



Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
T +1 202 637 5600
F +1 202 637 5910
www.hoganlovells.com

MEMORANDUM

From: Elizabeth Barr Fawell
Brian D. Eyink
Christine Forgues

Date: May 20, 2020

Re: COVID-19 Update: FDA and USDA Issue Memorandum of Understanding Regarding the Potential Use of the Defense Production Act with Regard to FDA-Regulated Food During the COVID-19 Pandemic

The Food and Drug Administration (FDA) and United States Department of Agriculture (USDA) recently issued a Memorandum of Understanding (MOU) regarding the potential use of the Defense Production Act (DPA) with regard to FDA-regulated food.¹ Importantly, USDA retains its DPA authority for products subject to FDA jurisdiction. The MOU, however, establishes that FDA will be responsible for monitoring the continued functioning of the FDA-regulated 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.² The MOU is intended to supplement preparedness efforts and directs FDA to take the lead for FDA-regulated industry and monitor the food supply, work with stakeholders to identify and assess potential supply chain disruptions, issue applicable guidance for workers, and educate stakeholders about the potential for use of DPA authority. To the extent FDA identifies disruptions to the supply or other issues, both Agencies will work together to discuss appropriate action, including potentially invoking USDA's DPA-delegated authorities. The MOU does not actually take any action under the DPA—it does not reflect action by USDA expanding the scope of the President's invocation of the DPA beyond the meat and poultry sectors, nor does it constitute an order under the DPA.³

Executive Order Authorities

As brief background, the DPA provides the President with authority to expedite and expand critical supplies and services that are needed to promote national defense, including protection and

¹ MOU 225-20-011 (May 18, 2020) <https://www.fda.gov/about-fda/domestic-mous/mou-225-20-011>; see also FDA Press Release "USDA, FDA Strengthen U.S. Food Supply Chain Protections" (May 19, 2020) <https://bit.ly/36isA7K>; see also USDA Press Release "USDA, FDA Strengthen U.S. Food Supply Chain Protections During COVID-19 Pandemic" (May 19, 2020) <https://bit.ly/2yjRVBr>.

² See FDA Letter to Industry Regarding the MOU (May 18, 2020) <https://www.fda.gov/media/138172/download>.

³ This memorandum is offered for general information and educational purposes. It is not offered as, intended as, and does not constitute legal advice. It is not intended to create, and receipt of it does not constitute, a lawyer-client relationship.

Hogan Lovells US LLP is a limited liability partnership registered in the District of Columbia. "Hogan Lovells" is an international legal practice that includes Hogan Lovells US LLP and Hogan Lovells International LLP, with offices in: Alicante Amsterdam Baltimore Beijing Birmingham Boston Brussels Colorado Springs Denver Dubai Dusseldorf Frankfurt Hamburg Hanoi Ho Chi Minh City Hong Kong Houston Johannesburg London Los Angeles Luxembourg Madrid Mexico City Miami Milan Minneapolis Monterrey Moscow Munich New York Northern Virginia Paris Perth Philadelphia Rome San Francisco São Paulo Shanghai Silicon Valley Singapore Sydney Tokyo Warsaw Washington, D.C. Associated Offices: Budapest Jakarta Riyadh Shanghai FTZ Ulaanbaatar Zagreb. Business Service Centers: Johannesburg Louisville. Legal Services Center: Berlin. For more information see www.hoganlovells.com

restoration of critical infrastructure.⁴ All components of the Food and Agriculture Sector are considered critical infrastructure as determined by Presidential Policy Directive 21 and under Department of Homeland Security guidance related to COVID-19.⁵

Under an earlier and still-in-force 2012 Executive Order (EO), President Obama delegated to the Secretary of Agriculture certain DPA authorities for the food and agriculture sector, including the authority to require acceptance and priority performance of contracts or orders 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.⁶ On April 28, 2020, President Trump issued an EO 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-19.⁷

Under EO 13917, President Trump 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).⁸ Additionally, the EO specifies that: "the Secretary of Agriculture may identify additional specific food supply chain resources that meet the criteria of section 101(b)."⁹ The MOU explains that it outlines the process and respective FDA and USDA responsibilities in the event the Secretary of Agriculture identifies specific food supply chain resources under FDA's jurisdiction that meet the criteria of Section 101(b) of the DPA. Importantly, the MOU is not itself a decision that any FDA-regulated aspects of the food supply chain meet this criteria.

⁴ 50 USC 4501, *et seq.*

⁵ See Presidential Policy Directive (PPD-21) - Critical Infrastructure Security and Resilience (Feb. 12, 2013) <https://bit.ly/3e2ZCLv>; see also CISA Guidance on the Essential Critical Infrastructure Workforce V. 3.1 (May 19, 2020) <https://bit.ly/2X9HcSA>.

⁶ Executive Order 13603 - National Defense Resources Preparedness, § 201(a) (Mar, 16, 2012) <https://bit.ly/2AGRwtz>. Of note, the 2012 Executive Order 13603 defines "food resources" which is subsequently mirrored in the MOU and Agency Press Releases, to mean "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." As the definitions for "food resources" and "food resource facilities" are broad and encompass "food" and "food facilities," this memorandum uses these terms interchangeably.

⁷ Executive Order 13917 - Delegating Authority Under the DPA with Respect to Food Supply Chain Resources During the National Emergency Caused by the Outbreak of COVID-19 (Apr. 28, 2020) <https://bit.ly/2Zo3sea>; see also *HL Memo - President Trump Issues Executive Order Invoking Defense Production Act for Meat and Poultry Processors* (Apr, 29, 2020) <https://bit.ly/2Tne6hy>.

⁸ See *HL Memo - COVID-19 Update: CDC and OSHA Release Interim Guidance for Meat and Poultry Processing Workers and Employers* (Apr. 27, 2020) <https://bit.ly/3e1hfLM>.

⁹ 50 U.S.C. 4511(b) ("The powers granted in this section shall not be used to control the general distribution of any material in the civilian market unless the President finds (1) that such material is a scarce and critical material essential to the national defense, and (2) that the requirements of the national defense for such material cannot otherwise be met without creating a significant dislocation of the normal distribution of such material in the civilian market to such a degree as to create appreciable hardship").

Substance of the Agreement under the MOU

The MOU outlines FDA's and USDA's responsibilities in the event USDA expands the scope of the EO to cover additional parts of the food supply chain. Generally, under the MOU, FDA would have initial responsibility for monitoring and interfacing with the FDA-regulated supply chain, but USDA would retain ultimate authority to invoke the DPA and issue DPA orders, at FDA's recommendation.

FDA Responsibilities

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

USDA Responsibilities

- Retain exclusive delegated authority to issue DPA orders or invoke DPA authorities with regard to food resources and domestic food resource facilities;
- 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;
- After consultation with FDA, issue orders related to or utilize other delegated USDA DPA authorities with regard to food resources and food resource facilities.

Mutual Responsibilities

- 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.
- A Party will immediately notify the other Party if it is unable to carry out any or all of its responsibilities under this MOU.

* * *

We will continue to monitor the federal government's response to COVID-19. Should you have any questions or if we can be of assistance with your COVID-19 response strategy, please do not hesitate to contact us.