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MEMORANDUM

From: Martin J. Hahn
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Date: March 18, 2020

Re: **COVID-19 Update: FDA and USDA Issue Guidance for Industry and Inspectors**

As the novel coronavirus (COVID-19) crisis has continued to escalate, both the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) have taken additional action to provide industry, the public, and inspectors with guidance concerning food safety and how to respond in the event that food industry personnel test positive for COVID-19. Importantly, FDA <u>does not</u> anticipate that food products would need to be recalled or be withdrawn from the market when a food employee tests positive for COVID-19, because there is currently no evidence to support the transmission of COVID-19 associated with food or food packaging. Similarly, USDA says 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.

This memorandum summarizes key takeaways in the following agency documents and communications:

- FDA's website on *Food Safety and the Coronavirus Disease 2019 (COVID-19)* [1]/;
- FDA's temporary policy on onsite audits under the Food Safety Modernization Act (FSMA) regulations [2]/;
- USDA's COVID-19 Questions & Answers (Q&As) [3]/; and
- USDA communications concerning Food Safety and Inspection Service (FSIS) and Agricultural Marketing Service (AMS) inspectional issues. [4]/

While this memorandum is focused on the guidance from federal agencies, state and local jurisdictions also are starting to issue their own guidance documents, and there are existing

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[1]/   *Food Safety and the Coronavirus Disease 2019 (COVID-19)*, available at https://www.fda.gov/food/food-safety-during-emergencies/food-safety-and-coronavirus-disease-2019-covid-19.

[2]/   *Temporary Policy Regarding Preventive Controls and FSVP Food Supplier Verification Onsite Audit Requirements During the COVID-19 Public Health Emergency: Guidance for Industry* (Mar. 2020), available at https://www.fda.gov/media/136142/download.

[3]/   *Coronavirus Disease (COVID-19)*, available at https://www.usda.gov/coronavirus.

[4]/   Dr. Mindy Brashears & Greg Ibach, USDA, *Statement to Industry* (March 16, 2020), available at https://www.ams.usda.gov/content/statement-industry; Memorandum from Dr. Philip Bronstein, Assistant Administrator, Office of Field Operations, FSIS, *USDA Guidance on COVID-19 Health Questionnaires* (March 13, 2020) (attached).

reporting requirements in some jurisdictions. Food companies will need to take account of federal, state, and local requirements and guidance when addressing this quickly evolving situation.

FDA COVID-19 Response

Yesterday, FDA launched a new website to capture its food-safety-specific advice regarding COVID-19. The website includes Q&As addressing issues such as how facilities should respond if an employee is diagnosed with COVID-19. The agency also released yesterday a guidance document announcing FDA's temporary policy regarding onsite audit requirements under FSMA.

1. FDA's COVID-19 Food Safety Q&As

Consistent with the agency's statements on COVID-19 5/, the agency's new Q&A continues to state: "Currently there is no evidence of food or packaging being associated with transmission of COVID-19." FDA also emphasizes that the primary responsibility of food companies with an infected worker is to take appropriate actions to protect other workers and people who may have come into contact with the ill employee.

FDA advises that if an employee in a food processing facility or farm tests positive for COVID-19, facilities should take the following steps to ensure the foods they produce are safe:
- Inform fellow employees of the possible exposure to COVID-19 in the workplace, while maintaining confidentiality;
- Instruct sick employees to follow the CDC's *What to do if you are sick with coronavirus disease 2019 COVID-19* guidance 6/;
- Re-double cleaning and sanitation efforts to control any risks that might be associated with workers who are ill, regardless of the type of virus or bacteria; 7/ and
- Consult with the local health department for additional guidance, including whether to request other workers who may have been exposed to the worker who tested positive for COVID-19 to self-quarantine for 14 days.

FDA does not anticipate that food products would need to be recalled or be withdrawn from the market because of COVID-19. FDA reaches this conclusion because "there is currently no evidence to support the transmission of COVID-19 associated with food or food packaging."

The guidance also addresses whether a food facility or farm must close after an employee has tested positive for COVID-19. FDA advises that "food facilities need to follow protocols set by local

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5/   *Coronavirus Disease 2019 (COVID-19) Frequently Asked Questions* (Updated February 17, 2020), available at https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19-frequently-asked-questions#food; *FDA Statement: Coronavirus (COVID-19) Supply Chain Update* (February 27, 2020),
available at https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-supplychain-update.

6/   Available at https://www.cdc.gov/coronavirus/2019-ncov/downloads/sick-with-2019-nCoV-fact-sheet.pdf.

7/   The Q&A includes a link to a list of EPA-registered "disinfectant" products for COVID-19 on the Disinfectants for Use Against SARS-CoV-2 list that have qualified under EPA's emerging viral pathogen program for use against SARS-CoV-2 (the coronavirus that causes COVID-19). The list is available at https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2. The EPA website identifies the disinfectants that meet the EPA criteria for use against SARS-CoV-2 and the amount of time the disinfectant must remain on the surface to achieve efficacy. FDA reminds food facilities to check product label guidelines for if and where these disinfectant products are safe and recommended for use in food manufacturing areas or food establishments.

and state health departments, which may vary depending on the amount of community spread of COVID-19 in a given area." FDA says that these decisions will be based on public health risk of person-to-person transmission – not based on food safety.

Other issues addressed in the Q&As include cleaning a facility and equipment to prevent the spread of COVID-19 (e.g., use of EPA-registered sanitizer; more frequent cleaning schedule), how to handle self-service food buffet areas in retail settings, whether there will be food shortages, and measures FDA and the CDC are taking to remain able to address foodborne illness outbreaks during the COVID-19 pandemic. 8/

2. FDA's Temporary Policy Regarding Onsite Audit Requirements

FDA also issued a guidance document announcing its temporary policy not to enforce requirements to conduct on site audits under three FSMA regulations under certain situations related to COVID-19 if other supplier verification methods are used instead.

The guidance affects the onsite audit requirements in the Preventive Controls for Human Food (PCHF), Preventive Control for Animal Food (PCAF), and Foreign Supplier Verification Programs (FSVP) rules. Under these rules, when a hazard in a raw material or other ingredient will be controlled by a supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death (i.e., a SAHCODHA hazard), the appropriate verification activity is an annual onsite audit, unless the receiving facility or FSVP importer issues a written determination that an annual onsite audit is not necessary.

In light of the travel advisories and restrictions that have been put in place in response to COVID-19, FDA will not enforce the requirements to conduct an onsite audit under the PCHF, PCAF, or FSVP regulations under the following circumstances:

- A receiving facility or FSVP importer determines that an onsite audit is the appropriate verification activity for an approved supplier, as reflected by its written food safety plan (FSP) or FSVP;
- The supplier that is due for an onsite audit is in a region or country covered by a government travel restriction or travel advisory related to COVID-19;
- Because of a government travel restriction or travel advisory, it is temporarily impracticable for the receiving facility or FSVP importer to conduct or obtain the onsite audit of the supplier (e.g., a receiving facility or FSVP importer is unable to obtain the services of a qualified auditor in the impacted country or region or travel to the foreign supplier to conduct the onsite audit); and
- The receiving facility or FSVP importer temporarily selects an alternative verification activity or activities, such as sampling and testing food or reviewing relevant food safety records, and modifies its FSP or FSVP to incorporate the alternative activity or activities. The alternative verification activity or activities must be designed, in consideration of the temporary unavailability of supplier onsite audits, to provide sufficient assurance that the hazard requiring a supply-chain-applied preventive control (or, for FSVP, the hazard that is being controlled by the foreign supplier) has been significantly minimized or prevented during the period of onsite audit delay.

8/ In particular, FDA advises that its Coordinated Outbreak Response and Evaluation (CORE) Network's full-time staff will continue to prepare for, coordinate, and carry out response activities to incidents of foodborne illness, and its Center for Veterinary Medicine is similarly prepared to respond to incidents of foodborne illness in animals.

FDA directs that receiving facilities and FSVP importers should resume onsite audits within a reasonable time after it becomes practicable to do so, and should update their FSPs and FSVPs accordingly. FDA states it intends to provide timely notice about the withdrawal of the policy.

USDA COVID-19 Response

USDA's coronavirus response thus far has focused on public-facing Q&As addressing food safety and general industry-facing communications focused on inspector staffing and business continuity.

1. Public Communications About Food Safety

USDA has developed a set of public-facing Q&As on its website, published at https://www.usda.gov/coronavirus, which explain that coronavirus does not appear to create food safety issues. The Q&As emphasize that USDA is "not aware of any reports at this time of human illnesses that suggest COVID-19 can be transmitted by food or food packaging," although they also note that "like other viruses, it is possible that the virus that causes COVID-19 can survive on surfaces or objects." The Q&As also reiterate the importance of following good personal hygiene and food safety practices.

The Q&As further emphasize that both domestically produced and imported food remains safe.

2. FSIS (and AMS) Inspectional Issues

FSIS has provided limited guidance on inspectional issues related to coronavirus. FSIS has advised inspectors not to complete or sign plant questionnaires or to make attestations about their medical conditions. FSIS has explained that privacy laws prevent the agency from requiring its employees to provide this information. Instead, FSIS explains that all FSIS employees have received and are expected to follow USDA guidance on COVID-19 prevention and mitigation procedures, which USDA says are consistent with guidance from the CDC and the Office of Personnel Management. FSIS guidance does not, however, prohibit plants from asking for this information.

More broadly, USDA leadership responsible for FSIS inspection and AMS grading services released a joint "Statement to Industry" addressing at a high level inspection continuity issues. In the statement, USDA recognizes industry concerns about the availability of USDA inspectors and graders and explains that FSIS and AMS "are prepared to utilize their authority and all administrative means and flexibilities to address staffing considerations." USDA also emphasizes the importance of "early and frequent communication" and local considerations.

In all, the USDA statements recognize the important issue of maintaining inspection staffing to support continued meat and poultry production but provide few details. Moreover, FSIS restrictions on inspectors providing health information could complicate companies' ability to implement screening protocols and will likely raise issues requiring resolution at the District Office or Headquarters level. Meat and poultry processors should carefully review their screening processes and continuity plans in light of USDA's policies and should be prepared to raise inspectional issues quickly with FSIS leadership.

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We will continue to monitor FDA and USDA'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.