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FDA and USDA Food Safety Response to COVID-19 & DHS "Critical Infrastructure" Classification of Food and Agriculture Sector

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In the U.S. Food and Drug Administration's (FDA) <u>March 18 briefing for stakeholders on COVID-19</u>, Frank Yiannas, deputy commissioner of the Office of Food Policy and Response, assured listeners that the FDA is "committed to ensuring the safety of the food supply and that the food supply chain from farm to table is not disrupted." Similarly, in a <u>letter to stakeholders</u>, U.S. Department of Agriculture (USDA) undersecretary for marketing and regulatory programs Greg Ibach and the USDA deputy undersecretary for food safety Dr. Mindy Brashears stated, "the U.S. Department of Agriculture is rising to meet the challenges associated with the new coronavirus disease, COVID-19.... The [USDA's Food Safety and Inspection Service, Animal and Plant Health Inspection Service, and Agricultural Marketing Service] are committed to ensuring the health and safety of our employees while still providing the timely delivery of services to maintain the movement of America's food supply from farm to fork."

As part of the agencies' work to ensure the food supply is both safe and not disrupted, over the past several weeks both agencies have made a number of significant announcements about their food safety enforcement approach and have issued guidance to industry addressing food safety concerns related to the coronavirus pandemic.

FDA

Q&A on COVID-19 and food safety

On March 17, 2020, the FDA launched a Food Safety and the Coronavirus Disease 2019 (COVID-19) website that includes a Q&A addressing food safety concerns about the coronavirus pandemic. The FDA has been updating this website regularly. Consistent with other statements, the FDA makes clear that "there is no evidence of food or food packaging being associated with transmission of COVID-19" but does indicate that the coronavirus may be transmitted via surfaces or objects. The Q&A includes guidance on the following:

• Steps to take if a worker in a food processing facility or farm tests positive for COVID-19: (1) Employers should inform other employees of possible exposure but maintain confidentiality; (2) sick employees should follow the CDC's <u>Steps to help prevent the spread of COVID-19 if you are sick</u>; (3) facilities should redouble cleaning and sanitation efforts to control any risks associated with sick workers; and (4) facilities should consult with the local

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health department for additional guidance and follow protocols set by local and state health departments to determine whether a food facility or farm should close.

- Social distancing in food facilities: When possible, the FDA recommends identifying and implementing operation changes that increase employee separation in accordance with the CDC's recommendation to employ social distancing. Additionally, the FDA reiterates the importance of effective hygiene practices.
- Recalls: The FDA is not anticipating that food products would need to be recalled or withdrawn because of COVID-19 because "there is no evidence of food or food packaging being associated with transmission of COVID-19." In its March 18 briefing for stakeholders, Dr. Susan Mayne, director of the Center for Food Safety and Applied Nutrition (CFSAN), made clear that "we are not asking that food be placed on hold or that food be recalled" if a food facility employee tests positive for COVID-19.
- Advice on handling self-service food buffets: As an extra precaution, the FDA recommends: (1) frequent washing and sanitizing of all food contact surfaces and utensils; (2) that workers must practice frequent hand washing and glove changes before and after preparing food; (3) frequent cleaning and sanitizing of counters and condiment containers; and (4) consumers wash their hands after using serving utensils. Ultimately, the FDA recommends discontinuing self-service buffets and salad bars until health authorities lift social-distancing measures.
- Cleaning and sanitizing: The FDA reminds food facilities to use EPA-registered sanitizer in cleaning and sanitizing practices and recommends considering a more frequent cleaning schedule. Some food establishments set up quaternary ammonium hand-dip stations and sprays at 200 ppm in the absence of hand sanitizer; the FDA advises against using these products as replacements for hand sanitizers. The agency notes it is aware of adverse event reports from consumers using these products as replacements.
- Food supply-chain issues: For those experiencing food supply-chain issues, the FDA directs businesses to contact the FEMA National Business Emergency Operations Center at <u>NBEOC@fema.dhs.gov</u>.

FDA-regulated facilities should consider reviewing their current good manufacturing practices (CGMPs) and food safety plans to determine whether any additional precautions and risk-based preventive controls related to the coronavirus should be incorporated.

Inspections

As we previously reported, the FDA has <u>postponed foreign inspections</u> through April except if "mission critical" and has temporarily postponed <u>all domestic routine surveillance facility inspections</u>. However, for-cause domestic inspections will proceed if mission-critical. In its March 18 briefing for stakeholders on COVID-19, Michael Rogers, assistant commissioner for human and animal food operations in the Office of Regulatory Affairs, further clarified that the FDA would consider inspections that "might be in support of a food-borne outbreak or in support of a Class One recall or in support of a product that is related to the COVID-19 pandemic" as mission-critical inspections. Departing from the agency's traditional approach of conducting unannounced inspections, Rogers noted that the agency will be pre-announcing domestic inspections. However, these inspections will only occur "if there is any possible way to get there and accomplish them in a way that does not put anyone at risk."

Rogers also referenced the FDA's plans to engage with industry on how best to accomplish the agency's mission without traditional on-site presence at firms. Industry should be prepared to engage with the FDA should the opportunity arise.

Temporary policy on meeting FSVP supplier verification onsite audit requirements

On March 17, 2020, the FDA issued a <u>temporary hold on the Food Safety Modernization Act's (FSMA) Foreign Supplier</u> <u>Verification Program (FSVP) onsite audit requirements</u> of food suppliers for receiving facilities and FSVP importers due to current travel advisories and restrictions. Found in the Preventive Controls for Human Food Rule (21 C.F.R. Part 117), Preventive Controls for Animal Food Rule (21 C.F.R. 507), and FSVP regulation (21 C.F.R. Part 1 Subpart L), these provisions require receiving facilities and FSVP importers to conduct supplier-verification activities (e.g., onsite audit, sampling and testing, review of food safety records) to ensure that imported food meets applicable U.S. food-safety standards. Onsite audits are the default verification activity when a hazard is controlled by the supplier and there is a reasonable probability that exposure to the hazard will result in serious health consequences.

Under this temporary policy, onsite audit requirements will not be enforced in specific circumstances because current travel advisories and restrictions "may impact the ability of receiving facilities and FSVP importers to conduct or obtain onsite audits of their suppliers." Specifically, for suppliers located in a region or country covered by a government travel restriction or advisory related to COVID-19 where an onsite audit has been identified as the appropriate verification activity, the FDA will not enforce the onsite audit requirement when it is "temporarily impracticable" for the receiving facility or FSVP importer to conduct or obtain the onsite audit if: (1) an alternative verification method is used instead; and (2) the food safety plan or FSVP is modified to incorporate the alternative activity. Importantly, the alternative verification activity must provide "sufficient assurance" that the hazard has been "significantly minimized or prevented" during the period of onsite audit delay.

USDA FSIS

FAQ

Like the FDA, the USDA has launched a <u>COVID-19 Q&A</u> that addresses food safety issues related to COVID-19. Similar to the FDA's statement, the USDA notes that it is "not aware of any reports at this time of human illnesses that suggest COVID-19 can be transmitted by food or food packaging." Among other items, the FAQ also advises the following:

- Food Safety Inspection Service (FSIS) in-plant personnel ill with COVID-19: FSIS personnel ill with COVID-19 or any other illness will be excluded from work activities that could create unsanitary conditions and will follow the recommendation of local public health authorities regarding notification of potential contacts.
- Plant personnel ill with COVID-19: Plants are encouraged to follow the recommendations of local public health authorities if there is a diagnosed COVID-19 illness.
- **Cleaning and sanitation:** Unlike the FDA, which has recommended more frequent cleaning schedules, the FSIS defers to the same sanitary procedures that establishments are already following to protect food safety to prevent the spread of respiratory illnesses like COVID-19 and directs readers to the EPA's list of disinfectants.

Inspections

According to its <u>March 17 press release</u>, meat, poultry, and processed egg inspection services under the FSIS will "continue as normal." The March 17 press release notes, however, that the FSIS will prioritize inspection at establishments "based on local conditions and resources available." In its FAQ, the USDA acknowledges that planning for absenteeism of food inspectors "is a part of normal FSIS operations" and the agency has "a plan and authority to address staffing considerations and is prepared to act accordingly."

The FSIS has also provided a March 20, 2020 guidance to industry indicating that establishments can ask USDA employees questions about COVID-19 before allowing entrance into the facility for inspection (e.g., whether the employee is experiencing symptoms of COVID-19, whether someone living with the USDA employee has been diagnosed with

COVID-19). The guidance makes clear that "USDA employees will only respond to questions orally and will not sign any attestations or submit any written questionnaires" and also notes that "the industry may not retain any confidential or medical information associated with any USDA employee's response." Ultimately, industry has the authority to determine whether to permit or deny entry into its facility, so procedures to evaluate FSIS personnel before entry should be reviewed taking this policy into account.

Ultimately, it remains to be seen whether the FSIS will be able to continue its inspection services "as normal" as the coronavirus pandemic evolves or whether further modifications and industry guidance may be necessary.

DHS "Critical Infrastructure" Classification for the Food and Agriculture Sector

The <u>President's Coronavirus Guidelines for America</u>, updated on March 16, 2020, states that "if you work in a critical infrastructure industry, as defined by the Department of Homeland Security, … you have a special responsibility to maintain your normal work schedule." As referenced in the FDA's Q&A on COVID-19 and food safety, in <u>guidance issued by the Department of Homeland Security (DHS) Cybersecurity and Infrastructure Security Agency (CISA)</u>, workers in the food and agriculture sector – agricultural production, food processing, distribution, retail, and food service and allied industries – are named as "essential critical infrastructure workers" required to maintain normal work schedules. Listed workers include workers supporting restaurant carry-out and quick-serve operations and groceries, pharmacies, and other retail that sells food and beverage; food manufacturer employees; and their supplier employees. The full list can be found under the "Food and Agriculture" tab of the guidance.

The guidance is advisory and meant to help state and local officials to "determine the sectors, sub-sectors, segments, or critical functions that should continue normal operation." We encourage industry to review the guidance to determine which workers may be identified as essential to critical infrastructure as state and local officials implement response activities.

Conclusion

With increasing demands on industry to ensure the food supply is safe and not disrupted and as the coronavirus pandemic evolves, the food industry should continue to implement best practices and be prepared to respond accordingly as the FDA and USDA modify their enforcement approach to food safety.

Alston & Bird has formed a multidisciplinary <u>task force</u> to advise clients on the business and legal implications of the coronavirus (COVID-19). You can <u>view all our work</u> on the coronavirus across industries and <u>subscribe</u> to our future webinars and advisories.

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