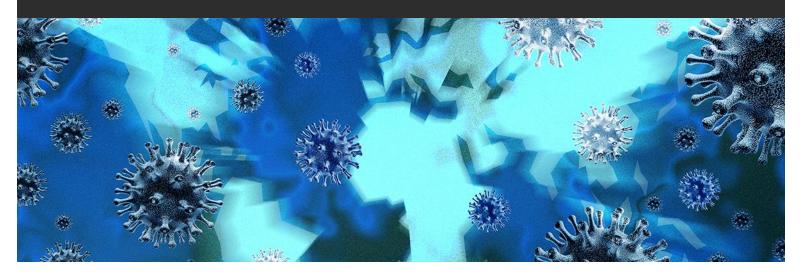


Alert | Health Emergency Preparedness Task Force: Coronavirus Disease 2019



March 23, 2020

FDA Announces Reduction in Inspections, Issues New Resources on Food Safety

The Food and Drug Administration (FDA) held a stakeholder call for interested parties on March 18, 2020, to discuss food safety and food supply questions related to Coronavirus Disease 2019 (COVID-19). FDA Commissioner Stephen M. Hahn M.D. also issued a statement outlining FDA's current focus and direction of resources towards safety of products while reducing facility inspections during the current crisis.

On the teleconference, FDA summarized current regulatory activities and highlighted newly added FDA resources pertaining to the COVID-19 pandemic. One of the new resources added is a Frequently Asked Questions (FAQ) on "Food Safety and the Coronavirus Disease 2019 (COVID-19)." This FAQ contains pertinent questions and answers addressing topical areas of food safety for food processors and manufacturers, such as "what should food processors do if a worker tests positive for COVID-19," "does food need to be recalled if a worker at a food processing facility tests positive," "can and should employers inform fellow employees of possible exposure to COVID-19," and "do other co-workers need to self-quarantine."

Another resource issued by FDA is a general FAQ entitled "Coronavirus Disease 2019 (COVID-19)." This FAQ addresses general questions and answers on COVID-19, potential COVID-19 countermeasures, drugs, medical devices and tests, and the food supply.



The third resource issued by FDA on March 18 is a guidance document entitled "Guidance for Industry: Temporary Policy Regarding Preventive Controls and FSVP Food Supplier Verification Onsite Audit Requirements During the COVID-19 Public Health Emergency." This guidance is intended for food suppliers and addresses the intent of FDA to exercise enforcement discretion and not enforce requirements in three food regulations to conduct onsite audits of food suppliers if other verification methods are used. In the guidance, FDA outlines the circumstances in which FDA will not require an onsite audit and the alternate verification activities that will allow companies to be compliant.

The guidance regarding onsite audits tracks with FDA Commissioner Hahn's public comments regarding the current focus of FDA resources to combat the COVID-19 pandemic. FDA has, for the time being, postponed most foreign facility inspections through April, and has postponed all domestic routine surveillance facility inspections. "For-cause" inspections, such as those necessary in light of a food contamination/food recall situation, will be evaluated and proceed only if critical. *See* Commissioner Hahn's full comments.

For more information and updates on the developing COVID-19 situation, visit GT's Health Emergency Preparedness Task Force: Coronavirus Disease 2019.

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