

MEMORANDUM

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Re: Impact of Government Shutdown on Scope of FDA, FSIS, and CSPC Activities

On December 22, 2018, funding expired for certain agencies within the federal government, including the Food and Drug Administration (FDA), the U.S. Department of Agriculture's (USDA's) Food Safety Inspection Service (FSIS), and the Consumer Product Safety Commission (CPSC). These agencies will be operating under significantly reduced functions until the shutdown ends, i.e., until Congress passes a new appropriations bill providing funding for these agencies. This memorandum provides a summary of the scope of each of these agencies' operations during the shutdown, as well as the implications for the food and other consumer product industries.

FDA

Generally speaking, the distinction for FDA activities that continue during the shutdown versus activities that are suspended during the shutdown is based on whether the work relates to an urgent public health standpoint, such as recalls, outbreaks, and traceback activities. FDA Commissioner Gottlieb has been using Twitter to communicate updates on the scope of FDA's activities during the shutdown, and said that FDA would be "continuing vital activities, to the extent permitted by the law, that are critical to ensuring public health and safety in the United States." Based on the Health and Human Services (HHS) contingency plan for shutdowns, ^{1/} the scope of FDA's food-related activities during the shutdown include:

- Vital activities to respond to emergencies;
- Supporting high-risk food product recalls;
- Pursuing civil and criminal investigations when the public health may be imminently at risk;
- Screening imported food products to determine potential risks to health; and
- Addressing other critical public health issues that involve imminent threats to the safety of human life, including outbreaks related to foodborne illness and infectious diseases.

^{1/} FY 2019 HHS Contingency Staffing Plan for Operations in the Absence of Enacted Annual Agriculture and Interior Appropriations, *available at* <https://www.hhs.gov/about/budget/fy-2019-hhs-contingency-staffing-plan/index.html>.

However, FDA is unable to support some routine regulatory and compliance activities, including the majority of food related activities. This includes routine establishment inspections, which are deferred during the shutdown. In addition, FDA has also paused nutrition and cosmetics work, and many ongoing research activities.

FSIS

Similar to FDA, FSIS's contingency plan 2/ provides that FSIS can continue certain functions necessary to protect public health such as recall management, outbreak investigations, and import reviews; however, unlike FDA, FSIS will continue in-plant inspections during the shutdown. FSIS will also continue outbreak investigations and recall management functions during the shutdown. Activities that will not continue during the shutdown include regulatory programs in the Office of Policy and Program Development, which encompasses the label approval program. Historically, during the 2013 and 2018 shutdowns, no Labeling Staff were available, and the label review/approval process was significantly delayed, without a mechanism to secure temporary label approvals.

CPSC

CPSC's shutdown contingency plan 3/ provides that only employees necessary to protect against imminent threats to human life are permitted to continue work, which is defined to include:

- Employees necessary to collect and analyze information about defective products to determine whether they create a substantial and immediate threat to the safety of human life;
- Employees necessary to work with manufacturers, distributors, and retailers to recall as quickly as practicable products that create an immediate threat to the safety of human life;
- Employees necessary to disseminate information to the public about products that create an immediate threat to the safety of human life;
- Employees necessary to coordinate and monitor recalls of products that create a substantial and immediate threat to the safety of human life; and
- Employees necessary to file an action in a United States district court with respect to products that create a substantial and immediate threat to the safety of human life.

The only work that may be conducted during the shutdown is work related to one of these excepted activities listed above.

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We will continue to monitor developments related to the government shutdown. Please contact us if you have questions on this or any other matter.

2/ USDA FSIS Operations Plan for Absence of Appropriations, *available at* <https://www.usda.gov/sites/default/files/documents/usda-fsis-shutdown-plan.pdf>.

3/ Commission Shutdown Procedures in the Event of a Lapse in Appropriations, *available at* https://cpsc.gov/s3fs-public/CPSC%20Shutdown%20Directive121818.pdf?82MBPG6JIMosZuiRprvlepb429_yO.YG.