

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

1. Purpose

The purpose of this Memorandum of Understanding (MOU) is to describe the intended roles of, and working relationship between, the U.S. Department of Health and Human Services, Food and Drug Administration (“HHS-FDA” or “FDA”) and the U.S. Department of Agriculture (“USDA”) (together the “Parties”), with respect to the potential use of the Defense Production Act (“DPA”) and oversight of those involved in the production of human and animal food other than facilities under USDA’s exclusive jurisdiction during the public health emergency caused by the outbreak of COVID-19 within the United States. In particular, this MOU establishes a process in which FDA and USDA will communicate and make determinations about circumstances in which USDA could exercise its authority under the DPA with regard to certain domestic food resource facilities that manufacture, process, pack, or hold foods, as well as to those that grow or harvest food. This MOU does not apply to food resource facilities under USDA’s exclusive jurisdiction.

2. Background

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named “SARS-CoV-2,” and the disease it causes has been named “Coronavirus Disease 2019” (COVID-19). On March 13, 2020, the President declared a national emergency in response to COVID-19.¹

All components of the Food and Agriculture Sector are considered critical infrastructure as determined by Presidential Policy Directive 21, and it is vital for the public health that they continue to operate. Moreover, the protection and restoration of the Food and Agriculture Sector may be considered necessary or appropriate to promote the national defense for purposes of the DPA.

Outbreaks of COVID-19 among workers at food resource facilities or among harvesting crews could lead to reduction in production capacity. Likewise, actions by States or localities could

¹ Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

lead to the closure of food resource facilities or to commodities not being harvested. In many instances, these operations could continue to operate consistent with guidance issued by the Centers for Disease Control and Prevention (CDC) of the Department of Health and Human Services and the Occupational Safety and Health Administration (OSHA) of the Department of Labor providing for the safe operation of such food resource facilities or farms.

Food resource facility closures or harvesting disruption could threaten the continued functioning of the national food supply chain, undermining critical infrastructure during the national emergency.

3. Statutory Authority

HHS-FDA is responsible for implementing and enforcing the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301, et seq.), the Public Health Service Act (42 U.S.C. 201, et seq.), and the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.). In carrying out its responsibilities under these acts, HHS-FDA maintains broad responsibility for ensuring that food is not adulterated or misbranded. In furtherance of this mission, HHS-FDA regulates food resource facilities that manufacture, process, pack, or hold foods, with the exception of certain establishments that are regulated exclusively by USDA.

USDA is responsible for implementing and enforcing the Federal Meat Inspection Act (21 U.S.C. 601, et seq.), the Poultry Products Inspection Act (21 U.S.C. 451, et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031, et seq.). In addition, USDA enforces the misbranding and adulteration provisions of its authorizing statutes for meat, poultry and egg products in commerce. Further, the Secretary enjoys general authority under the Agricultural Marketing Act of 1946 (7 U.S.C. § 1622(o)) to conduct such other research and services and to perform such other activities as will facilitate the marketing, distribution, processing, and utilization of agricultural products through commercial channels. Finally, as described below, USDA exercises presidentially delegated authority over food resources and food resource facilities under the Defense Production Act (DPA), (50 U.S.C. 4501 et seq.).

The DPA provides the President of the United States with authority to expedite and expand critical supplies and services from the private sector that are needed to promote national defense, including protection and restoration of critical infrastructure. Under Section 201(a) of Executive Order (EO) 13603, the President delegated to the Secretary of Agriculture the authority to require acceptance and priority performance of contracts or orders (other than contracts of employment) to promote the national defense over performance of any other contracts or orders, and to allocate materials, services, and facilities as deemed necessary or appropriate to promote

national defense with respect to food resources², food resource facilities³, livestock resources, veterinary resources, plant health resources, and the domestic distribution of farm equipment and commercial fertilizer.

On April 28, 2020, the President issued Executive Order 13917 additionally delegating authority to USDA under the DPA with respect to food supply chain resources specifically during the national emergency caused by the outbreak of COVID-19.

[\(https://www.whitehouse.gov/presidential-actions/executive-order-delegating-authority-dpa-respect-food-supply-chain-resources-national-emergency-caused-outbreak-covid-19/\)](https://www.whitehouse.gov/presidential-actions/executive-order-delegating-authority-dpa-respect-food-supply-chain-resources-national-emergency-caused-outbreak-covid-19/)

Under this executive order, which generally focuses on ensuring the continued functioning of the meat and poultry industries, the President directed the Secretary of Agriculture to take all appropriate actions to ensure that meat and poultry processors continue operations consistent with the guidance for their operations jointly issued by the Centers for Disease Control (CDC) and the U.S. Department of Labor’s (DOL) Occupational Safety and Health Administration (OSHA). Additionally, the executive order specifies that: “Under the delegation of authority provided in this order, the Secretary of Agriculture may identify additional specific food supply chain resources that meet the criteria of section 101(b).” Should the Secretary of Agriculture, pursuant to Executive Order 13917, identify specific food supply chain resources that are subject to FDA regulation, the Parties will collaborate as agreed below.

4. Substance of the Agreement

A. HHS-FDA will:

1. Monitor, to the extent feasible, the integrity and adequacy of the nation’s food supply that is subject to FDA regulation;
2. Work with stakeholders involved in the domestic production or distribution of FDA-regulated food to identify extant and potential domestic supply chain disruptions;
3. Direct FDA-regulated entities to applicable guidance, including guidance issued by CDC and OSHA for workers on farms and at food resource facilities;

² “Food resources” means all commodities and products, (simple, mixed, or compound), or complements to such commodities or products, that are capable of being ingested by either human beings or animals, irrespective of other uses to which such commodities or products may be put, at all stages of processing from the raw commodity to the products thereof in vendible form for human or animal consumption. “Food resources” also means potable water packaged in commercially marketable containers, all starches, sugars, vegetable and animal or marine fats and oils, seed, cotton, hemp, and flax fiber, but does not mean any such material after it loses its identity as an agricultural commodity or agricultural product.

³ “Food resource facilities” means plants, machinery, vehicles (including on farm), and other facilities required for the production, processing, distribution, and storage (including cold storage) of food resources, and for the domestic distribution of farm equipment and fertilizer (excluding transportation thereof).

4. Assess, to the extent possible, extant and potential disruptions to the nation's supply of FDA-regulated food, including, but not limited to, closures of American resource facilities or actions by states or localities that could lead to potential disruption to the harvest or production of such food;
5. As appropriate, educate domestic stakeholders about this MOU and the potential for use of DPA authority where necessary or appropriate to protect the supply of FDA-regulated food;
6. Upon identifying a potential or extant disruption to the supply of FDA-regulated food of sufficient likelihood, seriousness or significance, contact USDA to discuss appropriate action, including possibly invoking its delegated DPA authorities.

B. USDA will:

1. Retain exclusive delegated authority to issue DPA orders or invoke DPA authorities with regard to food resources and domestic food resource facilities;
2. Upon notification by FDA of a potential or extant disruption to the supply of FDA-regulated food of sufficient likelihood, seriousness or significance, consult with FDA about appropriate action, including whether to invoke USDA's DPA delegated authorities;
3. After consultation with FDA, issue orders related to or utilize other delegated USDA DPA authorities with regard to food resources and food resource facilities.

C. It is mutually agreed that:

1. The Parties will maintain a collaborative working relationship. HHS-FDA and USDA personnel will meet periodically, as appropriate, for purposes of coordination, evaluation, and review concerning the nation's food supply during the COVID-19 public health emergency.
2. A Party will immediately notify the other Party if it is unable to carry out any or all of its responsibilities under this MOU.

5. Limitations

Nothing in this agreement shall be construed to limit the statutory authority of HHS-FDA or USDA.

This agreement is solely for purposes of coordinating potential use of delegated USDA DPA authorities during the COVID-19 public health emergency. It represents the broad outline of the Parties' present intent on how they will approach the oversight of food resource facilities and farms that are not subject to USDA's exclusive jurisdiction and how they will approach possible use of the DPA with regard to such entities during the COVID-19 public health emergency.

It does not create binding, enforceable obligations against either Agency. All activities undertaken pursuant to the agreement are subject to the availability of personnel, resources, and funds.

This agreement does not affect or supersede any existing agreements or arrangements between the Parties and does not affect the ability of the Parties to enter into other agreements or arrangements related to this agreement.

This agreement and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which HHS-FDA and USDA operate.

Nothing in this agreement shall obligate HHS-FDA or USDA to any current expenditure or future expenditure of resources in advance of the availability of appropriations from Congress.

6. Liaison Officers

To facilitate the activities carried out under this agreement, each agency will establish a single agency liaison. The initial liaisons will be:

For HHS-FDA: Frank Yiannas
Deputy Commissioner
Food Policy and Response

For USDA: Mindy Brashears
Under Secretary for Food Safety

Each agency may designate a new liaison at any time by notifying the other in writing. If at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the agency will name a new liaison and notify the other agency through the designated liaison.

7. Effective Date, Terms, Termination and Modification

This agreement will become effective when signed by both parties and made publicly available on the USDA and FDA websites, and it will continue in effect unless modified by mutual written consent at any time or terminated by either party upon a 60 day advance written notice to the other, or upon the expiration of the presidentially declared emergency, whichever comes first.

Approved and Accepted for the Food and Drug Administration

Signed by: Frank Yiannas
Deputy Commissioner
Food Policy and Response
Date: 5/18/2020

Approved and Accepted for the United States Department of Agriculture

Signed by: Mindy Brashears
Under Secretary for Food Safety
Date: 5/18/2020