

MEMORANDUM

From: Elizabeth Barr Fawell
Maile Gradison Hermida
Samantha Dietle

Date: May 28, 2020

Re: COVID-19 Update: FDA Issues Guidance on Voluntary Reporting of Temporary Closures or Significantly Reduced Production by a Human Food Establishment and Requesting FDA Assistance During COVID-19 Public Health Emergency

On May 27, 2020, the U.S. Food and Drug Administration (FDA) issued new guidance for human food establishments on voluntarily reporting to FDA temporary closures or significantly reduced production due to the COVID-19 public health emergency. ^{1/} The agency's guidance document is entitled "Reporting a Temporary Closure or Significantly Reduced Production by a Human Food Establishment and Requesting FDA Assistance During the COVID-19 Public Health Emergency" ("Guidance"). The Guidance details a mechanism by which human food facilities and farms may voluntarily notify FDA of temporary closures and significant reductions in operations, or to request a dialogue with FDA on issues related to continuing or restarting their operations during the COVID-19 pandemic. This Guidance does not apply to restaurant and retail food establishments or to animal food operations. We summarize the Guidance below. ^{2/}

The Guidance explains that FDA has established a voluntary reporting mechanism for human food manufacturing facilities and farms that have temporarily closed or reduced operations due to COVID-19 or that are considering doing so. Although facilities that manufacture, process, pack, or hold food are required to register with FDA and update the registration within 60 days in the event of certain changes to operations, during the pandemic, FDA believes that more rapid and specific notifications regarding FDA-regulated food establishments will help the agency better understand the current status of the food supply and address challenges facing food producers to support food production.

^{1/} 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>; see also FDA Constituent Update, "Voluntary Reporting of Temporary Closures or Requesting Assistance for FDA-Regulated Food Establishments During COVID-19 Pandemic" (May 27, 2020) <https://www.fda.gov/food/cfsan-constituent-updates/voluntary-reporting-temporary-closures-or-requesting-assistance-fda-regulated-food-establishments>.

^{2/} 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

In addition, by voluntarily disclosing this information to FDA, FDA can provide relevant guidance to human food facilities, in areas including worker safety, inability to access personal protective equipment for personnel, and supply chain imbalances, in addition to engaging its federal, state, local, tribal, and territorial regulatory partners to provide the most up-to-date information.

Importantly, FDA states it does not intend to use the information reported to target establishments for inspections as a result of temporary closure or reduced production during the pandemic. In addition, FDA does not anticipate the risk profile of an establishment to change as a result of a temporary closure. If FDA learns that the establishment is making permanent changes to its operations, such as making a different type of commodity, this information can change the risk profile of a facility, and FDA will incorporate this information into its future work planning process. The purpose of the reported information is to help FDA understand the status of FDA-regulated food establishments and the food supply in light of circumstances associated with the pandemic.

Food manufacturing facilities and farms that wish to voluntarily report closures or reduced operations or seek assistance from FDA may do so using the following Reporting and Requesting Protocol:

1. Establishments should visit FDA's Center for Food Safety and Applied Nutrition's (CFSAN's) Food and Cosmetic Information Center (FCIC) webpage at <https://cfsan.secure.force.com/InquiryPage>;
2. Check the box "Is your inquiry specific to Coronavirus" on the FCIC webpage and there will be an option to choose to report a temporary closure or a significant reduction in production due to circumstances associated with COVID-19 and request assistance;
3. Check the box "Report a Temporary Closure/Production Reduction and Request Assistance" which will result in users receiving an email with a link to provide information;
4. Via the email link, complete and submit the form requesting the following information:
 - Whether the establishment is a facility, a farm, or a mixed-type facility;
 - Whether assistance is requested and a brief description of the nature of the request;
 - The name, address, and contact information for the establishment;
 - If applicable, the Food Facility Registration Number and Food Establishment Inventory (FEI) Number, so that FDA can cross reference the notification or request with information in our databases;
 - If applicable, information about when an establishment closed or reduced operations that significantly impact production (or estimates doing so) and an estimate of how long the establishment will likely remain closed or at partial operation;
 - Examples of reduced operations that significantly impact production include operation alterations that reduce production volume by a significant percentage (e.g., reductions of 15% or greater), but not temporary operation changes to accommodate activities like additional cleaning; and
 - The number of employees at the establishment.

*

*

*

The Guidance is intended to remain in effect only for the duration of the public health emergency.

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.