FDA Responds to AFDO Letter Urging Produce Inspections To Resume; Lays Out Plan

In a letter dated Friday, May 15, AFDO's Executive Director, Steve Mandernach urged the FDA to allow produce inspections to resume under certain conditions. Last Friday, June 5, the FDA responded to the request by outlining current FDA thinking that will allow domestic routine surveillance inspections to resume.

"The FDA is developing a process that would govern how and where to return to domestic on-site facility surveillance inspections. We are using data from HHS, in accordance with the gating criteria outlined in the National Guidelines for Opening Up America Again, and developing a rules-based prediction model, coupled with escalation scenarios." the letter states.

The letter also addressed state considerations when resuming inspections. "We encourage the States to follow the criteria above and we understand the President has asked the Governors to oversee the
OSHA guidance for those activities, then the FDA has no objections to States resuming produce inspections in such manner. The FDA is actively charting a path forward to allow the States to resume work supported by the FDA awarded grants under the Produce Cooperative agreement. The Agency will notify each awardee regarding how they may resume work.

Read the entire response here.

**Best Practices for Conducting Produce Farm Inspections During the COVID-19 Pandemic From AFDO**

While the FDA was evaluating when and how the Stop Work Order for Produce Safety Inspections will be lifted, some states have been proactive and are beginning to develop Standard Operating Procedures (SOPs) that include social distancing and personal safety for the return to work during COVID-19. AFDO has developed Best Practices for Conducting Produce Farm Inspections During the COVID-19 Pandemic using FDA, CDC, and state recommendations to provide information to be used as guidance as states develop SOPs in anticipation of returning to on-farm inspection work. You can download the MS Word document here. Also available as a PDF here.

**FDA COVID-19 Briefing for Produce Industry Stakeholders - Tuesday, June 9, 2020 from 1:30 – 2:30pm ET**

The U.S. Food and Drug Administration (FDA), with our partners from the Centers for Disease Control and Prevention (CDC) and the Occupational Safety and Health Administration (OSHA), will host a stakeholder call on **Tuesday, June 9, 2020** to discuss produce food safety issues, food supply questions, and new relevant guidance related to COVID-19.

Frank Yiannas, Deputy Commissioner, FDA Office of Food Policy and Response; Jennifer Lincoln, Associate Director, CDC/NIOSH Office of Agriculture Safety and Health; and Mark Moorman, Director, Office of Food Safety, FDA Center for Food Safety and Applied Nutrition, will serve as speakers.

Please find details below:

**Date:** Tuesday, June 9, 2020

**Time:** 1:30 – 2:30pm ET (Please call in by 1:25 pm ET)
Additional Information:

Interim Guidance from CDC and the U.S. Department of Labor regarding Agriculture Workers & Employers

Temporary Policy During the COVID-19 Public Health Emergency Regarding the Qualified Exemption from the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Voluntary Reporting of Temporary Closures or Requesting Assistance for FDA-Regulated Food Establishments During COVID-19 Pandemic

USDA, FDA Strengthen U.S. Food Supply Chain Protections

FDA and USDA Release Recommendations for those in the Food and Agriculture Sector Experiencing Shortages of PPE, Cloth Face Coverings, Disinfectants, and Sanitation Supplies

Pandemic Challenges Highlight the Importance of the New Era of Smarter Food Safety

Stephen M. Hahn, M.D., Commissioner of Food and Drugs, and Frank Yiannas, Deputy Commissioner for Food Policy and Response issued an update regarding progress and challenges with the development of the New Era of Smarter Food Safety Blueprint.

In March, we were a few days away from announcing the release of the New Era of Smarter Food Safety Blueprint when the FDA's focus turned to the COVID-19 pandemic. Our plans for the New Era
The FDA will release the blueprint in the coming weeks, outlining our plans over the next decade to create a more digital, traceable, and safer food system. The challenges that have arisen during the pandemic have made it clear that the actions called for in the blueprint will strengthen how we approach the safety and security of the food supply, not just in the normal course of events but especially in times of crisis.

In fact, over the past few months we have revised the blueprint in light of the lessons learned during the pandemic. It is clear that COVID-19 has accelerated the need for these measures. Some element of the blueprint are particularly meaningful now, and we’d like to touch on these, starting with tech-enabled traceability.

Read the entire update here.

**FDA Extends Comment Period for Third Installment of the Draft Guidance for the Intentional Adulteration Rule**

The U.S. Food and Drug Administration is extending the comment period for the third installment of the draft guidance designed to support compliance with the Mitigation Strategies to Protect Food Against Intentional Adulteration (IA) rule under the FDA Food Safety Modernization Act (FSMA).

The Agency released the third installment of the draft guidance in February 2020. Since that time, FDA has received a request for extension to allow stakeholders sufficient time to provide comprehensive feedback. The comment period will be extended until August 14, 2020.

This last installment of the IA rule draft guidance adds to the previously published revised draft guidance. Chapters in the last installment cover topics focusing on food defense corrective actions, food defense verification, reanalysis of food defense plans, and recordkeeping; it also includes appendices on FDA’s online Mitigation Strategies Database and how a business can determine if it is a small or very small business under the rule.

Comments can be submitted electronically via Regulations.gov to docket FDA-2018-D-1398

**For More Information**

- Draft Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration
- Supplemental Draft Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration
- Food Defense Plan Builder (Version 2.0)

Food Safety Preventive Controls Alliance (FSPCA) Training Materials and Courses

**AFDO Announces Virtual Annual Education Conference**
COVID-19 may have canceled the in person meeting of the AFDO Annual Education Conference but you won't to miss the virtual meeting of the Association the afternoon of Monday, June 29, 2020. Mark you calendar now and watch your inbox for details next week. Speakers will include leadership from the FDA Office of Regulatory Affairs. We hope you will save the date and join us.

Call for AFDO Committee Charges for 2020/2021

AFDO is looking for recommendations for 2020/2021 committee charges. If you have any suggestions, please submit your recommendations by Friday, June 12, 2020.
Governments around the globe are observing the second annual World Food Safety Day on this Sunday, June 7 to promote collective and individual actions to ensure a safe food supply. To mark the occasion, The Pew Charitable Trusts spoke with three veteran public health officials who have encouraged the use of root cause analysis (RCA) to improve food safety. Included is AFDO's Executive Director Steven Mandernach. Read more here....

FSIS Posts After-Action Review Report for Foodborne Listeria Monocytogenes Outbreak

FSIS has posted on its website an after-action review report for the investigation of a 2017–2018 outbreak of Listeria monocytogenes illnesses associated with ready-to-eat, country-cured ham. During April–November 2018, public health officials from Virginia, North Carolina, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and FSIS investigated an outbreak of four reported L. monocytogenes illnesses linked to ready-to-eat country-cured ham manufactured at an FSIS-regulated establishment.

This was the first reported multistate outbreak of listeriosis associated with an FSIS-regulated product since 2005. Whole genome sequencing (WGS) was instrumental in detecting this outbreak and determining its source. The investigation revealed that production practices may have led to cross-contamination and that the cooking of the product may have been insufficient to address L. monocytogenes.

In response to this outbreak, FSIS plans to update Directive 10,240.4, Verification Activities for the
Listeria monocytogenes Regulation and the Ready-to-Eat (RTE) Sampling Program. Additionally, FSIS added a related study to its Food Safety Research Priorities on the FSIS website and plans to update its “Appendix A” cooking guidance in 2020.


The purpose of FSIS after-action review reports is to share lessons learned with industry and public health partners from outbreak investigations to help prevent illness and improve response. To view additional reports and learn more about outcomes of FSIS outbreak investigations, please visit https://www.fsis.usda.gov/OutbreakOutcomes.

IAFP Explores Food Safety Culture in Series of Webinars With Expert Panels

Anyone interested in the culture of food safety is invited to attend a series of free webinars with panels of international presenters and organized by the International Association for Food Protection.

The non-profit group has thousands of members worldwide, including government leaders and employees, academics, industry representatives and others interested in food safety.

The free webinar sessions are free and open to the public, but registration is required.

The series begins May 26 and wraps up on July 22. Check out all of the webinars in the series

AFDOSS Mary Logan Scholarship
The AFDOSS Board regrets to announce the cancellation of the 2020 Fall Conference scheduled for September in Gatlinburg. Some of the affiliate's annual activities will continue as planned (see below about the Mary Logan scholarship), while others will be on hold until next year. Please mark your calendars now for the AFDOSS AEC 2021 in Asheville, North Carolina (Sept. 12-15, 2021; the Crowne Plaza in Asheville is booked!), and there is a contract to return to the Park Vista Doubletree in Gatlinburg in Sept. 2022.

As of this month, AFDOSS has opened the 2020-2021 Mary Logan Scholarship Application process, with applications accepted through July 15. Once the Scholarship Committee has reviewed applications and determined if there is an appropriate candidate to select, the $4,500 annual scholarship award will be awarded for the 2020-2021 school year. More details can be found here, and the new online scholarship application is available here: https://forms.gle/hw5PtC8AmwSJQ6M59 (please share with potential applicants you know in the SE region!).

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**How OSHA thinks of the Body Art Industry**

Ensuring a safe and healthy working condition for workers by establishing and enforcing regulations and the importance of providing training, consistence and education.

*Registration is limited to 1,000 seats

If you are having trouble connecting to GotoWebinar, please contact abonsell@afdo.org

**Date: Wednesday, June 10, 2020**
**Time: 2:00PM - 3:00PM ET**
**Who: Cathy Montie, OSHA Body Art Trainer**

Register Now
The Food and Drug Administration’s (FDA) Food and Cosmetic Information Center (FCIC)/Technical Assistance Network (TAN) continue to released responses for questions of interest to AFDO members regarding COVID-19. These answers can be found here.

It's important to check back frequently for the latest as well as visit the AFDO COVID-19 Resource Page.

This is in addition to updating its COVID-19 Frequently Asked Questions page to include guidance regarding food products. Real time updates of the FDA's Food Safety and the Coronavirus Disease 2019 (COVID-19) page can be found at https://www.fda.gov/food/food-safety-during-emergencies/food-safety-and-coronavirus-disease-2019-covid-19. Updates are dated so you are able to tell what information has been added each time.

As part of the AFDO commitment to providing information and resources to members and the those we serve, we continue to add resources to the COVID-19 Resource Page. We continue to offer links to information that has been developed by our partnerships and other subject matter experts. If you identify resources that should be considered or your organization develops some of your own that can be shared with other members, please email them or the link to bbenschoter@afdo.org. We appreciate everyone who helps us be more prepared.
Today, the U.S. Food and Drug Administration published the findings of an investigation into the contamination of romaine lettuce implicated in three outbreaks of E. coli O157:H7 during the Fall of 2019.

Late last year the FDA, the Centers for Disease Control and Prevention and state partners investigated the contamination of romaine lettuce with several strains of E. coli O157:H7 that resulted in three outbreaks of foodborne illness traced back to the Salinas Valley growing region in California. These outbreaks -- two multi-state and one single-state beginning in September and ending in December 2019 -- collectively resulted in 188 people falling ill.

Please see below for further information,

Constituent Update,
Statement,
Investigation Report,

The investigation was conducted at several farms identified in the outbreak traceback, as well as at other businesses and public access areas and resulted in several key findings:

1. Each of these three outbreaks, identified in the report as Outbreaks A, B and C was caused by distinctly different strains of E. coli O157:H7 as determined by whole genome sequencing (WGS) analysis;
2. Traceback investigations of multiple illness sub-clusters and supply chain information identified a common grower with multiple ranches/fields which supplied romaine lettuce during the timeframe of interest to multiple business entities associated with all three outbreaks.
3. The same strain of E. coli O157:H7 that caused Outbreak A was found in two different brands of fresh-cut salads containing romaine lettuce in 2019;
4. This same outbreak strain of E. coli O157:H7 in Outbreak A was detected in a fecal--soil composite sample taken from a cattle grate on public land less than two miles upslope from a produce farm with multiple fields tied to the outbreaks by the traceback investigations;
5. Other strains of Shiga toxin-producing E.coli (STEC), while not linked to any of the outbreaks, were found in closer proximity to where romaine lettuce crops were grown, including two samples from a border area of a farm immediately next to cattle grazing land in the hills above leafy greens fields and two samples from on-farm water drainage basins.

The FDA considers adjacent or nearby land use for cattle grazing as the most likely contributing factor associated with these three outbreaks. While the agency could not confirm a definitive source or route(s) of contamination of the romaine fields, the agency considers indirect transmission of fecal material from adjacent and nearby lands from water run-off, wind, animals or vehicles to the romaine fields, or to the agricultural water sources used to grow the romaine, as possible routes of contamination.

These findings, together with the findings from earlier leafy greens outbreaks, suggest that a potential contributing factor has been the proximity of cattle—a persistent source of E. coli O157:H7 and other STEC—to the produce fields identified in traceback investigations. These key findings reinforce our concern about the possible impacts of nearby and adjacent land use on the safety of leafy green crops and further underscore the importance of implementing appropriate risk-based preventive measures to reduce the potential for contamination of leafy greens.
Because of the reoccurring nature of outbreaks associated with leafy greens, the FDA recently released a **2020 Leafy Greens STEC Action Plan**, which outlines a three-pronged approach for tackling this problem. It describes the FDA’s plans for working with industry, federal partners, state and local regulators, academia and others to address the safety of leafy greens by advancing work in three areas: prevention, response, and addressing knowledge gaps.

Food safety is a shared responsibility that involves food producers, distributors, manufacturers, retailers, and regulators. FDA is committed to working with these stakeholders to implement this action plan to ensure that America’s food supply remains among the safest in the world.

**For More Information**

- Factors Potentially Contributing to the Contamination of Romaine Lettuce Implicated in the Three Outbreaks of *E. coli* O157:H7 During the Fall of 2019
- 2020 Leafy Greens STEC Action Plan
- FDA Outlines 2020 Action Plan to Help Advance the Safety of Leafy Greens
- Outbreak Investigation of *E.coli*: Romaine from Salinas, California (November 2019)
- Outbreak Investigation of *E.coli*: Salad Mix (December 2019)

**Other Training Opportunities**

**Preventive Controls for Human Foods and Foreign Supplier Verification Programs**

Intentional Adulteration Conducting Vulnerability Assessments (IAVA) – 1 Day
Course Information/Schedule Page

Preventive Controls for Human Foods Course (PCQI) – 3 Day
Course Information/Schedule Page

Preventive Controls for Human Foods Course (PCQI) Blended Course Part 2 – NEW
Course Information/Schedule Page

Foreign Supplier Verification Programs Course (FSVP) – 2 Day
Course Information/Schedule Page
EAS Consulting Group Training

EAS Consulting Group Offers Complimentary Webinar Best Practices for Food Manufacturers, Restaurants and Food Distributors During the COVID-19 Pandemic – Conducted in Spanish

Top Advances in Food Safety Technology
June 4, 2020 at 2:00PM

Virtual Book Tour
Food Safety Lessons for Cannabis-Infused Edibles
May 27, 2020 at 1pm eastern

Dietary Supplement Good Manufacturing Practices (GMP) Compliance Seminar
September 29-30, 2020 • Dallas, TX

The Food Safety Doctor LLC
Promoting Public Health and Food Safety through Training and FSMA Awareness

While sheltering in place, The Food Safety Doctor LLC is offering

- ONLINE Preventive Controls for Human Foods (PCQI) Courses
  - July 21 - 23
  - Click here to access the schedule of online PCQI Courses
ONLINE Foreign Supplier Verification Courses (FSVP-QI) Courses
- June 23 - 24
- August 11 - 12
- Click here to access the schedule of online FSVP-QI courses

Laws and Regulations Committee Updates

Laws and Regulations Committee Update
A collection of current food, drug, device, and consumer product regulatory issues and news

June 1 - 2, 2020
June 3 - 4, 2020
June 5, 2020