency action, both in emergency situations as well as day-to-day regulatory activities.

This Article focuses on the early weeks and months of the COVID-19 crisis in the United States—a time when information was scarce, the threats were significant, and quick action was critical.[2] This Article begins by describing in Part II the key statutory authorities available to FDA and FSIS. The experienced food law practitioner will be familiar with these authorities, but they're presented briefly because they provide important framing for the types of issues and considerations that FDA and FSIS have geared their traditional regulatory processes toward addressing. As we will see, those issues are markedly different than the ones presented by COVID-19. Part III reviews the key developments in the early stages of the COVID-19 pandemic. As the passage of time blurs details and current scientific understanding brings more clarity to COVID-19 transmission and treatment, it's important to remember just how quickly the situation unfolded and how dynamic it was. FDA, FSIS, and the food industry had to operate quickly while within a state akin to a thick fog of war. This context is important for understanding the need for agency action. Part IV captures the key challenges that faced the food and agriculture sector during the early stages of the COVID-19 crisis, as those were the challenges that FDA and FSIS were tasked with addressing. Part V describes the key FDA and USDA regulatory responses related to maintaining the food supply and includes discussion of state and local actions as well. Capturing those actions for their historical value alone is important and doing so here provides a framework for analyzing the situation. Part VI identifies common themes in those responses. Part VII concludes by identifying key learnings for the food industry and the agencies in preparing for future emergencies (and perhaps continuing to respond to this one).

II. FOOD FEDERAL REGULATORY FRAMEWORK: BASIC AUTHORITIES THAT COME INTO PLAY AND INFORM FEDERAL AGENCIES' RESPONSE TO THE PANDEMIC

There is a robust federal regulatory framework established to oversee the food supply, including various emergency authorities. This framework is rooted in several key statutes, which we review below. We need review this framework only briefly, however, because as we develop later in this Article, the agencies' statutory authorities played very little direct role in how the agencies responded in the early stages of the pandemic. It's still useful to review the basic statutory framework, however, because fundamentally, agencies orient themselves around their statutory mission.

[2] In general, this Article focuses on the events of Spring into early Summer 2020.

A. Overview of the Primary Statutory Authorities for FDA and USDA

Although a number of agencies at the federal and state levels are involved in regulating food products in the United States, two federal agencies—the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS)—are the primary food product regulators.

FDA's authorizing statute, the Federal Food, Drug, and Cosmetic Act (FDCA),[3] generally provides FDA with regulatory authority over a broad definition of "food" that encompasses conventional human food, individual food components, food ingredients, dietary supplements, pet food, and animal feed.[4] FDA's laws and regulations apply to food produced in the United States and offered for import into the United States.[5] FSIS primarily regulates meat, poultry, and processed egg products under a series of authorizing statutes: the Federal Meat Inspection Act of 1906 (FMIA),[6] the Poultry Products Inspection Act of 1957 (PPIA),[7] and the Egg Products Inspection Act of 1970 (EPIA).[8] Under USDA's framework, all meat and poultry products must be inspected by FSIS.[9]

Although there are significant differences between FDA and FSIS's authorizing statutes, both agencies' frameworks are grounded in two key food law concepts: adulteration and misbranding. At the most basic level, adulteration refers to the safety of a food,[10] while misbranding addresses how the food is labeled.[11] The majority of FDA and FSIS regulatory requirements are aimed at preventing adulteration or misbranding of food products. Each of the four authorizing statutes (FDCA, FMIA, PPIA, and EPIA) also identify various "prohibited acts," which generally include introducing adulterated or misbranded foods into commerce or various conduct generally related to food safety or labeling.[12]

Even those statutory provisions, the violation of which are "prohibited acts" but don't necessarily adulterate food—such as FDA's facility registration requirements or the agencies' records-access requirements—function directly to support the agencies'

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3 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*

4 *Id.* § 321(f).

5 *See, e.g.*, 21 U.S.C. § 331 (identifying various prohibited acts under the FDCA that are defined in relation to the food being in interstate commerce).

6 Federal Meat Inspection Act of 1906, 21 U.S.C. § 601 *et seq.*

7 Poultry Products Inspection Act of 1957, 21 U.S.C. § 451 *et seq.*

8 Egg Products Inspection Act of 1970, 21 U.S.C. § 1031 *et seq.*

9 21 U.S.C. § 606(a) (meat); *id.* § 455 (poultry).

10 The authorizing statutes of both FDA and USDA set forth a number of grounds upon which a food could be deemed adulterated, including the presence of poisonous or deleterious substances in the food that may render the food injurious to health; filthy or insanitary conditions under which the food was produced, processed, or held; or use of an unapproved food additive in the food. 21 U.S.C. § 342; 21 U.S.C. § 601(m). 21 U.S.C. § 458.

11 Under the authorizing statutes of both FDA and FSIS, a product is deemed "misbranded" if its label or labeling is "false or misleading in any particular," or if the food is mislabeled in any of a number of ways enumerated in the statutes. *See* 21 U.S.C. § 343(a)(1); 21 U.S.C. § 301(n); 21 U.S.C. § 453(g); 21 U.S.C. § 1033(a).

12 *See* 21 U.S.C. § 352; 21 U.S.C. § 601; 21 U.S.C. § 458; 21 U.S.C. § 1037.

core mission of making sure that food is not adulterated or misbranded.[13] The FDCA, FMIA, PPIA, and EPIA fundamentally lack authorities allowing FDA or FSIS to organize or otherwise oversee the food industry outside of safety and labeling. To the extent the statutes include emergency authorities, the authorities are generally intended to allow food safety emergencies to be addressed expeditiously or prevent widespread intentional contamination of food.[14] In other words, none of these statutes establish a premise that FDA or FSIS are supposed to support a food industry; they merely require FDA or FSIS make sure that whatever industry exists is producing safe and accurately labeled food.

This statutory framing is significant, both because it means that FDA and FSIS would naturally center their regulatory structures and tools toward their core missions of preventing adulteration and misbranding, and because it means that the agencies' core authorizing statutes do not provide an obvious framework for stepping into a supportive role in a crisis.

B. Other Significant Statutes and Authorities

Although FDA's and FSIS's core authorizing statutes do not include authorities geared toward addressing potential supply chain shocks or stabilizing the industry in the face of a national emergency, various other federal statutes do specifically address emergencies. We briefly review several here for context, but again, aside from a very limited role played by the Defense Production Act (DPA), none of these statutory authorities played a prominent role in FDA's or FSIS's response to the pandemic. The point remains that, aside from background effects (such as the federal government's declaring of an emergency), these tools played no real role in FDA's and FSIS's approach to overseeing the food supply. However, understanding what tools may have been available to FDA is illuminating when considering what tools FDA actually used.

1. Public Health Service Act

The Public Health Service Act (PHSA) is the primary statute from which the U.S. Department of Health and Human Services (HHS) derives its legal authority to respond to public health emergencies.[15] Although the PHSA focuses directly on preventing the spread of communicable diseases, it is focused more on responding to the disease rather than mitigating collateral consequences on key commercial sectors.[16]

2. The Defense Production Act (DPA)

The Defense Production Act (DPA) is the primary authority that allows the President in relevant part to 1) require companies to offer priority treatment to certain orders that are issued in support of national defense and energy programs; and 2) allocate certain materials, facilities, and services to further national defense and/or

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[13] 21 U.S.C. § 350(d); 21 U.S.C. § 350(c); 21 U.S.C. § 542; 21 U.S.C. § 467(e); 21 U.S.C. § 1040.

[14] *See, e.g.*, 21 U.S.C. § 381(q); 21 U.S.C. § 350(i).

[15] Public Health Service Act, 42 U.S.C. § 201 *et seq.*

[16] *See, e.g.*, *HHS Legal Authorities Related to Disasters and Emergencies*, U.S. DEP'T HEALTH & HUM. SERVS. (Oct. 22, 2021), https://www.phe.gov/Preparedness/planning/authority/Pages/default.aspx (describing the core features of the PHSA) [https://perma.cc/GCZ6-9MLL].

energy needs.[17] The government may exercise this authority through "allocation" orders "when there is insufficient supply of a material, service, or facility to satisfy national defense requirements through the use of the priorities authority or when the use of the priorities authority would cause a severe and prolonged disruption in the supply of materials, services, or facilities available to transport normal U.S. economic activities . . . ."[18] The Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act) extends the DPA's priorities and allocations authority to the area of emergency preparedness activities.[19]

Going back to the Truman Administration, presidents have issued and periodically updated executive orders delegating the authorities under the DPA. Executive Order 13603, issued by President Obama in 2012, is the most current broadly applicable iteration.[20] EO 13603 requires that federal executive agencies "be prepared, in the event of a potential threat to the security of the United States, to take actions necessary to ensure the availability of adequate resources and production capability . . . for national defense requirements."[21] Specifically delegating the DPA's allocation authority, EO 13603 places the Secretary of Agriculture in charge of DPA allocations "with respect to food resources, food resource facilities, livestock resources, veterinary resources, plant health resources, and the domestic distribution of farm equipment and commercial fertilizer."[22]

The federal government thus entered the COVID-19 pandemic with a longstanding plan for how to execute its DPA authorities. Of all the statutory authorities reviewed, the DPA played perhaps the most prominent role in FDA and USDA's response to the pandemic in terms of stabilizing the food supply, but even the DPA ultimately played a background role.[23]

3. The PATRIOT Act and Critical Infrastructure Industries

Under the larger umbrella of federal emergency preparedness planning, the Department of Homeland Security (DHS) has prioritized the protection and continued operation during crises of the food and agriculture industry and related transportation activities by designating them as "critical infrastructure."[24] The USA PATRIOT Act of 2001 defines "critical infrastructure" as "systems and assets, whether physical or virtual, so vital to the United States that the incapacity or destruction of such systems

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[17] Defense Production Act, 50 U.S.C. § 4501 *et seq*.

[18] Export Administration Regulations, 15 C.F.R. § 700.30(a) (2014). The government may also exercise this authority using "rated orders," which are priority ratings assigned to government contracts.

[19] The Stafford Act, 42 U.S.C. § 5121 *et seq*.

[20] *See* Exec. Order No. 10480, 18 Fed. Reg. 4,939 (Aug. 14, 1953); Exec. Order No. 13603, 77 Fed. Reg. 16,651 (Mar. 22, 2012). During the coronavirus pandemic, President Trump issued several executive orders regarding specific aspects of the response to the COVID-19 pandemic. *See, e.g*., Exec. Order No. 13911, 85 Fed. Reg. 18,403 (Apr. 1, 2020).

[21] Exec. Order No. 13603 § 103(c), 77 Fed. Reg. 16,651 (Mar. 22, 2012).

[22] *Id.* § 201(1).

[23] The DPA played a more direct role in other COVID-19 response efforts, such as securing ventilators. *Applying the Defense Production Act*, FED. EMERGENCY MGMT. AGENCY (Apr. 13, 2020), https://www.fema.gov/press-release/20210420/applying-defense-production-act [https://perma.cc/4PXB-DFET].

[24] *Food and Agriculture Sector*, CYBERSECURITY & INFRASTRUCTURE SEC. AGENCY (Dec. 17, 2020), https://www.cisa.gov/food-and-agriculture-sector [https://perma.cc/YSM3-YUVA].

and assets would have a debilitating impact on security, national economic security, national public health or safety, or any combination of those matters."[25] Through the Act, Congress established "the policy of the United States" is "that any physical or virtual disruption of the operation of the critical infrastructure of the United States be rare, brief, geographically limited in effect, manageable and minimally detrimental to the economy, human and governmental services, and national security of the United States."[26]

Presidential Policy Directive 21 identifies sixteen Critical Infrastructure Sectors under the USA PATRIOT Act, including "Food and Agriculture" and "Transportation."[27] DHS's Cybersecurity and Infrastructure Security Agency (CISA) describes the Food and Agriculture sector as being "composed of an estimated 2.1 million farms, 935,000 restaurants, and more than 200,000 registered food manufacturing, processing, and storage facilities" and having "critical dependencies" with the transportation sector for "movement of products and livestock."[28]

This critical infrastructure designation played an important background role in that it established that national policy was to support continuity in the food supply, but aside from making this policy clear, the federal government's critical infrastructure framework provided little real guidance to the agencies on how to make the day-to-day decisions necessary to respond to the pandemic.

C. Regulatory Processes and Framework

When implementing their statutory authorities, federal agencies must follow various procedural frameworks. We briefly touch on three here: notice and comment rulemaking under the Administrative Procedure Act (APA), agency guidance and enforcement discretion, and presidential executive orders. We need touch on these only briefly. As with the agencies' core statutory authorities, these procedural frameworks are noteworthy here primarily because they largely were not used. But they nonetheless shaped the agencies' responses by constraining some behavior. It's also important to understand how agencies normally operate, because the further the situation at hand is from "business as usual," the less likely it is that the agencies will have established processes for addressing it.

1. Administrative Procedure Act (APA)

The Administrative Procedure Act (APA) applies to all executive branch and independent agencies and prescribes the procedures for how agencies promulgate rules.[29] Most commonly, agencies must engage in "notice and comment" rulemaking under § 553 of the APA.[30] Under this process, an agency must propose a rule, provide

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[25] Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), 42 U.S.C. § 5195(c)(e).

[26] *Id.* § 5195(c)(1).

[27] Press Release, White House, Presidential Policy Directive 21 (PPD-21): Critical Infrastructure Security and Resilience (Feb. 12, 2013), https://obamawhitehouse.archives.gov/the-press-office/2013/02/12/presidential-policy-directive-critical-infrastructure-security-and-resil [https://perma.cc/P9PT-HZN9].

[28] *Food and Agriculture Sector*, supra note 24.

[29] Administrative Procedure Act, 5 U.S.C. § 551 *et seq*.

[30] *Id.* § 553. *See also* TODD GARVEY, CONG. RSCH. SERV., R41546, A BRIEF OVERVIEW OF RULEMAKING AND JUDICIAL REVIEW (2017). A "rulemaking" is defined as "formulating, amending, or repealing a rule." 5 U.S.C. § 551(5).

meaningful opportunity for public comment, consider relevant comments, and then publish the rule as final.[31] This is not a fast process. Although the APA also contemplates Interim Final Rules (IFRs),[32] which allow agencies to skip straight to issuing a final rule when following typical rulemaking procedures is "impracticable, unnecessary, or contrary to the public interest,"[33] this process still requires painstakingly assembling a robust administrative record, including justification for the expediency, as well as a process to solicit and consider public comment afterward.

The APA created an exception for interpretive rules and general statements of policy.[34] These "non-legislative rules" do not carry the force of law, allowing agencies to bypass the often-burdensome notice-and-comment requirements of the APA to issue timely policy guidance.

2. Guidance Documents and Related Procedures

i. FDA Good Guidance Practices

FDA routinely issues guidance documents that explain the agency's interpretation of a given regulatory issue. These documents are used by industry, stakeholders, and FDA's own staff, and while instructive, they "do not establish legally enforceable rights or responsibilities. They do not legally bind the public or the FDA."[35] FDA typically issues more than 100 guidance documents each year.[36]

As a practical matter, the process used to issue these documents somewhat mirrors the APA notice-and-comment rulemaking. By statute, FDA is required to develop these guidance documents "with public participation."[37] In implementing the requirements of the statute, FDA promulgated its Good Guidance Practices regulation, which addresses the manner in which public participation can occur.[38] There are two types of guidance documents: 1) Level 1 guidance documents (which include those that set forth an initial interpretation of a law or regulation, include complex scientific issues, cover highly controversial issues, or offer changes to an existing guidance that are "more than minor in nature"); and 2) Level 2 guidance documents (which lay out existing practices or make minor changes in policy).[39]

When issuing a Level 1 guidance document, FDA must make a draft available on its website, publish a notice in the Federal Register for public inspection, and provide an opportunity for public comment before implementation.[40] However, the regulations allow FDA to bypass the public comment period and implement a guidance document

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[31] 5 U.S.C. § 553(b)–(c).

[32] *Id.* § 553(b)(3)(B).

[33] *Id.*

[34] *Id.* § 553(b)(3)(A).

[35] FDA Good Guidance Practices, 21 C.F.R. § 10.115(d) (2018).

[36] *Fact Sheet: FDA Good Guidance Practices*, U.S. FOOD & DRUG ADMIN. (Dec. 2017), https://www.fda.gov/about-fda/transparency-initiative/fact-sheet-fda-good-guidance-practices [https://perma.cc/2MNK-WLCM].

[37] 21 U.S.C. § 371(h) provides that FDA shall develop guidance documents "with public participation."

[38] 21 C.F.R. § 10.115(b).

[39] *Id.* at § 10.115(c)(1)–(2).

[40] *Id.* at § 10.115(g)(1).

immediately if "the agency determines that prior public participation is not feasible or appropriate."[41]

As with the APA rulemaking process on which it's based, FDA's guidance practice injects non-trivial time delays into the guidance development process, and guidance documents can often take years to finalize.[42]

ii. FSIS

USDA published a final rule codifying internal procedures that must be followed when issuing agency guidance documents in June 2020.[43] The new procedures are in some ways similar to FDA's Good Guidance Practices regulations, and while published too late to directly affect much of the Department's COVID-19 response, the procedures could be relevant for future emergencies. The final rule defines two key types of guidance documents that would receive closer scrutiny under the final rule: 1) "significant" guidance (which includes guidance documents that are reasonably expected to have an annual effect on the economy of $100 million or more, create inconsistency with the actions of another agency, or raise novel legal or policy issues); and 2) guidance that is "otherwise of importance to the Department's interests" (which includes guidance reasonably likely to relate to a major policy of the Department, receive significant press or congressional attention, or raise significant concerns from important constituencies).[44] Both types of documents must receive departmental review before issuance, but only "significant" guidance is required to undergo public notice and comment.[45]

3. Enforcement Discretion

A federal agency may also announce through guidance or statements its intention not to enforce certain regulatory requirements as they apply to certain entities and/or activities. By exercising enforcement discretion, an agency is not changing the existing law or regulations, but rather announcing that it will not enforce a given law or policy if specific criteria are met.[46] An agency may announce that the enforcement discretion only applies for a set amount of time, with the option to extend as necessary.

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[41] *Id.* at § 10.115(g)(2). The regulations do not specify how the agency makes such a determination.

[42] For example, FDA's Draft Guidance on whole grain label statements was issued in draft in 2006 and has yet to be finalized. *See* U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY AND FDA STAFF: WHOLE GRAIN LABEL STATEMENTS (Feb. 2006), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-and-fda-staff-whole-grain-label-statements [https://perma.cc/TAQ9-546B].

[43] 7 C.F.R. §§ 1.900–1.911 (2020).

[44] *Id*. at §§ 1.900, 1.904.

[45] *Id*. at §1.906.

[46] *See, e.g.*, Heckler v. Chaney, 470 U.S. 821, 834–35 (1985) (considering a case of involving enforcement discretion of the FDCA, and explaining that if Congress "has indicated an intent to circumscribe agency enforcement discretion, and has provided meaningful standards for defining the limits of that discretion, . . . courts may require that the agency follow that law; if it has not, then an agency refusal to institute proceedings is a decision 'committed to agency discretion by law'").

4. Executive Orders

Independent from the APA process, the president may issue federal directives in the form of executive orders and proclamations.[47] These documents are not legislation and do not need approval from Congress, but they do have the effect of directing how an executive branch agency must operate. Once issued, executive orders remain in force unless a court determines it unlawful, or they are overturned by a sitting president. The latter is often the case when there is a change in administration. Executive orders govern various aspects of federal rulemaking, requiring, for example, detailed cost-benefit analyses.[48]

III. GLOBAL PANDEMIC REACHES U.S.: CHALLENGES FACING FOOD INDUSTRY AND REGULATORS AT FEDERAL, STATE, AND LOCAL LEVELS

The regulatory framework outlined above was not designed for speed. Yet once COVID-19 reached the United States, flexible regulatory approaches were necessary to allow federal agencies to respond to the public's need for access to food and personal protective equipment. It's impossible to understate, yet easy to forget, how rapidly evolving and dynamic the situation was when COVID-19 first established a foothold in the United States. But those frenetic first few months in the spring and early summer of 2020 placed maximum stress on the food industry and the regulators suddenly tasked with supporting it. This section briefly reviews key developments in that early period, which we must remember in order to place agency action and challenges in their proper context.[49]

A. Early COVID-19 Timeline: Key Milestones in Its Emergence

In December 2019, SARS-CoV-2 was first detected in Wuhan, Hubei Province, People's Republic of China.[50] By January 21, 2020, the Centers for Disease Control and Prevention (CDC) announced the first confirmed case in the United States.[51] Days later, the central government of China suspended all public transport and travel in and out of Wuhan, placing all 11 million residents of the city under quarantine,[52] while the

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47 *See* U.S. CONST. art. II.

48 The particular changes that the Trump Administration imposed on the rulemaking process through Executive Orders are beyond the scope of this Article, in large part because the rulemaking process was not used to address the issues at hand.

49 Each of the authors was closely involved in advising food companies and food industry trade associations and working with FDA and FSIS on COVID-19 response issues throughout this time period. Much of the following discussion draws on the authors' personal experience working with these issues during the throes of the pandemic.

50 Helen Branswell, *WHO Says Mysterious Illness in China Likely Being Caused by New Virus,* STAT NEWS (Jan. 8, 2020), https://www.statnews.com/2020/01/08/who-says-mysterious-illness-in-china-likely-being-caused-by-new-virus/ [https://perma.cc/4ME7-7J5L].

51 Press Release, Ctrs. for Disease Control & Prevention, First Travel-Related Case of 2019 Novel Coronavirus Detected in United States (Jan. 21, 2020), https://www.cdc.gov/media/releases/2020/p0121-novel-coronavirus-travel-case.html [https://perma.cc/X5YZ-4XJT].

52 Emily Feng, Amy Cheng & Merrit Kennedy, *Chinese Authorities Begin Quarantine of Wuhan City as Coronavirus Cases Multiply*, NAT'L PUB. RADIO (Jan. 23, 2020), https://www.npr.org/2020/01/23/

White House announced the creation of a Coronavirus Task Force.[53] On January 31, with seven confirmed cases in the U.S. and reports of the global spread of the disease throughout China and Europe, the Secretary of HHS declared a public health emergency under § 319 of the PHSA, 42 U.S.C. 247d.[54] The World Health Organization (WHO) officially dubbed the virus "COVID-19" on February 11.[55] In late February, CDC published interim guidance for businesses and employers that provided strategies to plan and respond to COVID-19.[56] By March 11, with more than 118,000 cases worldwide, the WHO declared the COVID-19 outbreak a pandemic.[57] On March 13, 2020, with more than 1,645 cases in the U.S., President Trump declared the COVID-19 outbreak in the United States a National Emergency.[58]

B. Federal Response, State Mitigation Strategies, and Critical Infrastructure

The effort to contain the virus in the United States involved multiple strategies at the federal and state levels. One included restriction on foreign travel.[59] Others,

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798789671/chinese-authorities-begin-quarantine-of-wuhan-city-as-coronavirus-cases-multiply [https://perma.cc/MHZ5-VE27].

53 Press Release, White House, Statement from the Press Sec. Regarding the President's Coronavirus Task Force (Jan. 29, 2020), https://trumpwhitehouse.archives.gov/briefings-statements/statement-press-secretary-regarding-presidents-coronavirus-task-force/ [https://perma.cc/F7WK-7SEN].

54 U.S. Dep't of Health & Hum. Servs., *Determination that a Public Health Emergency Exists*, PUB. HEALTH EMERGENCY (Jan. 31, 2020), https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx [https://perma.cc/9FRP-AG7X].

55 Brett Dahlberg & Elena Renken, *New Coronavirus Disease Officially Named COVID-19 by the World Health Organization*, NAT'L PUB. RADIO (Feb. 11, 2020), https://www.npr.org/ sections/goatsandsoda/2020/02/11/802352351/new-coronavirus-gets-an-official-name-from-the-world-health-organization [https://perma.cc/UKY9-VMTK].

56 *Interim Guidance for Businesses and Employers to Plan and Respond to Coronavirus Disease 2019 (COVID-19)*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 8, 2021), https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-business-response.html [https://perma.cc/2JFH-WLBC].

57 *WHO Director-General's Opening Remarks at the Media Briefing on COVID-19*, WORLD HEALTH ORG., (Mar. 11, 2020), https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020 [https://perma.cc/J5J7-S6FB].

58 Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak, Proclamation No. 9994, 85 Fed. Reg. 15,337 (Mar. 13, 2020), https://www.federalregister.gov/documents/2020/03/18/2020-05794/declaring-a-national-emergency-concerning-the-novel-coronavirus-disease-covid-19-outbreak [https://perma.cc/V73U-GHQJ].

59 President Trump announced that starting February 2, his administration would bar entry to foreign nationals that pose a threat of transmitting the virus and will quarantine U.S. citizens and foreign nationals traveling to the U.S. from China for up to fourteen days. *See* Suspension of Entry as Immigrants and Nonimmigrants of Persons Who Pose a Risk of Transmitting 2019 Novel Coronavirus and Other Appropriate Measures To Address This Risk, Proclamation No. 9984, 85 Fed. Reg. 6,709 (Jan. 31, 2020), https://www.federalregister.gov/documents/2020/02/05/2020-02424/suspension-of-entry-as-immigrants-and-nonimmigrants-of-persons-who-pose-a-risk-of-transmitting-2019 [https://perma.cc/LFT2-7KU5]; Suspension of Entry as Immigrants and Nonimmigrants of Certain Additional Persons Who Pose a Risk of Transmitting 2019 Novel Coronavirus, Proclamation No. 9992, 85 Fed. Reg. 12,855 (Feb. 29, 2020), https://www.federalregister.gov/documents/2020/03/04/2020-04595/suspension-of-entry-as-immigrants-and-nonimmigrants-of-certain-additional-persons-who-pose-a-risk-of [https://perma.cc/J9HR-HD9W]; Suspension of Entry as Immigrants and Nonimmigrants of Certain Additional Persons Who Pose a Risk of Transmitting 2019 Novel Coronavirus, Proclamation No. 9993, 85 Fed. Reg. 15,045 (Mar. 11, 2020), https://www.federalregister.gov/documents/2020/03/16/2020-05578/suspension-of-entry-as-immigrants-and-nonimmigrants-of-certain-additional-persons-who-pose-a-risk-of [https://perma.cc/W9NU-PEVV].

discussed below, included the President's "15 Days to Slow the Spread" strategy and state and locality-mandated stay-at-home orders.

1. Federal Emergency Responses: 15 Days to Slow the Spread

President Trump announced the *Coronavirus Guidelines for America*, also referred to as "15 Days to Slow the Spread," on March 16, 2020.[60] The voluntary guidelines instructed citizens to stay home, avoid social gatherings, and avoid discretionary travel. However, the first item listed, bolded and capitalized, was: "[l]isten to and follow the directions of your STATE AND LOCAL AUTHORITIES."[61]

The White House also emphasized that food industry sector workers should continue to work during the national effort to halt the spread of COVID-19, noting:

> If you work in a critical infrastructure industry, as defined by the Department of Homeland Security, such as healthcare services and pharmaceutical and food supply, you have a special responsibility to maintain your normal work schedule. You and your employers should follow CDC guidance to protect your health at work.[62]

As a result, this federal directive carved out a specific role to state and local governments to set COVID-19 policies, leading to developments at the state and county levels. Additionally, it brought heightened attention to who and what qualified as a "critical infrastructure industry."

2. State and Local "Stay-at-Home" Orders

By the time the *Coronavirus Guidelines for America* were announced, nearly every U.S. state had made an emergency declaration. As the pandemic continued to escalate, state and local governments began implementing increasingly aggressive measures, including restrictions on when and which businesses may operate, as well as quarantines, curfews, and stay-at-home orders. The restrictions varied in scope from state-to-state and county-to-county, leading to confusion about who was covered and who was exempt.

Companies with operations across state lines faced the unique challenge of harmonizing conflicting and at times contradictory state guidance. Some of the state measures were tailored to accommodate continued operation of the food sector, while others were more general. Many relied upon DHS's definition of "critical infrastructure worker" to, for the most part, exempt those individuals from the various shut down requirements.

3. Food Industry as Critical Infrastructure

Recognizing the need for direction and clarity, on March 19, DHS CISA released its *Guidance on the Essential Critical Infrastructure Workforce: Ensuring Community and National Resilience in COVID-19 Response* and a companion "Critical

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[60] WHITE HOUSE, THE PRESIDENT'S CORONAVIRUS GUIDELINES FOR AMERICA: 15 DAYS TO SLOW THE SPREAD (Mar. 16, 2020), https://web.archive.org/web/20200316222805/https:/www.whitehouse.gov/wp-content/uploads/2020/03/03.16.20_coronavirus-guidance_8.5x11_315PM.pdf [https://perma.cc/GH7V-LV5D].

[61] *Id.* (emphasis as written).

[62] *Id.*

Infrastructure List."[63] The guidance was "intended to support State, Local, and industry partners in identifying the critical infrastructure sectors and the essential workers needed to maintain the services and functions Americans depend on daily and that need to be able to operate reliantly during the COVID-19 pandemic response."[64] The guidance "identifies workers who conduct a range of operations and services that are essential to continued critical infrastructure viability" across a number of critical sectors, including food and agriculture workers.[65]

The guidance is represented as the federal government's policy, yet CISA prominently discloses, in bold text, that its "list is advisory in nature" and "[i]t is not, nor should it considered to be a federal directive or standard in and of itself."[66] Instead, CISA notes, "State, local, tribal, and territorial governments are ultimately in charge of implementing and executing response activities in communities under their jurisdiction," and that the CISA list is intended to "assist prioritizing activities related to continuity of operations and incident response, including the appropriate movement of critical infrastructure workers within and between jurisdictions."[67]

IV. FOOD AND AGRICULTURE SECTOR CHALLENGES AND NEEDS

As the pandemic unfolded, a number of challenges confronted the food industry and the agencies that regulate it.[68] The nature of these challenges provides a useful context for understanding the regulatory response that followed. It would be unwieldy to attempt to capture all the issues presented by a global pandemic. Nonetheless, looking back from the vantage point of the time of authorship, it appears that five basic challenges predominated the early months of the pandemic. These include 1) navigating the federal, state, and local response; 2) managing supply chain disruptions; 3) safeguarding the health of employees; 4) ensuring confidence in the safety of the food supply; and 5) how to enforce existing regulatory requirements against this backdrop.

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[63] CYBERSECURITY & INFRASTRUCTURE AGENCY, MEMORANDUM FROM CHRISTOPHER C. KREBS, DIRECTOR OF CYBERSECURITY AND INFRASTRUCTURE SECURITY AGENCY ON IDENTIFICATION OF ESSENTIAL CRITICAL INFRASTRUCTURE WORKERS DURING COVID-19 RESPONSE (Mar. 19, 2020), https://www.cisa.gov/sites/default/files/publications/CISA-Guidance-on-Essential-Critical-Infrastructure-Workers-1-20-508c.pdf [https://perma.cc/G6U6-BUJT].

[64] *Id.*

[65] *Id.*

[66] *Id.*

[67] *Id.* As of October 2020, CISA updated the Critical Infrastructure Workers Guidance three times, on March 28, 2020, April 17, 2020, and August 18, 2020. *CISA Releases Version 3.0 of Guidance on Essential Critical Infrastructure Workers During COVID-19*, CYBERSECURITY & INFRASTRUCTURE SEC. AGENCY (Apr. 17, 2020), https://www.cisa.gov/news/2020/04/17/cisa-releases-version-30-guidance-essential-critical-infrastructure-workers-during [https://perma.cc/W7UM-UTKX]; *CISA Releases Updated Guidance on Essential Critical Infrastructure Workers*, CYBERSECURITY & INFRASTRUCTURE SEC. AGENCY (Aug. 18, 2020), https://www.cisa.gov/news/2020/08/18/cisa-releases-updated-guidance-essential-critical-infrastructure-workers [https://perma.cc/V3RJ-VHMH]. Updates included additional recommendations for government and businesses to conform with evolving guidance issued by CDC, as well as various changes clarifying the scope of food and agriculture sector workers.

[68] The discussion in this section is drawn largely from the authors' lived experiences advising companies and trade associations through the early stages of the COVID-19 pandemic.

As discussed above, as COVID-19 rapidly spread in the United States, the federal government, states, and localities responded. The nature of these responses varied significantly. In some cases, there were quarantine, lock-down, or shut down orders of some kind, though the restrictions, timing, and nature of the businesses affected varied. Similarly, in some jurisdictions there were requirements for workers to wear face masks and other worker safety protocols were mandated. Yet simultaneously, other regulatory bodies issued recommendations or guidance for worker safety practices, not requirements. For the food industry, navigating these overlapping and sometimes conflicting approaches presented significant obstacles.

Moreover, both the industry and the regulators were confronted with a trifecta of challenges related to the pandemic response. The first of these related to the disruptions in the food supply. These disruptions could be seen as items flew off the shelves at grocery stores creating shortages as those "sheltering in place" sought out comfort foods, stocked pantries, and engaged in cooking more meals at home. Meanwhile, restaurants and food service operators faced unsold inventory because no longer were significant portions of the population dining out or eating in workplace cafeterias. Further, the global nature of the pandemic also meant that certain ingredients and foods were not always available. Food manufacturers needed to produce more food, produce particular types of food, produce it for retail channels, and produce it faster. And the government needed to assure consumers that disruptions were only temporary and localized, and that the overall integrity of the food supply chain was strong.

Contributing to and compounding the supply chain issues was the need to implement workplace safety measures to keep employees safe and prevent the spread of COVID-19. Although the food and agriculture sector and the government shared the goal of safeguarding worker health and safety, in the spring of 2020 very little was known or agreed upon about the best way to do so. One only needs to recall the early advice not to wear a face mask to be reminded of just how confusing it was.[69] Food manufacturers, distributors, retailers, and restaurants needed to give their employees the confidence that it was safe to come to work, but also that their interactions with the public would be safe as well. And not only did the industry need to know what practices to implement, but it also needed the tools and equipment to do so, such as personal protective equipment and cleaning and sanitation supplies, which were in short supply.[70]

Additionally, the uncertainties presented by the novel coronavirus and the best methods to control the spread also led to confusion and concern about whether food

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[69] *See, e.g.*, Huo Jingnan, Allison Aubrey & Carmel Wroth, *Should We All Be Wearing Masks in Public? Health Experts Revisit the Question*, NAT'L PUB. RADIO (Mar. 31, 2020), https://www.npr.org/sections/health-shots/2020/03/31/824560471/should-we-all-be-wearing-masks-in-public-health-experts-revisit-the-question [https://perma.cc/8LQD-M5L8]; Alexi Cohan, *Timeline: Changes to CDC Mask Guidelines Since the Pandemic Began*, BOSTON HERALD (July 27, 2021), https://www.bostonherald.com/2021/07/27/timeline-changes-to-cdc-mask-guidelines-since-the-pandemic-began/ [https://perma.cc/9BKE-RZGK].

[70] *See* Tara Lagu, Rachel Werner & Andrew W. Artenstein, *Why Don't Hospitals Have Enough Masks? Because Coronavirus Broke the Market*, WASH. POST (May 21, 2020), https://www.washingtonpost.com/outlook/2020/05/21/why-dont-hospitals-have-enough-masks-because-coronavirus-broke-market/ [https://perma.cc/25RZ-AMWR]; Andrew Jacobs, *Grave Shortages of Protective Gear Flare Again as Covid Cases Surge*, N.Y. TIMES (July 8, 2020), https://www.nytimes.com/2020/07/08/health/coronavirus-masks-ppe-doc.html [https://perma.cc/CH9K-UKXF].

and/or food packaging could be a source of transmission of the virus.[71] Videos of how to wipe down food packaging went viral. Consumers were attempting to wash fruits and vegetables with soap. And of paramount concern, if there was evidence of food as a vector of transmission, the disruptions to the food supply could be so insurmountable so as to produce chaos, panic, and societal disorder. As a result, both the industry and the government had a keen interest in assuring consumers that the food supply was safe.

For the regulatory agencies, they were tasked with responding to and resolving these challenges while also considering whether and how to enforce the basic rules on which they rely to protect public health. FDA and FSIS needed to decide how to conduct inspections at food facilities in light of concerns about both inspector safety and the safety for the workers at the facility. They also had to select which labeling requirements to enforce and which food safety regulations to prioritize. Moreover, responding to the pandemic and the problems presented also meant shifting pre-existing work plans and ongoing policy initiatives. As a result, much of the work that was not focused on responding to the pandemic was placed on the backburner for several months, if not longer.[72] Nonetheless, other food safety issues—such as those related to outbreaks and recalls—continued, necessitating the agencies' attention and response.

Against this backdrop of challenges, we can review the agencies' response.

V. REGULATORY RESPONSE

A. Federal Agencies' Response to Fast-Paced, Complex Novel Coronavirus

Federal agencies and the White House responded to the pandemic challenges and uncertainties using an assortment of regulatory mechanisms, from Executive Orders and agency guidance to informal statements issued through "Q&A's." Regardless of the form, each action can be described as responding to one or more of four primary challenges as discussed above: 1) supply chain disruptions; 2) the health and safety of food industry employees; 3) consumer confidence in the food supply;[73] and 4) agency

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[71] *See, e.g.*, Michael Sullivan, *Should You Sanitize Your Groceries?* N.Y. TIMES: WIRECUTTER (Mar. 30, 2020), https://www.nytimes.com/wirecutter/blog/should-you-sanitize-groceries/ [https://perma.cc/3BST-JLFE]; Tara Parker-Pope, *Is the Virus on My Clothes? My Shoes? My Hair? My Newspaper?*, N.Y. TIMES (Apr. 17, 2020, Updated May 13, 2020), https://www.nytimes.com/2020/04/17/well/live/coronavirus-contagion-spead-clothes-shoes-hair-newspaper-packages-mail-infectious.html [https://perma. cc/S4MM-866D]; Emily Anthes, *Has the Era of Overzealous Cleaning Finally Come to an End?* N.Y. TIMES (Apr. 8, 2021), https://www.nytimes.com/2021/04/08/health/coronavirus-hygiene-cleaning-surfaces.html [https://perma.cc/H9AX-J77E].

[72] For example, from March 16, 2020 through September 1, 2020, the *Federal Register* shows that FDA published thirteen notices, proposed rules, or final rules having to do in some way with human food but not related to COVID-19. During that same period in 2019, FDA published twenty-five such documents, or nearly twice as many. This is an admittedly crude analytical approach with ample room for refinement, but it at the least shows a drop in regulatory activity, and it is consistent with the authors' experience that the amount of FDA regulatory activity unrelated to COVID-19 dropped precipitously during this period.

[73] Notably absent from this list is food safety. Fortunately, regulators early on determined that the coronavirus did not present a food safety risk, and to the extent food safety presented a challenge, the challenge was communicating to consumers that there were no food safety issues related to COVID-19, as will be seen further below.

enforcement of existing requirements. A discussion of the key regulatory actions as they relate to the primary challenges follows.

1. Supply Chain Disruptions

In March and April 2020, consumers in the United States cleared out grocery store shelves while newly shuttered restaurants and their suppliers faced a mounting surplus of inventory. FDA and USDA worked to recalibrate these disrupted distribution channels by redirecting resources through labeling flexibilities, expanding production capabilities, activating systems to ensure continued production of meat and poultry, and promoting voluntary reporting procedures to gain insights into supply chain issues.

i. Diverting Product

FDA and USDA both require food products to bear a label, the contents of which vary in part depending on whether the product is sold at retail (e.g., grocery stores) or to food service establishments (e.g., restaurants, hotels, or cafeterias).[74] Both agencies announced similar changes in their approach toward enforcing these labeling requirements.

For example, on March 23, 2020, FSIS announced in a Constituent Update that the agency was temporarily exercising enforcement discretion to provide labeling flexibilities for redirecting to retail meat and poultry products originally intended for food service.[75] Notably, the enforcement discretion applied only to food that had already been produced, while FSIS continued to expect all food currently in production to meet all requirements.[76] The Constituent Update addressed temporary allowances under three scenarios: 1) labeling product at a federal establishment; 2) labeling at retail for bulk product already in commerce; and 3) labeling at retail for product in unlabeled protective coverings already in commerce.[77] Similarly, on April 13, USDA's Agricultural Marketing Service (AMS) announced through a press release that it would temporarily exercise enforcement discretion for its law requiring certain foods sold at retail to include a label stating where the product originated (Country of Origin Labeling or "COOL"), and the method of production.[78] The stated purpose of the enforcement discretion was to facilitate the redistribution of food products intended for food service to be sold in retail establishments.[79]

FDA permitted similar flexibilities, making two labeling announcements on March 26. First, FDA published a guidance document detailing the conditions under which a restaurant or food manufacturer may sell packaged food labeled for foodservice use

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74 *See* 21 C.F.R. § 101 (2020); 9 C.F.R. § 317 (2020); 9 C.F.R. § 381 (2020).

75 *FSIS Constituent Update Special Alert: Temporary Allowances for Labels Going to Retail*, FOOD SAFETY & INSPECTION SERV., U.S. DEP'T OF AGRIC. (Mar. 23, 2020), https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/SpecialAlert03232020.pdf [https://perma.cc/2WQU-4V4A].

76 *Id.*

77 *Id.*

78 *USDA Announces Labeling Flexibilities to Facilitate Distribution of Food to Retail Locations*, U.S. DEP'T OF AGRIC. AGRIC. MKTG. SERV. (Apr. 13, 2020), https://www.ams.usda.gov/content/usda-announces-labeling-flexibilities-facilitate-distribution-food-retail-locations [https://perma.cc/4P7X-9SRD] [hereinafter *USDA Announces Labeling Flexibilities*]. *See also COOL Frequently Asked Questions Regarding COVID-19 Enforcement Discretion*, U.S. DEP'T OF AGRIC. AGRIC. MKTG. SERV. (Apr. 13, 2020), https://www.ams.usda.gov/rules-regulations/cool/covid-qa [https://perma.cc/RGJ9-HTKA].

79 *USDA Announces Labeling Flexibilities*, *supra* note 78.

(i.e., without nutrition labeling) directly to consumers.[80] The same day, FDA also announced it would not focus on enforcement actions related to the use of the recently updated Nutrition and Supplement Facts labels, which had a compliance date of January 2020.[81] Through this decision, FDA extended an earlier announcement that it would use this form of enforcement discretion for the first six months of implementation of the regulation.[82]

Shortages of certain ingredients led FDA to issue a temporary policy allowing the food industry to make minor formulation changes that may cause the finished food label to be inaccurate but do not pose a health or safety issue or otherwise cause significant changes in the finished food.[83] A manufacturer could omit or substitute a labeled ingredient if it was present at sufficiently low quantity (2% or less by weight of the finished food), it was not a major or characterizing ingredient, its omission or substitution would not affect the nutrient content claims or health claims on the label, and it would not impact the nutritional differences or functionality of the finished product.[84]

In some cases, FDA issued guidance specific to a particular commodity. For example, FDA issued two guidance documents to facilitate the production and sale of eggs. First, FDA provided retailers with some flexibility from labeling requirements for shell eggs, laying the basis for retailers to sell unlabeled cartons or flats.[85] FDA provided certain conditions that must be met in order for the flexibility to apply (such as requiring the retailer to state on a display card or tag basic information, including Statement of Identity, and name and place of manufacturer, packer, or distributor), and noted that as the availability of packaging and labeling materials improved, the agency encouraged industry to "resume full labeling as soon as practicable."[86] Second, FDA later issued a temporary guidance providing flexibility regarding Egg Safety Rule requirements, permitting egg producers who only sold eggs to egg-breaking facilities

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[80] U.S. FOOD & DRUG ADMIN., FDA GUIDANCE FOR INDUSTRY: TEMPORARY POLICY REGARDING NUTRITION LABELING OF CERTAIN PACKAGED FOOD DURING THE COVID-19 PUBLIC HEALTH EMERGENCY (Mar. 2020), https://www.fda.gov/media/136469/download [https://perma.cc/M2X6-V64Q]. Additionally, on March 26, FDA announced it will not focus on enforcement actions related to the use of the updated Nutrition and Supplement Facts labels. FDA had previously announced this form of enforcement discretion for the first six months of implementation of the regulation.

[81] *FDA Constituent Update: FDA Provides Temporary Flexibility Regarding Nutrition Labeling of Certain Packaged Food in Response to the COVID-19 Pandemic*, U.S. FOOD & DRUG ADMIN. (Mar. 26, 2020), https://www.fda.gov/food/cfsan-constituent-updates/fda-provides-temporary-flexibility-regarding-nutrition-labeling-certain-packaged-food-response-covid [https://perma.cc/QEF4-H7TN].

[82] *Id.*

[83] U.S. FOOD & DRUG ADMIN., FDA GUIDANCE FOR INDUSTRY: TEMPORARY POLICY REGARDING CERTAIN LABELING REQUIREMENTS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY: MINOR FORMULATION CHANGES AND VENDING MACHINES (May 2020), https://www.fda.gov/media/138315/download [https://perma.cc/ES3H-GMP5].

[84] *Id.*

[85] U.S. FOOD & DRUG ADMIN., FDA GUIDANCE FOR INDUSTRY: TEMPORARY POLICY REGARDING PACKAGING AND LABELING OF SHELL EGGS SOLD BY RETAIL FOOD ESTABLISHMENTS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY (Apr. 2020), https://www.fda.gov/media/136671/download [https://perma.cc/DM8D-LGHN].

[86] *Id.*

for further processing to sell eggs directly to consumers in retail establishments (i.e., the table egg market).[87]

In addition to increased demand for groceries, restaurants needed to alter their business practices quickly, switching from dine-in to takeout-only or making menu substitutions. While FDA generally requires chain restaurants and other food service establishments to provide nutrition information on menus and menu boards,[88] FDA issued guidance temporarily waiving these labeling provisions.[89]

ii. Maintaining Operations Across Industries

The meat and poultry industry received special attention as the months continued. On April 26, CDC and the Occupational Safety and Health Administration (OSHA) issued interim guidance on COVID-19 considerations for meat and poultry processing workers and employers.[90] This was one of the most comprehensive COVID-19 workplace safety guidance documents to date for a specific industry. It provided detailed instructions on worker safety practices and previously identified mitigation strategies such as social distancing, engineering controls to minimize potential contact, protective gear and face coverings, shift staggering, health screenings, training and awareness, and financial incentives not to report to work sick.[91] USDA strongly recommended meat and poultry processing plants use the guidance to implement their own practices and protocols "for staying operational."[92]

Building on the CDC/OSHA guidance, President Trump issued an Executive Order on April 29 invoking the DPA to protect the meat and poultry production supply chain.[93] In the Executive Order, entitled *Delegating Authority Under the Defense Production Act with Respect to Food Supply Chain Resources During the National Emergency Caused by the Outbreak of COVID-19*, the President found that the meat and poultry supply chain met the criteria under Section 101(b) of the DPA.[94] This meant that meat and poultry products were considered "scarce and critical material essential to the national defense" and such national defense requirements "cannot otherwise be met without creating a significant dislocation of the normal distribution"

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87 U.S. FOOD & DRUG ADMIN., FDA GUIDANCE FOR EGG PRODUCERS: TEMPORARY POLICY REGARDING ENFORCEMENT OF 21 CFR PART 118 (THE EGG SAFETY RULE) DURING THE COVID-19 PUBLIC HEALTH EMERGENCY (Apr. 2020), https://www.fda.gov/media/136732/download [https://perma.cc/L879-B8QW].

88 *See* 21 U.S.C. § 403(q)(5)(H); 21 C.F.R. § 1010.11.

89 U.S. FOOD & DRUG ADMIN., FDA GUIDANCE FOR INDUSTRY: TEMPORARY POLICY REGARDING NUTRITION LABELING OF STANDARD MENU ITEMS IN CHAIN RESTAURANTS AND SIMILAR RETAIL FOOD ESTABLISHMENTS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY (Apr. 2020), https://www.fda.gov/media/136597/download [https://perma.cc/YLF2-QA5N].

90 *Interim Guidance for Meat and Poultry Processors*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/meat-poultry-processing-workers-employers.html (last updated July 9, 2020) [https://perma.cc/7Y8F-Q9VM].

91 *See generally id.*

92 *Food Supply Chain Q&A*, U.S. DEP'T OF AGRIC., https://www.usda.gov/coronavirus/food-supply-chain [https://perma.cc/YPE9-QQ8T].

93 Exec. Order No. 13917, 85 Fed. Reg. 26,313 (Apr. 28, 2020), https://trumpwhitehouse.archives.gov/presidential-actions/executive-order-delegating-authority-dpa-respect-food-supply-chain-resources-national-emergency-caused-outbreak-covid-19/ [https://perma.cc/9GBU-8DCK].

94 *Id.*

of these products in the marketplace.[95] This designation triggered various mechanisms that would allow the federal government to require companies to prioritize production and allocate supply of meat and poultry products should it wish to do so. Accordingly, the Executive Order ordered USDA to take all appropriate actions to ensure that meat and poultry plants continue operation consistent with industry guidance jointly issued by CDC and OSHA intended to protect worker safety.[96]

Following the Executive Order, USDA took three actions. First, USDA Secretary Sonny Perdue sent letters to state governors and meat and poultry processing company leaders setting forth USDA's expectations for continued operations during the COVID-19 pandemic.[97] In the letters, Secretary Perdue explained that he had "directed" meat and poultry processors to utilize CDC and OSHA guidance.[98] Second, USDA updated its Q&As on May 10 to address the Executive Order, notably stating that, if necessary, USDA may issue orders under the EO and DPA requiring meat and poultry establishments that were currently closed to fulfill their contracts.[99]

Third, on May 18, USDA and FDA issued a Memorandum of Understanding (MOU) regarding the potential use of the DPA with regard to FDA-regulated food.[100] While USDA retained its DPA authority for products subject to FDA jurisdiction, the MOU established that FDA would be responsible for monitoring the continued functioning of the FDA-related food production sector, bringing issues to USDA's attention should FDA believe that USDA may need to exercise its DPA authorities to address a situation.[101] The MOU did not actually take any action under the DPA—it did not reflect action by USDA expanding the scope of the President's invocation of the DPA beyond the meat and poultry sectors, nor did it constitute an "order" under the DPA. Although attracting much industry attention at the time, this EO had only indirect consequences in the industry, serving more as federal leverage with states than the DPA's more traditional procurement function.

FDA took a different approach to supporting food production. In an effort for the agency to "better understand the current status of the food supply and address challenges facing food producers," FDA issued guidance for human food establishments establishing a voluntary reporting system.[102] The guidance detailed a mechanism by which human food facilities and farms could voluntarily notify FDA of temporary closures and significant reductions in operations, or to request a dialogue

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95 50 U.S.C. § 4511(b).

96 *See id.*

97 Letter from Sec'y Perdue, Sec'y of Agric., on Exec. Order Delegating Authority Under the Defense Production Act with Respect to the Food Supply Chain Resources During the National Emergency Caused by the Outbreak of COVID-19 (May 5, 2020), https://www.usda.gov/sites/default/files/documents/governor-letters-covid.pdf [https://perma.cc/6T8D-ATT8].

98 *Id.*

99 *Food Supply Chain Q&A*, *supra* note 92.

100 Letter from FDA to Industry Regarding MOU No. 225-20-011, Potential Use of the Defense Production Act with Regard to FDA-Regulated Food During the COVID-19 Pandemic (May 18, 2020), https://www.fda.gov/media/138172/download [https://perma.cc/2R5E-T7SP].

101 *Id.*

102 U.S. FOOD & DRUG ADMIN., FDA GUIDANCE FOR INDUSTRY: REPORTING A TEMPORARY CLOSURE OR SIGNIFICANTLY REDUCED PRODUCTION BY A HUMAN FOOD ESTABLISHMENT AND REQUESTING FDA ASSISTANCE DURING THE COVID-19 PUBLIC HEALTH EMERGENCY (May 2020), https://www.fda.gov/media/138375/download [https://perma.cc/FB8J-VS6L].

with FDA on issues related to continuing or restarting their operations during the COVID-19 pandemic.[103] FDA did not traditionally collect such information, demonstrating a shift toward a broader agency interest, not necessarily on the products it regulates, but rather the businesses that produce them.[104]

Separate from food, hygienic products such as hand sanitizer were a particularly elusive commodity. Typically, FDA permits only licensed or registered drug manufacturers to produce alcohol-based hand sanitizers.[105] However, responding to the heightened demand for hand sanitizer, FDA updated two guidance documents announcing 1) that it would exercise enforcement discretion for entities (such as food and beverage alcohol manufacturers) that were not at the time licensed but would like to prepare alcohol-based hand sanitizer;[106] and 2) the guidelines for the manufacture of alcohol to be incorporated in alcohol-based hand sanitizer products.[107] These guidance documents opened the door for food and alcohol manufacturers to repurpose their facilities to provide the nation, including their own employees, with the necessary supplies to combat the virus.[108] Ensuring employee access to critical personal protective equipment, such as hand sanitizer, was an important element for maintaining operations.

2. Worker Health and Safety

Designated as "essential workers" responsible for maintaining the nation's food supply, food industry employees who worked on farms, in factories, grocery stores, and restaurants, and anywhere in between, faced a heightened risk of exposure to COVID-19. Accordingly, agencies took various measures to protect their health and safety.

Both FDA and USDA launched new websites in mid-March to capture their food-industry-specific advice regarding COVID-19.[109] FDA's website included Q&As addressing issues such as how food facilities should respond if an employee is diagnosed with COVID-19; reference guides on the use of respirators, facemasks, and

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[103] *Id.*

[104] In the authors' experience, FSIS also informally encouraged regulated establishments to report potential disruptions but did not establish a formal mechanism for doing so.

[105] *See, e.g.*, *Registration and Listing Assistance for Non-Traditional Manufacturers of Hand Sanitizer and Related COVID-19 Drugs*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/coronavirus-covid-19-drugs/registration-and-listing-assistance-non-traditional-manufacturers-hand-sanitizer-and-related-covid (last accessed Oct. 22, 2021) (noting that drug manufacturers, which include manufacturers of alcohol-based sanitizers, must register with FDA) [https://perma.cc/7QKS-FMEK].

[106] U.S. FOOD & DRUG ADMIN., FDA GUIDANCE FOR INDUSTRY: TEMPORARY POLICY FOR THE PREPARATION OF CERTAIN ALCOHOL-BASED HAND SANITIZER PRODUCTS DURING THE PUBLIC HEALTH EMERGENCY (COVID-19), https://www.fda.gov/media/136289/download (last updated Aug. 7, 2020) [https://perma.cc/TUU3-8AN3].

[107] *Id.* FDA took many other actions outside the immediate food context—including vaccine authorizations—but we emphasize the sanitizer issue because it was immediately useful for procuring needed supplies and because it helped repurpose otherwise idle capacity.

[108] Jaewon Kang, *Retailers Couldn't Stock Hand Sanitizer Fast Enough. Now They Can't Give It Away*, WALL ST. J. (May 20, 2020), https://www.wsj.com/articles/america-is-awash-in-hand-sanitizer-11621522829 [https://perma.cc/PUZ7-AJXJ].

[109] *Food Safety and the Coronavirus Disease (COVID-19)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/food-safety-during-emergencies/food-safety-and-coronavirus-disease-2019-covid-19 [https://perma.cc/5QRD-58B7]; *Coronavirus Disease (COVID-19)*, U.S. DEP'T OF AGRIC., https://www.usda.gov/coronavirus [https://perma.cc/9F6E-ZZVK].

cloth face coverings; and a document outlining key steps that employers and workers could take to help businesses stay open, prevent and slow the spread of COVID-19, and support continuity of essential operations if workers are diagnosed or exposed to COVID-19.[110] With more people turning to takeout and delivery, on April 8, FDA issued a fact sheet and corresponding summary infographic on Best Practices for Retail Food Stores, Restaurants, and Food Pick-Up and Delivery Services During the COVID-19 Pandemic.[111] The first section of the document included the heading "Managing Employee Health (Including Contracted Workers)."[112] Similarly, on May 20, USDA published recommendations for prioritizing personal protective equipment and other sanitation supplies during the COVID-19 pandemic.[113] The document identifies the Food and Agriculture sector as a priority industry for distribution of supplies, preceded only by healthcare-providing establishments and emergency responders.[114]

For both agencies, many of these documents and statements direct employers to consult CDC and OSHA guidance. CDC and OSHA issued guidance generally applicable to all employers, those in critical infrastructure industries, as well as food and agriculture-specific guidance. For example, on June 1, CDC and OSHA issued an interim guidance on agriculture workers and employees, which addresses, among other things, COVID-19 exposure risk among agricultural workers, creating COVID-19 assessment and control plans, screening and monitoring workers, managing sick workers, and special considerations for shared housing and transportation.[115]

In addition to safeguarding the health of the workers producing, delivering, and selling food and beverages, FDA and USDA needed to ensure there were customers who felt safe consuming the food supply.

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[110] *What to Do if You Have a COVID-19 Confirmed or Exposed Worker or Workers in Your Food Production, Storage, or Distribution Operations Regulated by FDA*, U.S. FOOD & DRUG ADMIN. (Apr. 2020), https://www.fda.gov/food/food-safety-during-emergencies/what-do-if-you-have-covid-19-confirmed-positive-worker-or-workers-who-have-been-exposed-confirmed [https://perma.cc/SN97-V976]. FDA updated its Q&A website on April 4 to COVID-19 and Food Safety Q&As guidance to identify protocols prepared by the food industry trade association, Food and Beverage Issue Alliance (FBIA), which addressed how establishments should respond when a worker in a food production facility or on a farm tests positive for COVID-19. *Food Industry Recommended Protocols When Employee/Visitor/Customer Tests Positive for COVID-19*, ASS'N OF FOOD & DRUG OFFS. (Apr. 2, 2020), https://static1.squarespace.com/static/5e7d1107dac60a6b3e3f098d/t/5e8664c27e5db072ad336918/1585865924826/FBIA%20COVID19+Case%20Recommended%20Protocols_2April20%20Version%204.pdf [https://perma.cc/LKT8-MYT3].

[111] U.S. FOOD & DRUG ADMIN., FDA BEST PRACTICES FOR RETAIL FOOD STORES, RESTAURANTS, AND FOOD PICK-UP AND DELIVERY SERVICES DURING THE COVID-19 PANDEMIC (Apr. 2020), https://www.fda.gov/media/136811/download [https://perma.cc/FN2C-B4KR].

[112] *Id.* at 1.

[113] U.S. DEP'T OF AGRIC., CONSIDERATIONS FOR PRIORITIZATION OF PPE, CLOTH FACE COVERINGS, DISINFECTANTS, AND SANITATION SUPPLIES DURING THE COVID-19 PANDEMIC (May 20, 2020), https://www.usda.gov/sites/default/files/documents/food-ag-considerations-prioritization-supplies-during-covid-19.pdf [https://perma.cc/9WGY-T5TL].

[114] *Id.*

[115] *Agriculture Workers and Employers*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-agricultural-workers.html (last updated June 11, 2020) [https://perma.cc/74PX-MSTG]. *See Protecting Seafood Processing Workers from COVID-19*, CTRS. FOR DISEASE CONTROL & PREVENTION (June 24, 2020), https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-seafood-processing.html (issuing an interim guidance, developed in consultation with FDA, addressing the health of seafood processing workers) [https://perma.cc/DSY4-46QT].

3. Consumer Confidence

Empty grocery shelves left consumers questioning whether there was sufficient food supply to meet demand.[116] Moreover, if food was available, concerns of COVID-19 transmission led consumers to fear that food products and food contact surfaces could carry the virus.[117] The agencies' respective coronavirus websites offered a vehicle to keep consumers informed of the developments on the supply chain and the science of transmission.

FDA typically conveyed consumer messages through FDA Deputy Commissioner Frank Yiannas. On April 2, for example, FDA posted a video titled "What you Need to Know: Food and COVID-19 PSA with Frank Yiannas," where the Deputy Commissioner reiterated the safety of the food supply and the steps FDA had taken to protect both government and industry workers.[118] On April 16, FDA posted a separate conversation with Deputy Commissioner Yiannas, addressing many of the same topics, but with a particular focus on food availability and the supply chain challenges discussed in section (A) above.[119] Through each statement, FDA repeatedly assured that there were no nationwide shortages of food and the food supply remained safe. USDA disseminated similar messaging in a joint appearance by Deputy Commissioner Yiannas and USDA Undersecretary for Food Safety Dr. Mindy Brashears on Secretary of Agriculture Sonny Perdue's podcast in July.[120]

Growing evidence confirmed that the virus did not appear to create food safety issues, which both agencies addressed through their websites. Yet some countries restricted global food exports citing COVID-19 transmission. On June 24, FDA and USDA issued a joint statement in response, stating that these restrictions "are not consistent with the known science of transmission," and, once again, "there is no evidence that people can contract COVID-19 from food or from food packaging. The

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[116] Laura Reiley, *The Industry Says We Have Enough Food. Here's Why Some Store Shelves Are Empty Anyway*, WASH. POST., Apr. 14, 2020, https://www.washingtonpost.com/business/ 2020/04/14/ grocery-stores-empty-shelves-shortage/ [https://perma.cc/NS7E-WLAB]; Corina Knoll, *Panicked Shoppers Empty Shelves as Coronavirus Anxiety Rises*, N.Y. TIMES, Mar. 13, 2020, https://www.nytimes.com/2020/03/13/nyregion/coronavirus-panic-buying.html [https://perma.cc/H4FB-ZTM9]; Vivian Manning-Schaffel, *Coronavirus Fears Have Emptied Supermarket Shelves. Are You Panic-Buying?*, NBC NEWS, Mar. 5, 2020, https://www.nbcnews.com/better/lifestyle/coronavirus-fears-have-emptied-supermarket-shelves-are-you-panic-buying-ncna1148536 [https://perma.cc/MVJ7-5B3A].

[117] Katherine J. Wu, *You Probably Won't Catch the Coronavirus From Frozen Food*, N.Y. TIMES, Aug. 13, 2020, https://www.nytimes.com/2020/08/13/health/coronavirus-frozen-food.html [https://perma.cc/9KW8-CRJH]; Amelia Nierenberg, *Is Takeout and Delivery Food Safe?*, N.Y. TIMES, Aug. 13, 2020, https://www.nytimes.com/2020/05/27/dining/takeout-delivery-safety-coronavirus.html [https://perma.cc/G5HQ-WTAA].

[118] Frank Yiannas, *FDA Offers Assurance About Food Safety and Supply for People and Animals During COVID-19*, U.S. FOOD & DRUG ADMIN. (Apr. 2, 2020), https://www.fda.gov/news-events/fda-voices/fda-offers-assurance-about-food-safety-and-supply-people-and-animals-during-covid-19 [https://perma.cc/EP96-Y542].

[119] *FDA's Perspective on Food Safety and Availability During and Beyond COVID-19*, U.S. FOOD & DRUG ADMIN. (Apr. 16, 2020), https://www.fda.gov/food/conversations-experts-food-topics/fdas-perspective-food-safety-and-availability-during-and-beyond-covid-19 [https://perma.cc/79VR-8KFQ]

[120] *The Sonnyside of the Farm: Food Safety During the Coronavirus*, U.S. DEP'T OF AGRIC. (July 9, 2020), https://soundcloud.com/user-460120911/food-safety-during-the-coronavirus [https://perma.cc/DB8Z-E82C].

U.S. food safety system, overseen by our agencies, is the global leader in ensuring the safety of our food products, including product for export."[121]

4. Agency Enforcement of Existing Requirements

COVID-19 disrupted the operations of not only the food industry, but also the agencies charged with regulating the sector. Concerns of inspector safety made onsite inspections of food facilities and establishments and other mandated enforcement actions impractical. Recognizing these limitations, FDA, USDA, as well as the White House, took several actions to redefine agency enforcement of the governing laws and regulations.

The White House Office of Management and Budget (OMB) led the effort, issuing guidance on March 17 directing the heads of all departments and agencies to "reduce and re-prioritize non-mission-critical services to free up capacity for critical services" and "consider streamlining regulations and approval processes for critical services, including issuing general waivers policies and delegating decision-making where appropriate."[122] Under the guidance, OMB stated: "Agency heads shall utilize the full extent of their legal authority and discretion to execute this realignment of non-mission-critical activities, while also ensuring that their agencies continue to serve the American people and operate in the most efficient manner possible to deal aggressively and promptly with the current situation."[123]

USDA and FDA adjusted their facility inspection policies accordingly. On March 20, USDA issued guidance instructing industry what questions concerning COVID-19 it may ask of USDA employees (generally inspectors) to use as grounds to permit or deny USDA employees entry into its facility.[124]

FDA quickly scaled back its inspection operations, postponing foreign inspections on March 10, and all domestic routine facility inspections by March 18, with the caveat that inspections considered "mission critical" would still be considered on a case-by-case basis.[125] By eliminating most on-site inspections, FDA considered alternative

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[121] Press Release, U.S. Dep't of Agric., Sonny Perdue & Stephen M. Hahn: Joint Statement on Food Export Restrictions Pertaining to Covid-19 (June 24, 2020), https://www.usda.gov/media/press-releases/2020/06/24/joint-statement-usda-and-fda-food-export-restrictions-pertaining [https://perma.cc/BMU6-4MMX]; *see also* Minh Duong & Ali Webster, *COVID-19 and Food Safety Concerns: Results from the 2020 Food and Health Survey*, FOOD INSIGHT (June 26, 2020), https://foodinsight.org/covid-19-and-food-safety-concerns-results-from-the-2020-food-and-health-survey/ [https://perma.cc/H678-VKXB].

[122] OFF. OF MGMT. & BUDGET, FEDERAL AGENCY OPERATIONAL ALIGNMENT TO SLOW THE SPREAD OF CORONAVIRUS COVID-19 (Mar. 17, 2020), https://www.whitehouse.gov/wp-content/uploads/2020/03/M-20-16.pdf [https://perma.cc/K6YM-FGFD].

[123] *Id.*

[124] U.S. DEP'T OF AGRIC., MEMORANDUM FOR THE HEADS OF DEPARTMENTS AND AGENCIES: USDA GUIDANCE ON COVID-19 HEALTH QUESTIONNAIRES (Mar. 20, 2020), https://www.nichemeatprocessing.org/wp-content/uploads/2020/05/20200320_Coronavirus_questionaires-memo-for-establishments.pdf [https://perma.cc/3VB8-YJE7]. FSIS and AMS also issued a joint "Statement to Industry" addressing at a high-level inspection continuity issues. *See* U.S. Dep't of Agric., Statement to Industry from Mindy Brashears & Greg Ibach (Mar. 16, 2020), https://www.ams.usda.gov/content/statement-industry [https://perma.cc/2ZM4-JC6B].

[125] Press Release, Food & Drug Admin., Coronavirus Disease 2019 (COVID-19) Update: Foreign Inspections (Mar. 10, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-disease-2019-covid-19-update-foreign-inspections [https://perma.cc/5Z5H-W2JT]; Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Focuses on Safety of Regulated Products While Scaling Back Domestic Inspections (Mar. 18, 2020), https://www.fda.gov/news-events/press-

tools and approaches to verify food safety remotely. On March 17, FDA released a temporary guidance regarding Preventive Controls and the Foreign Supplier Verification Program (FSVP), announcing that the agency would not enforce requirements to conduct onsite audits under the FSVP regulations in certain situations related to COVID-19 and if other supplier verification methods were used instead, such as remote access.[126] On April 3, FDA announced in a Constituent Update that it would conduct FSVP inspections remotely, requesting that importers send the agency records required under the FSVP rule electronically or through "other prompt means."[127] Months later, FDA announced on July 10 its intentions to resume on-site domestic inspections, highlighting, however, that they would all be pre-announced.[128]

By May, government focus began to shift to overcoming the effect of the virus on the economy. Acting as a companion to OMB's March guidance encouraging agencies to provide regulatory flexibility, President Trump issued an Executive Order requiring agencies to review the regulatory standards they had temporarily rescinded or modified during the COIVD-19 pandemic and determine which, if any, would "promote economic recovery" if made permanent.[129] It also instructed agencies to consider situations in which a person or entity makes a reasonable attempt to comply with existing guidance—but fails to legally comply—to function as a rationale for declining enforcement of existing law and policy.[130] With the Executive Order, President Trump signaled a potential shift in the regulatory framework for agencies following the COVID-19 public health emergency.

B. Emergence of State and Local Regulatory Activities Created a Myriad of Approaches to a Food Industry Long Regulated Predominantly at Federal Level

The federal government was not the only actor responding to the COVID-19 crisis. State and local governments sprang to action with emergency actions of their own. Some of these actions were similar to federal responses, whereas others differed in significant ways. But throughout, food companies had to navigate an extremely complex web of state and local emergency actions. Complicating matters, nearly every major food company operates across state lines, and the broader food supply chain is a complicated network of multi-jurisdictional nodes. Although this Article's focus is

announcements/coronavirus-covid-19-update-fda-focuses-safety-regulated-products-while-scaling-back-domestic [https://perma.cc/LH69-JWRP].

[126] *See* U.S. FOOD & DRUG ADMIN., TEMPORARY POLICY REGARDING PREVENTIVE CONTROLS AND FSVP FOOD SUPPLIER VERIFICATION ONSITE AUDIT REQUIREMENTS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY (June 2020), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/temporary-policy-regarding-preventive-controls-and-fsvp-food-supplier-verification-onsite-audit [https://perma.cc/WTY9-CSJK].

[127] *FDA to Temporarily Conduct Remote Importer Inspections Under FSVP due to COVID-19*, U.S. FOOD & DRUG ADMIN. (Apr. 3, 2020), https://www.fda.gov/food/cfsan-constituent-updates/fda-temporarily-conduct-remote-importer-inspections-under-fsvp-due-covid-19 [https://perma.cc/MUZ3-6UBD].

[128] Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Prepares for Resumption of Domestic Inspections with New Risk Assessment System (July 10, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-prepares-resumption-domestic-inspections-new-risk-assessment-system [https://perma.cc/N78R-BANM].

[129] Exec. Order No. 13924, 85 Fed. Reg. 31,353 (May 19, 2020).

[130] *Id.*

federal action, it is important to understand the multifaceted state and local dynamic that served as a powerful undercurrent throughout the early COVID-19 crisis.

1. State Lockdown Orders

State and local orders took a variety of forms, and, like federal actions, were diverse in their nature. Many if not most state governors issued some sort of emergency order, but these varied tremendously in their scope. States such as New York[131] and Ohio[132] saw very aggressive lockdown orders, significantly restricting all but the most essential business operations and imposing substantial limitations on public gatherings. Other states took more targeted action or responded weeks or months after others.[133] Navigating lockdown orders presented multiple challenges for food companies trying to fulfill their societal mandate to feed the population.

Most orders operated by limiting public gatherings and ordering closures of or imposing restrictions on the operation of all but essential businesses. But essential businesses were not defined uniformly. Some states looked to the CISA list, although even when states looked to CISA's guidance, they did so differently. Some included a simple cross-reference to the prevailing list of critical infrastructure sectors as defined by CISA.[134] Others prepared their own lists that were drawn from CISA's guidance, but because of how lists were framed, in many instances the CISA influence would not have been obvious to the untrained observer. Other states developed their own lists with seemingly little reliance on the CISA guidance.[135] And many states expanded the list of critical infrastructure workers to include favored local industries.[136]

Lockdown orders were also executed in different ways. Some merely restricted business operations to only essential workers. Others imposed hours-of-operation restrictions. These limitations sometimes overlapped with worker density restrictions with exemptions for certain manufacturing segments.[137] Further complicating matters, some of the orders were challenged in court as exceeding the governor's emergency authority, raising questions about whether or how they would be enforced.[138]

Food companies operating across multiple jurisdictions had to track and rapidly analyze each of these orders, any of which could significantly jeopardize a critical part of a company's national supply chain. Moreover, in the initial phase in which

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[131] N.Y. Exec. Order No. 202.3, Continuing Temporary Suspension and Modification of Laws Relating to the Disaster Emergency (2020).

[132] Ohio Dep't of Health, Director's Order that All Persons Stay at Home Unless Engaged in Essential Work or Activity (2020).

[133] *See, e.g.*, Ga. Exec. Order 03.23.20.01 (2020) (ordering shelter-in-place for specific populations); Ga. Exec. Order 04.04.40.01 (2020) (issuing statewide shelter-in-place).

[134] *See, e.g.*, Cal. Exec. Order N-33-20 (2020).

[135] *See, e.g.*, Mass., COVID-19 Essential Services, Exhibit A of the Order of the Governor Assuring Continued Operation of Essential Services in the Commonwealth, Closing Certain Workplaces and Prohibiting Gatherings of More than 10 People, https://www.mass.gov/doc/covid-19-essential-services/download (attached to Mass. COVID-19 Order No. 13 (2020)).

[136] *See* Ill. Exec. Order No. 2020-10, COVID-19 Exec. Order No. 8 (2020) (exempting "firearm and ammunition suppliers and retailers for purposes of safety and security").

[137] *See, e.g.*, Wis. Emergency Order No. 12 (2020).

[138] *See, e.g.*, *In re* Certified Questions from the U.S. Dist. Ct., W. Dist. of Mich., S. Div., 958 N.W.2d 1 (Mich. 2020); Cnty. of Butler v. Wolf, 486 F. Supp. 3d 883 (W.D. Pa. 2020); Wisc. Leg. v. Palm, 942 N.W.2d 900 (Wis. 2020).

shutdown orders were rapidly deployed across the country, there was significant confusion on whether and how they would be enforced, to the extent that companies were unsure whether an individual commuting to or from work or a truck driver transporting product across state lines would face checkpoints or be required to prove they were fulfilling an essential function, and even how that proof would be made. Indeed, many food companies took to supplying their workers with company-generated letters identifying the worker as a critical infrastructure worker in the hopes that might satisfy a county sheriff.[139]

2. State Workplace Safety Orders

Following closely on the heels of the initial lockdown orders came state and local workplace safety guidance, and in some cases regulation.[140] As one of the industries continuing to operate—and as one of the essential industries with regular physical contact with the public—the food sector faced unique vulnerabilities regarding the potential for COVID-19 transmission among workers and with the public. Food companies therefore had to respond quickly to rapidly issued workplace safety guidance, which had the potential to vary by jurisdiction and even by county. Some of this guidance was consistent with federal guidance, whereas other states took different approaches, and guidance was often updated regularly. Companies were thus forced to piece together varying guidance for the different jurisdictions in which they operated, often requiring either different programs for different facilities or developing a single program that would satisfy every jurisdiction.

In adapting to state and local workplace safety guidance, companies also had to determine how to prioritize among recommendations. "Guidance" is a double-edged sword, providing both the potential for flexibility and the risk of applying flexibility too liberally. Companies, faced with extremely little established scientific information on COVID-19 transmission, had to determine which recommendations from state and local guidance to implement, with the recognition that their decisions could be viewed in the future through the lens of much more nuanced scientific understanding about the novel coronavirus. Moreover, there was the possibility that state or local guidance could be interpreted as the basis for state enforcement or presented as the appropriate standard of care in future litigation, forcing companies to continuously reevaluate their programs in the face of ever-changing information. In other words, it was often unclear whether a state viewed guidance as a mere suggestion or as a recommendation that would be expected to be implemented.

Moreover, regardless of whether or how a state's guidance would be enforced, state workplace safety guidance varied in the flexibility provided to food manufacturers. For example, maintaining physical distance between workers was one common recommendation. Some state guidance, consistent with federal guidance, qualified that physical distancing recommendations should be adopted when feasible.[141] Others,

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[139] The authors are familiar with such letters.

[140] *See, e.g.*, WIS. DEP'T OF HEALTH SERVS., GUIDANCE ON PREPARING WORKPLACES FOR COVID-19: PROFESSIONAL SERVICES INDUSTRY: COMMERCIAL OFFICE SPACES (2020); CAL. DEP'T. OF PUB. HEALTH & CAL DEP'T OF INDUS. RELS., COVID-19 INDUSTRY GUIDANCE: OFFICE WORKSPACES (2020); 16 VA. ADMIN. CODE § 25-220 (2020).

[141] *See, e.g.*, WIS. DEP'T OF HEALTH SERVS., *supra* note 140, at 3 ("Employers should recommend use of face masks or cloth face coverings by employees when social distancing is not feasible in the work environment.").

however, lacked that nuance. For some parts of the food industry, that was a critical distinction.

State-by-state workplace safety guidance became further complicated as some states transitioned from guidance to mandatory orders or regulations. Virginia, for example, appears to have been the first state to pass COVID-19-specific workplace safety regulations when the Virginia Safety and Health Codes Board codified emergency temporary standards governing COVID-19 controls in the workplace.[142] In Michigan, the governor issued an emergency order imposing workplace safety requirements.[143]

This patchwork of varying state and local provisions, each different, some with more flexibility than others, some mandatory and some of uncertain enforcement, created a hodgepodge of considerations that food companies operating across multiple jurisdictions had to manage.

These issues were particularly challenging for companies with food production operations in multiple jurisdictions or that were involved in transporting or distributing food across jurisdictions. Consider, for example, a hypothetical food company with three processing facilities, one in the Northeast, one in the South, and one on the West Coast. That company likely would have had to develop programs to address federal guidance (which was subject to periodic change), three different state lockdown orders, three different state workplace safety guidances, and three different county-level approaches to contract tracing and public health protections. And the company would have to understand and find a way to comply with any restrictions imposed by any of the state or county jurisdictions through which its truck drivers transported products or raw materials.[144] This company's operations would also be dependent on the continuity of operations for every single one of its raw material suppliers, and if this company's own operations were disrupted, retailers might not have product to sell. This patchwork effect presented extremely complex challenges across the food supply.

VI. COMMON THEMES FOUND IN THE COVID-19 REGULATORY RESPONSE

The COVID-19 crisis required FDA and USDA to respond with unprecedented speed and scope. Flexible regulatory approaches emerged by necessity. The agencies had to respond nimbly, with at times imperfect information, and in unfamiliar territory beyond their core mission areas. When we examine the tools used and the process by which FDA and USDA responded, key themes emerge. These include 1) the role of food regulatory bodies during a pandemic; 2) the nature of the existing regulatory framework (which was not built for speed or flexibility); 3) the significance of frequent engagement with stakeholders; and 4) the role and coordination between federal, state, and local authorities.

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[142] *See* 16 VA. ADMIN. CODE § 25-220; *see also* Va. Exec. Order No. 63 (2020).

[143] Mich. Exec. Order No. 2020-145: Safeguards to Protect Michigan's Workers from COVID-19 (2020).

[144] In the authors' experience, these were very much real and challenging concerns.

A. Role of Food Regulatory Bodies During a Pandemic

At the outset, the COVID-19 crisis for the food industry was a supply chain crisis. Namely, the objective for the food regulatory agencies was how to keep the supply chain moving and the country fed.[145] As discussed above, this included keeping food manufacturing facilities, retailers, and other operations open and workers safe; ensuring continued food distribution despite temporary shortages and disruptions; addressing closures of restaurants and many food service operations (e.g., workplace cafeterias); and maintaining consumer confidence in the safety of the food supply. In short, FDA and USDA needed to facilitate commerce and oversee a broad swath of the U.S. economy.

This was new or different territory for FDA and USDA, as their core mission is to ensure the safety of the food supply. As FSIS states: "The Food Safety and Inspection Services (FSIS) is the public health agency in the U.S. Department of Agriculture (USDA) responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged."[146] Similarly, FDA states: "The Food and Drug Administration is responsible for protecting the public health . . . by ensuring the safety of our nation's food supply . . . ."[147] Facilitating the supply chain is not the core mission of either FDA or USDA, and the agencies were forced learn a new role, in the midst of an emergency.

B. Nature of Existing Regulatory Framework

Not surprisingly, the agencies did not have the experience or framework for confronting supply chain challenges of the scope and scale presented by the COVID-19 crisis. For example, although food facilities are required to register with FDA, the agency realized that it did not have a mechanism in place to track temporary closures or significant changes in production capabilities due to absentee workers or otherwise. Further, the agencies did not have insights into supply chain disruptions, shortages, and marketplace imbalances such as where they were occurring and why. Indeed, FDA has pointed to the enhanced traceability component of its New Era of Smarter Food Safety blueprint as a potential tool for enhanced supply chain visibility.[148]

Moreover, it became apparent rather quickly that the twin pillars of food regulatory law—adulteration and misbranding—were not the appropriate tools for responding to the pandemic and its impact on the food supply. Preventing contamination of food with SARS-Coronavirus-2 was not the primary objective. And while FDA and the

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[145] *See, e.g.*, Exec. Order No. 13917, 85 Fed. Reg. 26,313 (May 1, 2020) ("[T]he Secretary of Agriculture shall take all appropriate action under [the DPA] to ensure that meat and poultry processors continue operations."); Cybersecurity and Infrastructure Security Agency, Food and Agriculture Sector-Specific Plan, 13 (2015) ("The mission of the [Food and Agriculture] Sector is to protect against a disruption anywhere in the food system that would pose a serious threat to public health, safety, welfare, or to the national economy."); Exec. Order No. 13603, 77 Fed. Reg. 16,651 (Mar. 16, 2012) (delegating to USDA general responsibility for issuing DPA orders with respect to the food supply chain as part of the federal government's general emergency preparedness response).

[146] U.S. DEP'T OF AGRIC., FSIS STATUTES, MISSION, AND AUTHORITY (2015).

[147] *What We Do*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/what-we-do (last updated Mar. 28, 2018) [https://perma.cc/9YC3-WFKA].

[148] *See* Stephen Hahn & Frank Yiannas, *Pandemic Challenges Highlight the Importance of the New Era of Smarter Food Safety*, U.S. FOOD & DRUG ADMIN. (June 2, 2020), https://www.fda.gov/news-events/fda-voices/pandemic-challenges-highlight-importance-new-era-smarter-food-safety [https://perma.cc/RQ3Y-HACV].

Federal Trade Commission have taken action against products with misleading claims regarding prevention or treatment for COVID-19, FDA and FSIS soon learned that it was necessary to relax some of the historical labeling requirements to confront the challenges of the pandemic, rather than enacting new requirements.

Similarly, although the PHSA certainly provided HHS with the authority to respond to the public health threat posed by the pandemic and prevent the spread of disease, it did not set forth an obvious path for addressing supply chain disruptions, food distribution logistics, worker safety, and consumer confidence.

Even the DPA had limitations. This authority had not been exercised with respect to the food supply before. There was significant confusion about how the DPA and USDA would affect FDA-regulated foods. Moreover, there were substantial questions about how the priorities and allocations authorities could compel food production in light of concerns about worker safety and, in some cases, the lack of workers to produce food.[149] For example, what would happen if USDA were to issue a procurement order but a state or county had ordered a quarantine for the facility? Indeed, the fact that FDA and USDA had to issue an MOU outlining how the two agencies would work together to address orders compelling production of FDA-regulated foods underscores the new territory the agencies found themselves navigating and the lack of an existing framework for responding to the crisis.[150] In short, the agencies found themselves operating outside of their core mission areas in an unfamiliar terrain and did not have the framework with which to respond.

Nonetheless, the agencies tried to address the challenges as best as possible. As we look back on the actions taken, we can see the limitations of the regulatory tools the agencies had at their disposal. Significantly, neither the rulemaking process nor the traditional good guidance practices were appropriate mechanisms to address the challenges of the pandemic. Neither regulatory device allowed the agency to respond with the speed and flexibility necessary based on the situation.

The COVID-19 pandemic evolved rapidly and presented a dynamic situation. The scientific and medical communities were frequently updating their recommendations as new learnings about the nature of the virus and how to control the spread emerged. When workers fell ill or tested positive, others needed to be immediately quarantined. Operations designed to achieve "just in time" production could quickly come to a halt if materials or workers were not available. And localities often enacted restrictions on operations, particularly for restaurants and other food service operators that went into effect immediately. FDA and FSIS needed to address these challenges in a timely way.

The agencies also needed to be mindful of the fact that however long the duration of the pandemic, it would not be permanent. For example, as the agencies continually reassured the public, the lack of certain foods at retail was only temporary and localized.[151] Further, the nature of the pandemic was not uniform across the country.

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[149] *See* Taylor Telford, Kimberly Kindy & Jacob Bogage, *Trump Orders Meat Plants to Stay Open in Pandemic*, WASH. POST (Apr. 29, 2020), https://www.washingtonpost.com/business/2020/04/28/trump-meat-plants-dpa/ [https://perma.cc/33L2-2SSA]; *see generally* Amy Gunia, *How Coronavirus Is Exposing the World's Fragile Food Supply Chain—and Could Leave Millions Hungry*, TIME (May 8, 2020), https://time.com/5820381/coronavirus-food-shortages-hunger/ [https://perma.cc/SH44-M3FS].

[150] *See* Letter from FDA to Industry Regarding MOU No. 225-20-011, Potential Use of the Defense Production Act with Regard to FDA-Regulated Food During the COVID-19 Pandemic (May 18, 2020), https://www.fda.gov/media/138172/download [https://perma.cc/2R5E-T7SP].

[151] *See generally* Peter Rubinstein, *Why Grocery Shelves Won't Be Empty for Long*, BBC (Apr. 2, 2020), https://www.bbc.com/worklife/article/20200401-covid-19-why-we-wont-run-out-of-food-during-

Certain areas of the country were hit harder with disease outbreaks,[152] and governing bodies enacted different restrictions in scale, scope, and length.[153] As such, the regulatory response needed to be flexible and one that could change as the situation demanded, both in the short and long term.

Neither rulemaking nor guidance practices currently are designed to be quick and nimble. Rulemaking is a major undertaking, often taking years if not decades to complete. There are multiple steps in the process, from drafting and seeking OMB review of proposed rules, soliciting comments, holding public meetings, and then reviewing and responding to comments in the final rule, which also must undergo OMB review.[154] These are just the external milestones and do not reflect the internal review and clearance process within the agencies. As a result of this long timeframe for promulgating regulations, they are not easily changed.

In recent years, Guidance has begun to look a lot more like rulemaking. FDA's GGPs, for example, require publication in the Federal Register and solicitation of public input.[155] In addition, Trump-era Executive Orders have sought to curtail the use of guidance and require OMB review in additional cases.[156] Accordingly, it is exceedingly challenging for the agencies to issue guidance documents quickly. Many guidance documents only ever make it to "draft" status and are never finalized.[157] Thus, although intended to be a more flexible and quicker tool for providing direction for the agency's current stance on a topic, issuing guidance has become significantly more cumbersome in recent years, offering neither speed nor flexibility.

If anything, the agencies' response to the pandemic illustrated that there was no real existing pathway to address emergency issues related to food access. This likely stems from the fact that FDA (for purposes of its food regulatory mission) and FSIS primarily

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coronavirus [https://perma.cc/5BUE-7MS4]; Hillary Russ & Lisa Baertlein, *Stretched Global Supply Chain Means Shortages on Summer Menus*, REUTERS (June 28, 2021), https://www.reuters.com/business/stretched-global-supply-chain-means-shortages-summer-menus-2021-06-28/ [https://perma.cc/YN3K-FB4G].

152 *COVID-19 Crisis Highlights Widening Regional Disparities in Healthcare and the Economy*, ORG. FOR ECON. COOP. & DEV. (Nov. 30, 2020), https://www.oecd.org/newsroom/covid-19-crisis-highlights-widening-regional-disparities-in-healthcare-and-the-economy.htm [https://perma.cc/JZZ8-7J8A].

153 *See* Lauren Leatherby & Rich Harris, *States that Imposed Few Restrictions Now Have the Worst Outbreaks*, N.Y. Times (Nov. 18, 2020), https://www.nytimes.com/interactive/2020/11/18/us/covid-state-restrictions.html; *see generally* Paul Solman, *How COVID-19 is Highlighting Racial Disparities in Americans' Health*, PBS NEWS HOUR (July 16, 2020), https://www.pbs.org/newshour/show/how-covid-19-is-highlighting-racial-disparities-in-americans-health [https://perma.cc/CC6F-ZSUK]; Max Fisher & Emma Bubola, *As Coronavirus Deepens Inequality, Inequality Worsens Its Spread*, N.Y. TIMES (Mar. 16, 2020), https://www.nytimes.com/2020/03/15/world/europe/coronavirus-inequality.html [https://perma.cc/P2GT-P6EJ].

154 *Learn About the Regulatory Process*, U.S. GEN. SERVS. ADMIN., https://www.regulations.gov/learn [https://perma.cc/X87J-JQLV].

155 21 C.F.R. § 10.115(g) (2021).

156 *See* Exec. Order No. 13891, 84 Fed. Reg 55,235 (Oct. 9, 2019) (requiring agencies to implement additional procedures for issuing guidance documents).

157 *See, e.g.*, U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY: QUESTIONS AND ANSWERS REGARDING THE REPORTABLE FOOD REGISTRY AS ESTABLISHED BY THE FOOD AND DRUG ADMINISTRATION AMENDMENTS ACT OF 2007 (EDITION 2) (May 2010), https://www.fda.gov/media/79130/download [https://perma.cc/3Z43-H8VV] (draft document never finalized).

exist to make sure that food is produced safely and labeled properly.[158] Premarket review plays an important role for ensuring food ingredient safety, but FDA and FSIS are not set up to facilitate food production itself or otherwise to support the food industry. Because FDA and FSIS have never been responsible for coordinating the food supply chain, there has not been a historical need to develop a pathway for responding to the crises presented by the pandemic and no need to develop an emergency response pathway. The closest analogue might be the agencies' oversight of food recalls. But outside of very limited situations in which FDA can mandate a recall,[159] the agencies largely play a consultative role during the recall process itself, and, after the fact, review recalls to verify they were effective.[160] The agencies may make recommendations about the scope of a recall, but they do not get involved in the actual mechanics of executing recalls or otherwise managing the supply chain.[161]

The lack of an established framework and regulatory pathway for addressing the impact of the virus on the food industry and the need to act quickly and with flexibility resulted in the agencies turning to different communication tools. Two tools in particular emerged: 1) Emergency Guidance (discussed here); and 2) public communications (discussed next).

The agencies, especially FDA, used tools such as Emergency Guidance—guidance issued without following the normal procedures.[162] FDA's use of Emergency Guidance actually is reflected in its GGPs in that the GGPs allow FDA to sidestep the typical "draft guidance–comments–final guidance" process when doing so is "not feasible or appropriate."[163] The GGPs provide little further direction on how this process should be used and what type of administrative clean-up ought to occur afterward. When FDA issues Emergency Guidance, in accordance with the agency's GGPs, it does not seek public comment prior to implementing a guidance document if the agency determines that prior public participation is not feasible or appropriate.[164] Instead, when issuing Emergency Guidance, FDA is to publish a notice in the Federal Register announcing the guidance's availability, post the guidance online, implement the guidance immediately, invite public comment, and review the guidance and make

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158 *See, e.g.*, 21 U.S.C. § 601 (identifying in the "Congressional Statement of Findings" that the purpose of the FMIA is to ensure that meat food is not adulterated or misbranded); 21 U.S.C. § 451 (describing similar findings for the PPIA); *Center for Food Safety and Applied Nutrition (CFSAN)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/fda-organization/center-food-safety-and-applied-nutrition-cfsan (last updated Sept. 19, 2018) [https://perma.cc/5AHV-B3WW] ("FDA is a scientific regulatory agency responsible for the safety of the nation's domestically produced and imported foods, cosmetics, drugs, biologics, medical devices, and radiological products.").

159 *See* 21 U.S.C. § 350i.

160 *See* U.S. FOOD & DRUG ADMIN., PRODUCT RECALLS, INCLUDING REMOVALS AND CORRECTIONS: GUIDANCE FOR INDUSTRY (Mar. 2020), https://www.fda.gov/media/136987/download; *see generally* U.S. FOOD & DRUG ADMIN., QUESTIONS AND ANSWERS REGARDING MANDATORY FOOD RECALLS: GUIDANCE FOR INDUSTRY AND FDA STAFF 5142 (Nov. 2018), https://www.fda.gov/media/117429/download [https://perma.cc/X6D3-4WSQ].

161 The closest they might come would be in the form of a product seizure action or shutting down a facility, but these too don't involve the agencies coordinating industry production.

162 *See* 21 C.F.R. § 10.115(g)(2) (2021) ("FDA will not seek your comment before it implements a Level 1 guidance document if the agency determines that prior public participation is not feasible or appropriate.").

163 *See id.*

164 *Id.*

changes in light of comments "when appropriate."[165] When issuing Emergency Guidance for COVID-19, FDA would typically post the guidance online and immediately implement the COVID-19-related guidance, soliciting comments after the fact. In addition, FDA began periodically publishing a consolidated Notice of Availability (NOA) announcing the availability of all COVID-19-related guidance documents FDA issued during the relevant period.[166]

These processes allowed the agency to formulate and communicate policy reasonably quickly, but it was also evidence that the agency was operating in an ad hoc framework. For example, some COVID-19 guidance evolved so rapidly—with corresponding changes to the guidance as posted—that it is highly doubtful there was an opportunity for the public to meaningfully prepare comments, much less for the agency to review, deliberate on, and act on comments.

Further, rather than outline new requirements, practices, or policies to help the food industry, the agencies frequently relied on enforcement discretion instead. For example, in deciding to postpone inspections, relaxing requirements for the use of supplier audits, providing labeling flexibilities, allowing the production of hand sanitizers, and permitting certain formulation changes, the agencies were decidedly choosing not to enforce certain existing requirements to tackle the supply chain disruption challenges and ensure continued food supply. Notably, there is no formal process to waive regulatory requirements.

C. Significance of Frequent Communication and Engagement with Stakeholders

In addition, we saw the agencies use alternative communication tools. For example, the agencies used Q&As posted on their websites to communicate agency policy and expectations.[167] These were updated frequently. They also issued statements to the press, both via traditional means and through social media platforms like Twitter.[168] For example, the agencies used these latter methods to assure consumers of the overall strength and health of the food supply and remind them that there is no evidence of the transmission of COVID-19 from food or food packaging. FDA released a Q&A reminding consumers the proper way to wash fruits and vegetables and providing guidance on how to wipe down packaging.[169] Looking back, it is challenging to

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[165] *See* 21 C.F.R. § 10.115(g)(3) (2021).

[166] *See, e.g.*, Guidance Documents Related to Coronavirus Disease 2019; Availability, 85 Fed. Reg. 46,641 (Aug. 3, 2020) (announcing a list of guidance issued in relation to COVID-19 and available for comment after the fact).

[167] *See, e.g.*, *Food Safety and the Coronavirus Disease 2019 (COVID-19), Questions & Answers for Industry: Food Supply Chain*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/food-safety-during-emergencies/food-safety-and-coronavirus-disease-2019-covid-19#foodsupply (last updated June 30, 2021) [https://perma.cc/D38W-5VCE]; *Food Supply Chain, Access to Food, Question: Will There be Food Shortages?*, U.S. DEP'T OF AGRIC., https://www.usda.gov/coronavirus/food-supply-chain [https://perma.cc/3DYR-9CC4].

[168] *See, e.g.*, U.S. Ctrs. for Disease Control & Prevention (@CDCgov), TWITTER (Jul. 8, 2020, 12:51 PM) ("Q: How do I clean fruits and vegetables during #COVID19?"), https://twitter.com/cdcgov/status/1280907263272681472?lang=en [https://perma.cc/4QQP-VKRJ].

[169] *See Shopping for Food During the COVID-19 Pandemic—Information for Consumers*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/food-safety-during-emergencies/shopping-food-during-covid-19-pandemic-information-consumers (last updated May 1, 2020) [https://perma.cc/C3RU-YV4B].

catalogue and record these communication tools in light of both the number issued and the process used.

The new terrain presented by the pandemic also placed a premium on frequent stakeholder communication.[170] The novel public health challenges presented and the dynamic environment in which the crisis unfolded led to repeated phone calls between industry stakeholders and the agencies. This helped the agencies gain critical insights into the questions and issues the food industry was confronting. It enabled the agencies to respond more rapidly and in a more targeted fashion. It was particularly important here, where the agencies have not historically had a window into issues such as logistics and supply chains, but also where the agencies were acting through the new tools discussed above. These frequent communications had the added benefit of increasing trust between the agencies and stakeholders.

D. Role and Coordination Between Federal, State, and Local Authorities

Finally, a look back at the agencies' response also highlights the importance of coordination between the federal government and states and localities. The manufactured food industry, for example, has historically operated under a uniform set of regulations affecting production and labeling.[171] Although inspections are conducted at both the state and federal level, these are generally aligned, with states often conducting inspections on behalf of FDA.[172] In addition, most states have adopted "mini FDCAs." In contrast, as discussed above, the pandemic ushered in a wave of differing responses from federal, state, and local governments. This presented significant hurdles to regulated industry but also to the federal agencies attempting to manage the food supply for the entire nation.

In sum, the dynamic nature of the COVID-19 crisis dictated a rapid and quick-footed federal response. Accordingly, the traditional regulatory tools of rulemaking and guidance were not well-suited for the situation. As a result, the agencies used new tools and communication platforms, drawing on frequent communications with stakeholders to tailor their responses and navigate the new territory.

VII. LOOKING BACK TO LEARN FOR THE FUTURE

Now that we've seen how FDA and FSIS responded to the early months of the COVID-19 crisis, the question becomes: How can the agencies build on this experience for the future? It's a simple question with difficult answers. What might we expect through the duration of the COVID-19 crisis, and what might FDA and FSIS consider doing differently?[173] What could FDA and FSIS do to prepare for future

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[170] The authors are familiar with regular communication between FDA and FSIS and industry stakeholders during this stage of the pandemic.

[171] *See* 21 C.F.R. §§ 1–199 (2021) (containing FDA's food labeling, processing, and ingredient safety regulation); *see also* 9 C.F.R. §§ 300–592 (2021) (containing FSIS's food labeling, processing, and ingredient safety regulations).

[172] For the meat and poultry industries, the situation is even simpler, as with only a few exceptions for intrastate operations, official establishments are regulated exclusively at the federal level by FSIS, and federal regulations preempt state requirements. *See* 21 U.S.C. § 678; 21 U.S.C. § 467e; 21 U.S.C. § 1052.

[173] Due to the publication process, there will necessarily be a lag between our making these comments (generally developed at the end of 2020) and publication of this Article. To the extent FDA and FSIS take

emergencies once the pandemic is behind us? And what aspects of the agencies' COVID-19 responses might we expect to see incorporated into regular agency practice, and what else might the agencies consider?

A. Future Agency Actions During the COVID-19 Crisis

1. What to Expect—More of the Same, But Less of It

Most immediately, what regulatory strategies might FDA and FSIS use as they continue to respond to the ongoing COVID-19 crisis? In short, absent significant change to the regulatory process and administration oversight of regulatory development, FDA and FSIS's easiest to use tools will likely remain public statements and occasional enforcement discretion, coupled with ongoing dialogue with stakeholders. Moreover, as the situation stabilizes into whatever form it takes, the agencies will likely feel less pressure to respond as though in "emergency response mode" and will be more likely to view issues as presenting standard policy issues, not emergency situations. The result would likely be a continued winnowing of COVID-19-specific responses and a gradual transition back to normal regulatory operations. This appears to be the trend during the first months of the Biden Administration.

As we've seen, the rulemaking process is simply too cumbersome and time-intensive of a process to be useful in responding to rapidly changing events. Satisfying the APA's notice-and-comment requirements takes too much time, and agency resources spent navigating that process could be better used in an emergency to develop and issue the less formal statements that the agencies have by and large relied on. It's not surprising, therefore, that neither FDA nor FSIS has issued actual regulations addressing the food supply in the context of COVID-19, nor should we expect that to change in the near term. It's worth emphasizing that the primary tool envisioned by Congress (through the APA) for the regulatory state is wholly inadequate for responding to a supply chain crisis.

Instead, FDA and FSIS could be expected to rely on what got them through the early stages of the pandemic, when supply chains were most stressed, when public alarm was at its height, and when information was least certain—public statements, informal guidance, and occasional enforcement discretion. Absent significant new information, the agencies would likely feel little impetus to deviate from approaches that worked, were relatively resource-efficient, and are least likely to be viewed as committing the agencies to permanent policy positions. Moreover, as the COVID-19 crisis stabilizes into some form of tense equilibrium, FDA and FSIS will likely feel less need to serve as "industry czars" or to help facilitate industry compliance with areas outside the agencies' core responsibilities, such as worker safety or community health.[174]

Indeed, in the months since the first major waves of the pandemic, USDA has largely stepped away from the brink of using its authorities delegated under the DPA to compel continued operation in the food manufacturing and distribution sectors.

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different actions between now and then not accounted for in this Article, the authors readily concede our crystal ball is at times hazy.

[174] As a parallel, consider the Occupational Health and Safety Administration's (OSHA's) determination to issue an emergency temporary standard addressing COVID-19 safety, but only for healthcare settings. *See* Occupational Exposure to COVID-19; Emergency Temporary Standard, 86 Fed. Reg. 32,376 (June 21, 2021) (to be codified at 29 C.F.R. pt. 1910). This action is consistent with taking a more targeted approach toward an issue that is perceived as having stabilized.

Moreover, state and local leaders appear to have reconsidered earlier positions that threatened to grind operations to a halt at certain types of facilities. After the initial few months, FDA and USDA by and large have not been called on to exercise their emergency response responsibilities to ensure continuity in the food supply. Given the agencies' reluctance to take drastic action in this area to begin with, it would likely require a significant change in the current dynamic to bring DPA issues back to the forefront.

Finally, FDA will have to continue managing inspections during the COVID-19 era. FDA has dramatically cut back on its inspection of food facilities but has pivoted toward taking more enforcement actions that are not dependent on in-person inspections.[175] FDA has also increasingly pushed for remote records access.[176] These steps are natural responses to the personal health risks posed by in-person inspection, but they also align with long-pursued FDA policies and help leverage agency resources efficiently. It will be interesting to see whether FDA continues to seek ways to rely on non-inspectional findings to support regulatory enforcement and whether the agency continues to push for remote records review, as this could have significant effects on FDA inspections and enforcement in years to come.

FDA similarly might be expected to continue evaluating what other policy priorities fit into the COVID-19 paradigm. FDA's focus on blockchain technology to enhance traceability may be one such policy. Already, FDA officials have suggested that blockchain technology could be useful in helping to manage the supply chain in the face of mass systemic disruption,[177] and it will be interesting to see whether FDA uses COVID-19 supply chain issues to push blockchain and whether the FDA-regulated industry views it as a potential solution.

2. Incremental Changes the Agencies Might Take as COVID-19 Progresses

As the COVID-19 situation stabilizes into whatever form it takes, FDA and FSIS should engage in steps to memorialize the flurry of communications and activity from the spring and summer period. Website Q&As are quickly deployed and easily accessed, but the ephemeral nature of websites is ill-suited for maintaining an administrative record, and they are no replacement for the Federal Register and well-organized regulatory dockets. Social media communications are even less so. Moreover, the hectic events of March, April, and June 2020 become blurrier in memory each day. At points, Q&As were updated nearly daily, multiple guidance documents were released without dates or version codes, and information changed rapidly. The regulated industry, states, and localities, however, had to make day-by-day decisions based on the most current information available. Those decisions have

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[175] This observation is based on the authors' extensive experience advising clients in response to FDA enforcement and inspection issues.

[176] *See, e.g.*, *FDA Constituent Update: FDA Opens Industry Portal for FSVP Records Submission*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/cfsan-constituent-updates/fda-opens-industry-portal-fsvp-records-submission (last updated May 10, 2021) [https://perma.cc/ZAA6-E6SJ]; *Remote Regulatory Assessments of Human Food Facilities*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/media/149712/download (last updated June 15, 2021) [https://perma.cc/XE7E-9CR8].

[177] *See, e.g.*, Frank Yiannas (@FrankYiannasFDA), TWITTER (May 26, 2020, 8:02 PM), ("What do airplane parts & food have in common? They both can strengthen trust, authenticity, and safety with tech-enabled supply chain traceability & transparency.").

the potential to expose the industry and state and local officials to significant scrutiny and, in the case of businesses, potential liability.

As time passes, it will become increasingly difficult to remember what we knew and when we knew it about the novel coronavirus, and the day-to-day changes in understanding and policy will further blur. It's therefore imperative that FDA and FSIS assemble clear and meticulous public records of every official statement, every website Q&A, every document, and every exercise of enforcement discretion, making available each version and showing what changed from one to the next. Stakeholders relied on agency guidance at the height of the crisis, and it is important there be a clear record showing what the prevailing recommendations were at any given time. Regardless of whether required by law, this is a necessary step to make sure that the government maintains clear and publicly available records for all to rely on.

FDA has taken some steps toward this by opening a public docket collecting its COVID-19 guidance information.[178] This is a prudent development, and FDA ought to ensure that it captures every action, including updates to Q&A documents, stakeholder communications, and even tweets by agency officials. FDA might go a step further, however, and create an easily accessed, user-friendly online dashboard that the public can use to identify what guidance was in place, and when, and to access copies of each iteration. That type of information will be crucial for helping stakeholders justify their decisions and for the public to understand what FDA did and when those actions were taken. USDA might consider doing the same. Unfortunately, in the months that have passed since the pandemic's initial waves, there appears to have been little additional efforts to memorialize this highly dynamic period.

Additionally, FDA and FSIS could review their current grants of enforcement discretion with an eye toward developing a clear framework for when and how those exercises of enforcement discretion will eventually be withdrawn and how products in the marketplace will be treated. As of this writing, the agencies are operating under essentially a "month to month" basis, periodically announcing that enforcement discretion will be extended for a set period.[179] Flexibility is important, but periodic extensions inject considerable uncertainty into an already uncertain system and presumably consume agency resources in constantly re-evaluating scenarios. Now that the initial crisis has passed, the agencies could publish the criteria they plan to use to decide when to end enforcement discretion. Those criteria can and should continue to embody a flexible approach, but developing and publishing them would help the industry better anticipate the intermediate-term regulatory landscape and take steps to align supply chains with regulatory expectations as well as let the agencies get input on key considerations from stakeholders.

The agencies also could consider communicating how they will approach marketplace oversight once enforcement discretion ends. For example, FDA currently

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[178] *See* Guidance Documents Related to Coronavirus Disease 2019 (COVID-19); Availability, 85 Fed. Reg. 65,820 (Oct. 16, 2020).

[179] *See, e.g.*, Press Release, U.S. Dep't of Agric., Food Safety and Inspection Service Constituent Update—September 18, 2020, USDA Releases Roadmap to Address Salmonella (Sept. 18, 2020) ("As a follow up to FSIS' May 1, 2020 and July 10, 2020 Constituent Update announcements, FSIS is again extending its enforcement discretion [for diverting to retail product labeled for foodservice] through the end of the year."), https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-september-18-2020 [https://perma.cc/4NL3-MFLS].

allows modest ingredient substitutions to be made in limited circumstances.[180] Products formulated under that grant of enforcement discretion could potentially remain on the marketplace for several years. If a regulator (federal, state, or local), a competitor, or a potential plaintiff were to test those products or otherwise evaluate their formulation, those products would appear to be out of compliance with the FDCA. The manufacturer would then likely bear the onus of demonstrating that the particular product was actually produced pursuant to the grant of enforcement discretion. It will be critical that manufacturers or retailers relying on a grant of enforcement discretion have the confidence that they will not later face class action liability or regulatory enforcement based on their actions. The agencies could clearly address their expectations for post-market surveillance of these types of products and ensure that state and local regulatory partners understand the federal expectations.

Finally, the agencies could develop and implement ways to empirically measure the effects of their regulatory or quasi-regulatory actions. The COVID-19 crisis presents a natural experiment, and the agencies could take advantage of the opportunity to evaluate whether certain guidance or exercises of enforcement discretion had measurable effects on consumer health and safety or the economics of businesses. For example, did policies intended to facilitate diversion of food service products to retail actually free up a significant amount of product that otherwise would have been held or destroyed due to lack of food service channels? Did policies to allow substitution of ingredients on a very limited basis result in any measurable effects on consumer confusion or misbranding of products or provide enough supply chain flexibility? Developing the data to answer these types of questions would prove immensely valuable as FDA and FSIS prepare for addressing future emergencies and for evaluating existing regulations.

B. Principles for Preparing for Future Emergencies

Although FDA and FSIS will likely find themselves relying on their current playbooks of public statements and occasionally enforcement discretion as COVID-19 drags on, the agencies would be wise to critically evaluate the COVID-19 response to be better prepared for the next emergency, regardless of whether it is another global pandemic, a terrorist attack on the food supply, a natural disaster, or something else entirely. When doing so, agencies should consider various steps, many of which go back to the idea that all crises will be unique, but they will all share the same characteristics of being unpredictable and rapidly moving.

1. A Clear Framework is Important

It will be impossible for FDA and USDA to guess what the next major crisis threatening the food supply chain will be. Attempting to prepare for a future crisis just like COVID-19 will simply be wasted effort. Instead, agencies could establish clear frameworks for acting, including identifying the tools they plan to use, how they plan to engage in stakeholder communications, and how they will prioritize resources and action.

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[180] U.S. FOOD & DRUG ADMIN., TEMPORARY POLICY REGARDING CERTAIN FOOD LABELING REQUIREMENTS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY: MINOR FORMULATION CHANGES AND VENDING MACHINES, GUIDANCE FOR INDUSTRY (May 2020), https://www.fda.gov/media/138315/download [https://perma.cc/CDD4-UHBE].

The early months of the COVID-19 crisis featured great confusion and uncertainty. That was inevitable to some degree, as the facts themselves were uncertain. However, it would provide a great service to stakeholders to identify what tools the agencies plan to rely on in an emergency. For example, if FDA and USDA determine that their tool of first resort will be public statements and Q&As, with occasional reliance on enforcement discretion, that approach could be clearly spelled out in plans and communicated to stakeholders. That way, stakeholders would understand what type of communication to expect and what type of actions to ask for in the midst of the crisis. Further, the agencies can develop systems in advance for capturing rapidly changing information, such as developing and making available historical copies of Q&As and agency statements so that stakeholders can identify what was said when, even during a time of crisis.

2. Open Communication is Essential

The COVID-19 crisis has seen a significant amount of communication between FDA and USDA and stakeholders. That communication is essential for an effective response, and the agencies should build on it for future emergencies. For example, there could be a clear agency point of contact for all stakeholder communications, and the stakeholder community should know who that is in advance of an emergency. The most important step may be to establish an ongoing framework for communication in advance of any emergency. As discussed below, FDA and USDA should build on the communications channels established during the COVID-19 crisis to create regular opportunities for informal dialogue with stakeholders on key issues. Indeed, FSIS has long pursued a successful model of meeting regularly with key stakeholder groups, and both agencies could seek out ways to build on those models. Not only does regular contact result in a better regulatory program, but it also helps to build familiarity and trust, both of which are essential for managing a crisis.

3. Prioritize Regulations for Enforcement Discretion

The COVID-19 crisis saw both FDA and FSIS exercise forms of enforcement discretion to facilitate rapid responses within the supply chain. Those actions included several actions designed to facilitate redirection of food service products into the retail supply chain and to facilitate minor ingredient substitutions to respond to short-term shortages. Given the highly regulated nature of the food supply, it is likely that future national emergencies will similarly require exercises of enforcement discretion to ensure that the regulatory apparatus continues to ensure basic safety but does not prevent nimble supply chain responses.

Given the potential for massive supply chain disruption and huge economic and public health consequences, FDA and FSIS could identify a prioritized list of regulations that could be temporarily waived—either through an express waiver or through enforcement discretion—to address supply chain issues. Importantly, the agencies would not have to commit themselves to waiving these regulations (nor would identifying them preclude waiving other regulations), but identifying options in advance will help with agency planning and will help stakeholders identify what regulatory strategies may be most appropriate in a given situation. In evaluating regulations, the agencies could identify requirements that have negligible short-term public health impacts and do not serve critical roles in managing consumer expectations. The agencies should engage stakeholders in identifying these lists, both to promote transparency and to understand what the regulated industry and other

stakeholders view as being necessary for providing flexibility. For example, the agencies might determine that allowing minor ingredient substitutions, temporarily allowing for somewhat greater nutritional variation, or allowing different forms of dietary fiber may be appropriate short-term changes to address disruptions in key sources of supply. Or, the agencies might determine that certain labeling formatting requirements might be relaxed to facilitate retailer repackaging of bulk products not typically sent to retailers.

Regardless of what regulations are identified, having some alignment on the ones that would be up for consideration first, or at least a set of principles that the agencies would follow in evaluating them, could greatly facilitate rapid agency decision-making and help the industry identify what changes would best address disruptions.

In addition, as discussed above, the agencies could explain in advance how they plan to extend and eventually conclude enforcement discretion, as well as how they expect to handle post-market surveillance related to products produced under enforcement discretion.

4. Identify Alternatives to Enforcement Discretion

Enforcement discretion is an important executive branch tool. It lets regulators make common-sense exceptions to ensure that agencies and industry's hands aren't tied by regulations ill-suited to the occasion. It should remain an important tool in agencies' rapid-response arsenals. However, enforcement discretion is imperfect in that the agency is simply indicating it won't enforce a requirement that technically remains in place. This presents potential consequences for companies that may face scrutiny by parties not beholden to that exercise of enforcement discretion—potentially state and local regulators, but especially potential plaintiffs. The exercise of enforcement discretion clearly demonstrates the federal regulators' intent, but it can still be a costly and time-consuming endeavor to defend against other legal actions.

One solution may be to waive regulatory requirements for a period of time or develop other tools that would make existing legal requirements non-binding (rather than simply not an enforcement priority, which is what enforcement discretion is). FSIS already has authority under the FMIA and PPIA to waive regulatory requirements in the face of an emergency,[181] although FSIS did not actually exercise that authority in response to the COVID-19 crisis. However, had it done so, the agency would have sent a clear signal to all parties that products produced in compliance with the waiver were in fact fully lawful under the FMIA or PPIA. FDA likewise could evaluate its ability to waive a regulation for a set period in response to an emergency and consider establishing regulations codifying a process for doing so. At the least, FDA could position this process as a more formal exercise of enforcement discretion. Establishing—and using—a clear waiver authority and process could provide significant clarity and benefit to companies relying on FDA or FSIS emergency action, and it would help ensure that companies relying in good faith on that emergency action are not later subjected inappropriately to after-the-fact scrutiny and enable them to establish that they are in legal compliance. Importantly, waivers can be used to send stronger signals to the industry and the general public rather than case-by-case

[181] 9 C.F.R. §§ 303.1(h), 381.3(b) (2021) ("The Administrator may in specific class of cases waive for limited periods any provisions of the regulations in this subchapter in order to permit appropriate and necessary action in the event of a public health emergency . . . *Provided*, That such waivers of the provisions of such regulations are not in conflict with the purposes or provisions of the Act.").

enforcement discretion. A well-developed waiver process can demonstrate that decisions are being made consistently using established criteria.

One option FDA might explore is codifying a process for exercising enforcement discretion under emergency situations, similar to the agency's GGP regulations. Such an approach could include clearly spelling out the legal effects of enforcement discretion and the agency's expectations of companies that are operating subject to enforcement discretion. Although such an approach would still fall short of FSIS's statutory waiver authority, it would help clarify to stakeholders the process to be followed and the effects of enforcement discretion in emergency situations.

Establishing a waiver or enforcement discretion framework is especially important because FDA, in particular, doesn't currently have an emergency response regulatory framework for foods. In some ways this makes sense, as FDA's typical regulatory mission is to protect food safety and labeling. This calls for a much different framework than FDA uses for drugs and medical devices, both of which require that FDA have an expedited way to get life-saving therapies and diagnostics onto the market quickly in emergency situations. However, if FDA is to assume responsibility not only for keeping the food supply safe, but also for keeping it functioning in an emergency, it is important for FDA to develop a robust regulatory framework for doing so.

Similarly, FSIS could develop a policy of using its waiver authority during an emergency situation. For example, FSIS has maintained a decades-long program waiving processing line speed limits (setting them slightly higher) for poultry slaughter plants if certain conditions are met.[182] The agency has used this authority successfully for years. If the agency can rely on its authority to waive regulations to experiment with new inspectional systems, it would be equally appropriate to rely on its parallel authority to waive specific regulations in emergency situations.

Finally, the agencies could open dockets soliciting stakeholder input on additional approaches to ensuring regulatory flexibility in response to emergency situations.

5. Inspectional Flexibility

The COVID-19 situation posed several inspection-related challenges. Under FSIS's inspectional model, which generally requires at least one inspector to be present for operations to occur (often more in slaughter establishments),[183] there were concerns that illnesses among inspectors or concerns about risks to inspectors would prevent establishments from being adequately staffed, which would prevent them from operating. For FDA-regulated facilities, there was concern that sending FDA investigators into facilities could expose the investigators to health risks or risk inadvertently transmitting the virus to plant workers at an inspected facility.

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[182] *See Salmonella Initiative Program Criteria*, U.S. DEP'T OF AGRIC., FOOD SAFETY & INSPECTION SERV., https://www.fsis.usda.gov/science-data/data-sets-visualizations/microbiology/microbiological-testing-program-rte-meat-and (last updated Nov. 9, 2021) [https://perma.cc/95KF-88HK]; *see also* 83 Fed. Reg. 49,048 (Sept. 28, 2018).

[183] *See, e.g.*, *Inspection of Meat Products*, U.S. DEP'T OF AGRIC., FOOD SAFETY & INSPECTION SERV., https://www.fsis.usda.gov/inspection/inspection-programs/inspection-meat-products (last updated Aug. 16, 2020) ("The Federal Meat Inspection Act (FMIA) requires that all meat sold commercially be inspected and passed to ensure that it is safe, wholesome, and properly labeled. The USDA Food Safety and Inspection Service (FSIS) is responsible for providing this inspection. The FMIA requires inspection for any product intended for human consumption, wholly or in part, from the carcass or parts of any cattle, sheep, swine, and goat.") [https://perma.cc/S4D2-YAJA].

Under both frameworks, contingency plans to handle inspectional gaps are essential. Each agency has different risks to balance. For both FDA and FSIS, lack of inspections could undermine confidence in food safety. For the FSIS-regulated industry, lack of inspection goes further, shutting down an industry that's deemed critical in an emergency. In both cases, the agencies should develop flexible approaches to facilitate inspection, leveraging new technologies as appropriate and allowed under their respective statutes. Moreover, because inspectional authorities are rooted in statute and because regulatory inspections can have significant legal consequences for inspected companies, the agencies may need to work with the regulated industry to align on temporary, flexible approaches that facilitate emergency inspection as needed but that respect the statutory limitations on agencies' authorities. In many cases, this may require voluntary collaboration between the regulatory agencies and the industry. Because FDA and FSIS inspection function somewhat differently, we address them separately.

i. FDA Inspectional Flexibility

Prioritizing inspections by potential food safety risks makes sense[184] and should be made a standard emergency response strategy. If agency resources are stretched or inspections are themselves higher-risk activities, then it makes sense to conduct them only if needed. FDA could continue to build out prioritization frameworks to be prepared to focus inspectional resources as needed. FDA could also evaluate whether a change in inspection prioritization has had any measurable effect on overall food safety outcomes.

FDA has also expressed a desire to pursue voluntary remote inspectional records access.[185] Remote records access is a touchy issue in the world of food regulation. This was an authority that Congress specifically contemplated but ultimate declined to provide when passing the landmark FDA Food Safety Modernization Act.[186] Therefore, FDA cannot compel facilities to provide records remotely during a typical

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[184] *See* U.S. FOOD & DRUG ADMIN., RESILIENCY ROADMAP FOR FDA INSPECTIONAL OVERSIGHT (May 2021), https://www.fda.gov/media/148197/download [https://perma.cc/9P22-USH6].

[185] *Id.* at 18 (stating "The agency has developed a process to conduct voluntary remote regulatory assessments of domestic human and animal food establishments during the pandemic because, as noted above, the regulatory authority under 704(a)(4) does not apply to FDA oversight of food. FDA will continue to utilize these assessments in the future, which provide an opportunity for increased oversight of the food supply. However, these remote assessments do not count towards the FSMA surveillance inspection requirement. Consistent with FDA's New Era of Smarter Food Safety vision, we plan to further leverage new and emerging technologies and data-driven, predictive analytical approaches to strengthen our compliance oversight work. This could involve working with Congress to make the policy changes needed to modernize and allow greater flexibility to achieve FSMA goals, which would include deploying tools that may not have been contemplated when FSMA was passed over a decade ago.").

[186] The food safety bill passed by the House of Representatives included two provisions that expressly would have granted FDA remote access to certain food records. *See* Food Safety Enhancement Act of 2009, H.R. 2749, 111th Cong. § 106(a) (2009). The food safety bill which ultimately became law, however, did not contain either of these provisions. *See* H.R. 2751, 111th Cong. (2010) (codified as Pub. L. 111-353). The fact that Congress did not adopt the language of the earlier House passed bill may be indicative of congressional intent against providing FDA with remote access authority to food safety plan records. Further, the House of Representatives would not have included the word "submit" in its legislation or entitled the section "remote access" if it already viewed FDA as having such authority, because Congress is expected to consider its bills in the context of the existing statutory scheme. *See* H.R. 2749.

inspection.[187] However, a facility faced with the choice between hosting a group of outside FDA investigators who may unknowingly be carrying a human virus or who may themselves be at greater risk of exposure to a virus may reasonably prefer to voluntarily provide materials remotely to decrease risk to all involved.[188] Doing so could be a reasonable choice, and FDA would be wise to continue offering it as an option. However, it would be important to avoid creating the appearance that providing remote records access is not a truly voluntary decision. Trust and goodwill are critical for managing emergency situations, and it's imperative that FDA be able to trust that facilities will make good-faith decisions to cooperate when possible and that facilities can trust that emergencies will not be used to establish precedent for de facto expanding FDA's investigational authority when there's not a true emergency.

FDA could help ensure voluntary cooperation by creating guidelines in conjunction with the regulated industry establishing when an emergency will create a situation where FDA should request voluntary remote records access, while making clear that cooperating with such a request is truly voluntary.

Further, FDA could consider other options to minimize risk posed by in-person inspections, such as by pre-announcing inspections during public health crises to ensure that facilities can implement safety protocols, minimizing the number of FDA and facility personnel involved in an inspection, using data-analytics tools to determine which situations truly present a potentially imminent food safety risk requiring an inspection, minimizing rotation of FDA investigators through plants in a way that could lead to investigators unknowingly transmitting a human virus, and increasing reliance on local authorities under appropriate circumstances. All of these steps focus on decreasing the risk of in-person inspections. As addressed elsewhere, the FDCA does not provide FDA with remote records access authority for food facilities, and so any remote inspectional programs would necessarily have to be done through voluntary programs.

ii. FSIS Inspectional Authorities

FSIS inspection raises different considerations. Because of continuous inspection requirements, FSIS inspectors generally must be present for an official establishment to operate.[189] Therefore, potential inspector staffing shortages are of critical importance, and concern about inspector staffing caused considerable industry concern during the early stages of the COVID-19 crisis. Inspector staffing problems during a crisis like the COVID-19 emergency present a number of challenges, including disruption to the food supply, economic harm to the industry and individual workers, and animal welfare concerns for the animals delivered to the plant for

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[187] *See* 21 U.S.C. §§ 374(a), 350g(h). *See also supra* note 184, at n.11 (stating "FDA's 704(a)(4) authority allows FDA to request, in advance of or in lieu of an inspection, within a reasonable timeframe, within reasonable limits, and in a reasonable manner, records or information that FDA may inspect under section 704(a). This authority is limited to drug and biologic products and does not apply to other programs . . . .").

[188] Or a company may have valid reasons for declining to do so. We are not offering a perspective on the right approach, but merely identifying reasonable potential outcomes.

[189] *See, e.g.*, U.S. DEP'T OF AGRIC., FOOD SAFETY & INSPECTION SERV., SUMMARY OF FEDERAL INSPECTION REQUIREMENTS FOR MEAT PRODUCTS (Sept. 2015), https://www.fsis.usda.gov/sites/default/files/media_file/2021-02/Fed-Food-Inspect-Requirements.pdf ("Federal inspection personnel must be present at all times during livestock slaughter operations and for at least part of each shift during which there is further processing of meat products.") [https://perma.cc/WW3Z-JS6B].

processing that day. FSIS could prepare for future emergencies by identifying a series of steps the agency would take to preserve inspector staffing and allow maximum flexibility when needed to stretch available inspector staffing to allow operations. These plans could be developed with public input to ensure they reflect real-world stakeholder concerns and so that stakeholders understand what to expect in emergency situations. FSIS might consider options such as increasing the ability for plants to operate under patrol inspection, temporarily decreasing needed inspector staffing for plants with multiple inspectors, using technologies in voluntary cooperation with establishments to increase efficiencies for carcass-by-carcass inspection, deputizing states or third parties, and if needed, waiving certain regulatory requirements for defined periods of time.

6. Evaluate Good Guidance Practices Regulations

FDA has long operated under a set of Good Guidance Practices regulations designed to ensure steady and well-informed agency guidance.[190] USDA has recently established similar regulations for significant guidance across the entire department.[191] Nonetheless, during the pandemic, FDA issued guidance without prior public comment because the agency determined that prior public participation was not feasible or appropriate.[192] The agencies could evaluate whether the process for Emergency Guidance worked well, whether there were any limitations, and whether any additional flexibilities may be needed in the future.

Further, to the extent the agencies decide that the most expedient approach is simply to issue Emergency Guidance, the agencies should develop clear protocols for the administrative good housekeeping that will be necessary for tidying up after issuing significant amounts of Emergency Guidance. The agencies need clear processes for collecting the guidance in a centralized location, collecting and reviewing comments, communicating when and how guidance will be withdrawn, and converting any long-term guidance in more formalized guidance under their respective protocols.

7. Defense Production Act Considerations

The Defense Production Act has laid a quiet but important backdrop to FDA and FSIS's response to the COVID-19 crisis. Although the DPA was invoked, FDA and FSIS have not relied on explicit DPA production orders or otherwise expressly used the DPA to stabilize the supply chain. Rather, the DPA appears to have been held as an option of last resort should voluntary actions prove unsuccessful. Setting aside debate about when and how the DPA ought to be used, FDA and USDA could provide significant clarity to the regulated industry and other stakeholders by establishing a clear, standing approach to how the agencies would use the DPA to manage supply chain emergencies during another emergency like the COVID-19 crisis.

For example, the MOU between USDA and FDA on the use of the DPA provided valuable clarity for the food industry by identifying how the agencies will work together to oversee the food supply. That arrangement is limited to actions "during the public health emergency caused by the outbreak of COVID-19 within the United

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[190] *See* 21 C.F.R. § 10.115(g) (2021).

[191] Review and Issuance of Agency Guidance Documents, 85 Fed. Reg. 34,085 (June 3, 2020).

[192] Notice: Process for Making Available Guidance Documents Related to Coronavirus Disease 2019, 58 Fed. Reg. 16,949 (Mar. 25, 2020).

States."[193] The agencies could execute a similar MOU establishing their default working relationship for all future presidential invocations of the DPA.

Moreover, the DPA can be executed in multiple ways, which could have significant consequences for the supply chain. The agencies could consider identifying the types of orders they would consider issuing and the circumstances under which those orders might be used. Doing so would allow the industry to become familiar with them in advance and to identify potential issues or considerations before the orders need to be used in an emergency.

8. Interaction with State and Local Authorities

The COVID-19 response has played out across a dizzying array of state, federal, and local jurisdictions, with many companies facing a multitude of at-times conflicting orders, recommendations, guidance, and requests from various levels of government. Emergencies are by definition chaotic, but the food supply chain cuts across many jurisdictions and likely would benefit from a flexible but unified approach. For example, a company with food processing plants in states in different parts of the country would have had to respond to federal guidance, state shutdown orders, possibly county and city orders, state and federal workplace safety guidance and regulations, and possibly restrictions in every jurisdiction through which its trucks had to drive. With nearly all supply chains stretching across state lines, unified policy is critical for protecting supply chains but complicated by our federal system.

Future nationwide crisis response plans may need to consider the potential need to address competing and inconsistent state and local requirements, drawing on the federal government's legal and persuasive authorities to try to drive uniform policy. Short of achieving that, FDA and USDA could establish and reinforce clear processes for the food industry to use when inconsistent state and local requirements risk undermining the continuity of the food supply in a national emergency.

C. Translating Learnings Into "Normal" Regulatory Practice

So far, we've been focused largely on the COVID-19 emergency response. Many of these learnings, however, may translate into agencies' day-to-day activities as well. FDA and USDA may wish to consider what processes, tools, and actions taken during the COVID-19 crisis could also be incorporated into their regular rulemaking procedures.

1. Acting Quickly

The COVID-19 crisis established that FDA and USDA can act quickly when presented with an emergency, although within certain confines. Some of that quick action was by necessity, and there certainly are limitations to how long any organization can operate in emergency-response mode with all hands on deck. However, the emergency showed that FDA and FSIS are capable of developing, clearing, and issuing guidance rapidly and equally are capable of quickly updating that

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[193] *See* Letter from FDA to Industry Regarding MOU No. 225-20-011, Potential Use of the Defense Production Act with Regard to FDA-Regulated Food During the COVID-19 Pandemic (May 18, 2020), https://www.fda.gov/media/138172/download [https://perma.cc/2R5E-T7SP]; *see also* U.S. FOOD & DRUG ADMIN., MOU 225–20–011, MEMORANDUM OF UNDERSTANDING BETWEEN FDA AND USDA REGARDING THE POTENTIAL USE OF THE DEFENSE PRODUCTION ACT WITH REGARD TO FDA-REGULATED FOOD DURING THE COVID-19 PANDEMIC (May 18, 2020), https://www.fda.gov/about-fda/domestic-mous/mou-225-20-011 [https://perma.cc/7G5K-24ZT].

guidance in response to developments. The challenge becomes how to capture the beneficial aspects of that speed to apply it to regular activity without compromising the agencies' core food safety missions relied on by the public, and without undermining the rights of regulated companies.

The agencies might look at several avenues. For example, should the agencies' good guidance practices be revised to allow the agencies to take certain actions more quickly, especially potential de-regulatory actions that do not affect food safety? Does OMB and administration review need to be adjusted so that agencies have more freedom to operate quickly for less economically significant issues? Should the agencies resume other stakeholder communications channels currently not used as frequently, such as "Dear Manufacturer" letters used to communicate policy? Speedy action must be balanced against protecting the rights of stakeholders and respecting parties' procedural rights when rulemakings and significant guidance are involved. But the agencies' COVID-19 experience shows that, with sufficient stakeholder engagement and broad consensus, it is possible for the agencies to act swiftly.

This type of action may be especially important if evidence shows that a particular agency requirement is no longer useful or is no longer worth the economic or other costs associated with it. In such a situation, it would be appropriate to move swiftly to communicate a policy of enforcement discretion while initiating the regulatory process to amend or remove a regulation. Although the agencies already at times take this type of approach, the COVID-19 experience suggests that there may be additional situations where doing so is appropriate.

2. Stakeholder Communication

As mentioned earlier, the COVID-19 crisis has highlighted the importance of clear and ongoing communication between stakeholders and regulators. This could be continued, and doing so would have multiple benefits. As discussed earlier, it's important that stakeholders and the agencies establish collective familiarity and trust before, not just during, a crisis. This enables swift and more effective action. But it also leads to better regulatory outcomes overall when not in a crisis situation. As regulatory frameworks become increasingly complex, and as layers upon layers of guidance are used to inform regulations that implement statutory requirements, it is essential that FSIS and FDA have active and meaningful feedback loops with stakeholders, including the regulated industry, so that they can understand what works, what doesn't, and what needs to be changed. The outcome is better regulation that requires fewer agency resources and imposes fewer burdens on the industry, with the same good outcomes.

3. Alternative Inspection and Enforcement Mechanisms

FDA has taken several innovative inspectional and enforcement steps during the COVID-19 crisis. There may be agency interest in continuing these to some degree after the COVID-19 crisis subsides. In particular, FDA might continue to push for remote records access, could emphasize the importance of blockchain or similar traceability technologies, and may continue its trend of taking enforcement action by issuing Warning Letters without actually conducting an inspection.[194] Depending on

[194] *See, e.g.*, U.S. Food & Drug Admin., Warning Letter on Dianne's Fine Desserts (Mar. 2, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/diannes-fine-desserts-600026-03022020 [https://perma.cc/E6BD-BDS6].

how FDA decides to pursue these inspectional strategies, these strategies could have significant consequences on regulatory enforcement and risk management for food companies.

For example, remote records access could result in more FDA inspections and inspections based more on recordkeeping than actual observable plant conditions. This might change facilities' regulatory priorities and almost certainly would change the types of observations reported in Form 483s. Similarly, issuing Warning Letters without conducting an actual inspection, for example based on information provided to FDA in the course of executing a recall, risks significantly altering the current dynamic when conducting recalls.

VIII. CONCLUSION

FDA and FSIS were called upon to rise to an immense challenge—act swiftly to buttress the food supply chain in the face of a global pandemic caused by a virus that we knew virtually nothing about, with nearly no notice. The stakes were high for the food industry, the American public, and the agencies. The COVID-19 crisis saw FDA and FSIS set aside their traditional regulatory tools and instead reach for public statements, guidance, and enforcement discretion, generally trying to collaborate with the food industry and state and local governments to keep the food supply operational. These actions provided valuable insights into which tools the agencies view as most appropriate for rapid response situations, as well as direction for further development, both to prepare for future crises and to transfer COVID-19 learnings into day-to-day regulatory practice.