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EAS Consulting Group Update
FDA COVID-19 Recommendations and Policy Changes:
3/19/20

EAS Consulting Group is providing the following summary gathered from recent information releases and summaries from the US Food and Drug Administration (FDA) regarding their operations during the continuing COVID-19 public health challenge. FDA, as part of their updates, does provide additional references, including questions and answers.

If you would like to discuss whether your food or dietary supplement manufacturing or retail food facility is properly prepared for COVID-19 transmission prevention, please contact:

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- **March 19, 2020**: FDA Commissioner Announcement for Eligible Staff to TeleWork: (see announcement below)
- **March19, 2020:** FDA Stakeholder Conference Call Briefing (see summary below)
- **March 18, 2020:** Coronavirus (COVID-19) Update: FDA Focuses on Safety of Regulated Products While Scaling Back Domestic Inspections - For the health and well-being of our staff and those who conduct inspections for the agency under contract at the state level, and because of industry concerns about visitors, FDA has temporarily postponed all domestic routine surveillance facility inspections. These are facility inspections the FDA traditionally conducts every few years based on a risk analysis. Importantly, all domestic for-cause inspection assignments will be evaluated and will proceed if mission-critical.
- **March 17, 2020:** Coronavirus (COVID-19) Update: FDA Issues Temporary Policy for FSMA Onsite Audit Requirements - The FDA took steps to help prevent disruptions in the food supply-chain by issuing a temporary policy for FDA Food Safety Modernization Act (FSMA) supplier verification onsite audit requirements during the coronavirus (COVID-19) public health emergency. The receiving facility or FSVP importer can identify

alternate activities to the on-site audit, such as sampling and testing or conducting a review of the manufacturer's food safety program and records in order to add these to support the FSVP Importer's documentation responsibilities. The alternative activities to an on-site audit must provide some level of certainty that the import food's hazard requiring a preventive control has been addressed to minimize it to an acceptable level or eliminate it.

- **March 10, 2020:** Coronavirus Disease 2019 (COVID-19) Update: Foreign Inspections - After careful consideration, the FDA postponed most foreign inspections through April, 2020 effective immediately. Inspections outside the U.S. deemed mission-critical will still be considered on a case-by-case basis.

FDA Stakeholder Conference Call Briefing – 3/19/20
Frank Yiannis, Deputy Commissioner for Food Policy and Response; Michael Rogers, Assistant Commissioner for Human & Animal Food (HAF) Operations, FDA ORA; and Dr. Susan Mayne, Director of FDA CFSAN

There has been NO evidence of the transmission of the COVID-19 virus to humans from food or food packaging. FDA is taking measures to protect the health of their staff, food workers and the public. The effectiveness of the ongoing effort by FDA and other government agencies is dependent upon a strong public-private partnership that takes precautions to minimize the spread of the virus. Based on these premises, the following points were made:

1) Starting immediately, "routine" domestic inspections will be postponed and only "mission critical" inspections will be conducted as necessary in cases where there is Class I Recall, a foodborne outbreak, or COVID-19 related situation.

2) Unannounced domestic inspections by FDA will be temporarily halted and announced inspections will temporarily take their place, with case-by-case exceptions. This is being implemented to ensure the safety of both the FDA inspector and the workers and management at the facility to be inspected. This is also intended to take into account the variety of COVID-19 sheltering and other measures implemented by state and local governments.

3) Existing FDA regulations require that food manufacturing facilities and retail food establishments screen all workers to ensure they are healthy and do not carry communicable diseases, foodborne or otherwise (COVID-19). FDA expects these types of facilities to enhance their employee health screening procedures during this public health crisis.

4) Food products do not have to be placed on-hold or recalled if an employee at a food facility is diagnosed with COVID-19. However, it is strongly recommended that other

employees be informed that someone in the facility has tested positive for COVID-19 and extra efforts be made at cleaning and sanitizing all surfaces to remove any potential virus.

5) Frequent hand washing, use of hand sanitizers, practicing social distancing and avoiding touching the face are still the most effective measures in avoiding becoming infected with COVID-19.

6) It is recommended that "self-help" salad bars and buffet-style food offerings in restaurants be temporarily discontinued.

7) Enhanced personal hygiene as well as facility, equipment, and utensil cleaning and sanitization procedures are strongly encouraged to be implemented and maintained during the COVID-19 public health crisis.

8) The FDA will be exercising enforcement discretion regarding the requirements for on-site supplier facility audits needed to comply with the Foreign Supplier Verification Program (FSVP) Rule under the Food Safety Modernization Act (FDA). See the March 17, 2020 Coronavirus (COVID-19) Update: FDA Issues Temporary Policy for FSMA Onsite Audit Requirements for more detailed information.

9) Routine foreign inspections were postponed earlier this month and only "mission critical" inspections will be conducted as deemed necessary. See the March 10, 2020 Coronavirus Disease 2019 (COVID-19) Update: Foreign Inspections for more detailed information.

10) Ensuring a continuous supply of safe food is a critical factor for the US and the FDA and Department of Homeland Security are working together to ensure that is the case. Food facilities involved in this supply, are therefore not subject to the quarantine and shelter in place orders and any issues with this should be addressed to the latter and FEMA. Food workers are deemed to be "essential" and all levels of government are encouraged to recognize this and allow these workers to travel to their workplaces and back home.

FDA FSMA Supplier Verification Onsite Audit Requirements March 17, 2020

Today, the U.S. Food and Drug Administration issued guidance to communicate FDA's intention to temporarily not enforce supplier verification onsite audit requirements for receiving facilities and importers under the FDA Food Safety Modernization Act (FSMA) in response to the global pandemic of COVID-19. FDA does not intend to enforce the onsite audit requirements if other supplier verification methods are used instead.

Three of the regulations created to implement FSMA - the Preventive Controls for Human Food (PC Human Food) rule, Preventive Controls for Animal Food (PC Animal Food) rule, and Foreign Supplier Verification Programs (FSVP) rule– require receiving facilities and importers to conduct supplier verification activities based on the hazard

analysis conducted as part of their written Food Safety Plan or FSVP. These verification activities generally include onsite audits, sampling and testing, or a review of food safety records.

Governments across the globe have instituted travel restrictions and advisories in an effort to curb the spread of the COVID-19 coronavirus. For example, the U.S. government issued a "Level 4 – Do Not Travel" advisory (the highest level) for China and on March 11 the government issued a "Level 3 – Reconsider Travel" advisory for global travel due to the pandemic, and some countries such as Italy instituted restrictions on internal travel. Following these travel advisories and restrictions may impact the ability of receiving facilities and FSVP importers to conduct or obtain onsite audits of their suppliers.

When receiving facilities and importers develop their Food Safety Plans or FSVP they sometimes determine onsite audits to be the most appropriate supplier verification activity. However, the travel restrictions and advisories associated with the novel coronavirus may make some audits temporarily impractical to conduct. Therefore, the guidance released today outlines the circumstances under which FDA does not intend to enforce the requirement to conduct or obtain an onsite audit of a food supplier when the food supplier is in a country or region covered by a government travel restriction or advisory related to COVID-19.

Specifically, FDA does not intend to enforce the requirement for an onsite audit in the following circumstances:

1. A receiving facility or FSVP importer has determined that an onsite audit is the appropriate verification activity for an approved supplier, as reflected by its written food safety plan or FSVP;
2. 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;
3. Because of the 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; and
4. 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 food safety plan or FSVP to incorporate the alternative activity or activities. The alternative verification activity or activities are designed to provide temporary assurance that the hazard requiring a supply-chain-applied 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.

FDA anticipates that receiving facilities and FSVP importers will resume onsite audits within a reasonable period of time after it becomes practicable to do so and update their food safety plans and FSVPs accordingly. FDA intends to provide timely notice before withdrawing this policy.

FDA Commissioner Announcement on Staff Tele-Working from Home March 19, 2020

Protecting the health and safety of our staff and their families is of paramount concern to the U.S. Food and Drug Administration. As a nation we must do everything we can to help slow the spread of the virus and help flatten the curve of the COVID-19 pandemic. Now more than ever, the American people are depending on us. We must ensure our workforce remains healthy to carry out the FDA's critical public health mission to keep Americans safe.

In keeping with the White House Coronavirus Task Force and cross-government guidance, this week we directed all eligible FDA employees to begin teleworking. While this does not apply to those carrying out non-portable activities, such as certain lab activities or the monitoring of imported products, we will continue to adjust our approach to a number of activities, including facility inspections for all FDA-regulated products such as food, animal feed, drugs, biological products, devices and tobacco. Earlier this month, we announced that we are postponing most foreign facility inspections through April and that inspections outside the U.S. deemed mission-critical will be considered on a case-by-case basis as this outbreak continues to unfold.

Today, we're announcing that for the health and well-being of our staff and those who conduct inspections for the agency under contract at the state level, and because of industry concerns about visitors, we have temporarily postponed all domestic routine surveillance facility inspections. These are facility inspections the FDA traditionally conducts every few years based on a risk analysis. Importantly, all domestic for-cause inspection assignments will be evaluated and will proceed if mission-critical. We will continue to respond to natural disasters, outbreaks and other public health emergencies involving FDA-regulated products.

I want to assure the American public that we have full confidence in the safety and quality of the products we all use every day and that the FDA will continue to leverage all available authorities to continue to ensure the integrity of the products we regulate. Importantly, during this interim period we're evaluating additional ways to conduct our inspectional work that would not jeopardize public safety and protecting both the firms and the FDA staff. This can include, among other things, evaluating records in lieu of conducting an onsite inspection on an interim basis when travel is not permissible, when appropriate.

Selected FDA Questions & Answers on COVID-19 Related to FDA Operations:

Q: A worker in my food processing facility/farm has tested positive for COVID-19. What steps do I need to take to ensure that the foods I produce are safe?

Coronaviruses are generally thought to be spread from person-to-person through respiratory droplets. Currently, there is no evidence to support transmission of COVID-19 by food. Unlike foodborne gastrointestinal (GI) viruses like norovirus and hepatitis A that often make people ill through contaminated food, SARS-CoV-2, which causes COVID-19, is a virus that causes respiratory illness. Foodborne exposure to this virus is not known to be a route of transmission.

If an employee is confirmed to have COVID-19, employers should inform fellow employees of their possible exposure to COVID-19 in the workplace but maintain confidentiality. Sick employees should follow the CDC's What to do if you are sick with coronavirus disease 2019 (COVID-19). Employers should consult with the local health department for additional guidance.

While the primary responsibility in this instance is to take appropriate actions to protect other workers and people who might have come in contact with the ill employee, facilities should re-double their 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. For example, facilities are required to maintain clean and sanitized facilities and food contact surfaces.

See: FSMA Final Rule for Preventive Controls for Human Food.

- Food facilities are required to use EPA-registered "sanitizer" products in their cleaning and sanitizing practices.

- In addition, there is 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.
- **IMPORTANT**: Check the product label guidelines for if and where these disinfectant products are safe and recommended for use in food manufacturing areas or food establishments.

Q: Do I need to recall food products produced in the facility during the time that the worker was potentially shedding virus while working?
We do not anticipate that food products would need to be recalled or be withdrawn from the market because of COVID-19, as there is currently no evidence to support the transmission of COVID-19 associated with food or food packaging.
Additionally, facilities are required to control any risks that might be associated with workers who are ill regardless of the type of virus or bacteria. For example, facilities are required to maintain clean and sanitized facilities and food contact surfaces.

Q: If a worker in my food processing facility/farm has tested positive for COVID-19, Should I close the facility? If so, for how long?
Food facilities need to follow protocols set by local and state health departments, which may vary depending on the amount of community spread of COVID-19 in a given area. These decisions will be based on public health risk of person-to-person transmission – not based on food safety.

Q: How do I handle self-service food buffets such as salad bars in a retail setting related to COVID-19?
Restaurants and retail food establishments are regulated at the state and local level. State, local, and tribal regulators use the Food Code published by the FDA to develop or update their own food safety rules. Again, there is no current evidence to support the transmission of COVID-19 associated with food or food packaging. It may be possible that a person can get COVID-19 by touching a surface or object that has the virus on it and then touching their mouth, nose, or possibly eyes, but this is not thought to be the main way the virus spreads. The coronavirus is mostly spread from one person to another through respiratory droplets. However, it's always critical to follow the 4 key steps of food safety—clean, separate, cook, and chill—to prevent foodborne illness.

As an extra precaution to help avoid the transmission of COVID-19 through surface contact, we recommend frequent washing and sanitizing of all food contact surfaces and utensils. Food-service workers also must practice frequent hand washing and glove changes before and after preparing food. Include frequent cleaning and sanitizing of counters and condiment containers. Consumers should wash their hands after using serving utensils. In communities with sustained transmission of COVID-19, state and local health authorities have implemented social-distancing measures which discourage or prohibit dining in congregate settings. We also recommend discontinuing self-service buffets and salad bars until these measures are lifted. Unlike foodborne gastrointestinal (GI) viruses like norovirus and hepatitis A that often make people ill through contaminated food, SARS-CoV-2, which causes COVID-19, is a virus that causes respiratory illness. Foodborne exposure to this virus is not known to be a route of transmission.

Q: What steps do I need to take to clean the facility/equipment to prevent the spread of COVID-19?
FDA-regulated food manufacturers are required to follow Current Good Manufacturing Practices (CGMPs) and many have food safety plans that include a hazards analysis and risk-based preventive controls. CGMPs and food

safety plans have requirements for maintaining clean and sanitized facilities and food contact surfaces. See: FSMA Final Rule for Preventive Controls for Human Food.

- Food facilities are required to use EPA-registered "sanitizer" products in their cleaning and sanitizing practices.
- In addition, there is 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.
- **IMPORTANT**: Check the product label guidelines for if and where these disinfectant products are safe and recommended for use in food manufacturing areas or food establishments.
- We encourage coordination with local health officials for all businesses so that timely and accurate information can guide appropriate responses in each location where their operations reside.
- Food facilities may want to consider a more frequent cleaning schedule.

Q: Do I need to ask other workers who may have been exposed to a worker who tested positive for COVID-19 to self-quarantine for 14 days?
Employers need to follow guidelines set by state and local authorities. If an employee is confirmed to have COVID-19, employers should inform fellow employees of their possible exposure to COVID-19 in the workplace but maintain confidentiality. Sick employees should follow the CDC's What to do if you are sick with coronavirus disease 2019 (COVID-19). Employers should consult with the local health department for additional guidance.

Q: What measures are FDA (and CDC, state partners, etc.) taking to ensure that we remain able to address foodborne illness outbreaks during the COVID-19 pandemic?
Unlike foodborne gastrointestinal (GI) viruses like norovirus and hepatitis A that often make people ill through contaminated food, SARS-CoV-2, which causes COVID-19, is a virus that causes respiratory, not gastrointestinal, illness. Foodborne exposure to this virus is not known to be a route of transmission. With respect to foodborne pathogens, CDC, FDA, and FSIS continue to work with state and local partners to investigate foodborne illness and outbreaks. FDA's Coordinated Outbreak Response and Evaluation (CORE) Network manages outbreak response, as well as surveillance and post-response activities related to incidents involving multiple illnesses linked to FDA-regulated human food products, including dietary supplements, and cosmetic products. During this coronavirus outbreak, CORE's full-time staff will continue to operate to prepare for, coordinate and carry out response activities to incidents of foodborne illness.
FDA's Center for Veterinary medicine manages outbreak response for animal food and is similarly staffed and prepared to respond to incidents of foodborne illness in animals.

CDC, FDA, FSIS and state and local public health partners are maintaining routine public health surveillance for infections and outbreaks that may be transmitted through foods. CDC continues to lead and coordinate investigations of multistate foodborne events, consults with states as needed on events within a single state, and works closely with FDA and FSIS investigators so that contaminated foods are traced back to their sources and controlled.