

COVID-19's Impact on the Food Chain

What We Know and What We Can Expect

Ashley W. Craig, International Trade

Partner | 202.344.4351 | awcraig@Venable.com

Todd H. Halpern, Food and Drug Law

Partner | 202.344.4152 | thhalpern@Venable.com

Claudia A. Lewis, Food and Drug Law

Partner | 202.344.4359 | calewis@Venable.com

VENABLE LLP

CLE Credit

This activity has been approved for Minimum Continuing Legal Education credit by the State Bar of California in the amount of one hour, of which one hour applies to the general credit requirement, and by the State Bar of New York in the amount of one credit hour, of which one credit hour can be applied toward the Areas of Professional Practice requirement. Venable certifies that this activity conforms to the standards for approved education activities prescribed by the rules and regulations of the State Bar of California and State Bar of New York, which govern minimum continuing legal education. Venable is a State Bar of California and State Bar of New York approved MCLE provider.

A code will be distributed through the Q&A chat section at the end of the program, and a CLE submission form will be sent to participants next week via email.

- *This presentation is intended as a summary of the issues presented and is not intended to provide legal advice. It is provided for the general information of the attendees. Legal counsel and advice should be sought for any specific questions and before taking any action in reliance on the information presented.*

Introduction

- FDA Assessment of the Food Supply Chain
- Planning for “Shelter-in-Place”
- Implications of Travel Restrictions
 - FDA Inspections
 - Supplier Audits
- FDA at the Ports
- Recommendations
- Resources
- COVID-19 Related Disruptions to the Food Supply Chain and Government Response



FDA Assessment of the Food Supply Chain

VENABLE_{LLP}

The Food Supply Is Safe and Secure

- No evidence of coronavirus transmission on food or food packaging
- High-touch surfaces present some risk, but transmission is primarily by close personal contact
 - Outsides of food containers at grocery store are not considered high-touch surfaces
- No evidence of transmission on imported foods or other goods
- No reported cases of COVID-19 in the U.S. associated with imported goods

The Food Supply Is Safe and Secure

- No signs of current or potential disruption
- FDA Actions to Enhance Security:
 - Priority on protecting the health of workers on farms, in food establishments, and at FDA
 - Public-private partnerships and partnering with government agencies at all levels to ensure food production operations continue – Prevent disruption by, for example:
 - Transportation Problems
 - Shelter-in-Place Orders

FDA: Message to Food Industry

- Continue to follow GMPs and safe food handling procedures
- Employee illness / positive test for COVID-19:
 - Follow CDC, OSHA, and other applicable guidelines if an employee becomes sick or is diagnosed with COVID-19
 - NOT a basis for suspending operations or conducting recall
 - NOT a deviation that triggers investigation



Planning for “Shelter-in-Place”

Planning for Shelter-in-Place

- Food and Agriculture Identified by Department of Homeland Security as “Critical Infrastructure Sector”
 - DHS Guidance identifies 13 categories of Essential Critical Infrastructure Workers that broadly encompass all those who support food production
- Requires careful assessment of the scope of each state’s order
 - Dietary supplements?
 - Which workers?
- Primary Critical Dependencies with Water and Wastewater Systems, Transportation, Energy, and Chemical Sectors (FDA is monitoring these sectors to ensure food supply security)
- Shelter-in-place orders should not prevent food production workers from going to
- FEMA’s National Business Emergency Center (NBEC) can help businesses respond to any potential issues



Implications of Travel Restrictions

FDA Compliance Activities

- FDA is suspending most foreign inspections through at least April 2020
 - Mission-critical inspections (decided on case-by-case basis) will continue
- Temporary enforcement policy for Foreign Supplier Verification Program (FSVP):
 - FDA to conduct remote inspections – electronic submission of documents for review
- China
 - Approx. 60% of imports from China are medical devices
 - Approx. 20% of imports from China are housewares (*e.g.*, food packaging)
 - *****All of these measures apply equally to China**
 - Higher volume of imports from China may be more mission-critical inspections

FSVP – Scheduled On-site Audits

- TEMPORARY FDA ENFORCEMENT POLICY
 - Because of travel restrictions, FDA is allowing alternative ways to comply if scheduled for on-site audits

FSVP – Scheduled On-site Audits

- FDA will not enforce FSVP on-site audit requirements under four conditions:
 - Company made determination that on-site audit was appropriate activity, and notes it in food safety plan/FSVP
 - Company scheduled for on-site audit in area with travel restrictions
 - On-site audit is impracticable due to travel restrictions
 - Company selects alternative verification activity as temporary substitute and modifies food safety plan/FSVP accordingly
- Alternative verification activities may include
 - Sampling of food products
 - Remotely reviewing food safety records of suppliers



FDA at the Ports

VENABLE_{LLP}

FDA Enforcement at the Ports

- No change to import procedures
- FDA actively using same enforcement tools currently available:
 - Import screening, examinations, and sampling
 - Import alerts
 - Looking to a firm's compliance history and information from foreign governments
- FDA focus at ports likely to increase during suspension of routine foreign inspections
- Shipment release times at ports may be impacted
- **Be careful to follow all administrative/paperwork requirements to avoid delays**

FDA Enforcement at the Ports

- Continue to use PREDICT to flag higher-risk import shipments
 - Based on confidential algorithm, which could be adjusted to account for any issues of heightened concern during pandemic (this would not be made public)
- Particularly on the lookout for port shopping
 - FDA's existing protocols will be used
 - If you choose a different port than usual, have justification readily available for review in case it is flagged by FDA
- Closely monitoring International Mail Facilities
 - FDA remaining vigilant in this area
 - **Ensure the contents of packages are accurately declared**



Recommendations

Recommendations

- Follow protocols set by local and state health departments
- Follow CDC Guidance
- If someone becomes infected:
 - Inform all other employees that someone has been infected
 - Maintain confidentiality of infected employee
- If onsite audit planned for FSVP, modify to (temporarily) include alternative verification activity(ies):
 - Sampling and testing
 - Review records
- Prepare Consumer Communication Plan:
 - Reference government resources
 - Ensure accuracy of information



Resources



Industry and Consumer Assistance from CFSAN

Get help with Food, Dietary Supplements, and Cosmetics questions.

[Share](#) [Tweet](#) [LinkedIn](#) [Email](#) [Print](#)

Coronavirus Disease 2019 (COVID-19)

Those who have **symptoms** should contact their health care provider to report their symptoms and receive care. For additional information, see CDC's [What to do if you are sick with coronavirus disease 2019 \(COVID-19\)](#).

If you are experiencing issues regarding your **supply chain, delivery of goods, or business continuity**, please contact the FEMA National Business Emergency Operations Center at NBEOC@fema.dhs.gov. This is a 24/7 operation and they can assist in directing your inquiry to the proper contact.

The Center for Food Safety and Applied Nutrition is prioritizing answering COVID-19 related questions. Please read the [Frequently Asked Questions](#) before you submit your question [↗](#).

The Center for Food Safety and Applied Nutrition, known as CFSAN, provides services to consumers, domestic and foreign industry and other outside groups regarding field programs; agency administrative tasks; scientific analysis and support; and policy, planning and handling of critical issues related to food, dietary supplements, and cosmetics.

[Report a Complaint](#)

[Submit an Inquiry](#) [↗](#)

[Follow Us \(Twitter\)](#) [↗](#)

[Get Email Updates](#)

To reach us by telephone:

1-888-SAFEFOOD (1-888-723-3366)
10:00 AM - 4:00 PM EST
Closed Thursdays 12:30 PM – 1:30 PM EST

To write us by mail:

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Outreach and Information Center
5001 Campus Drive, HFS-009
College Park, MD 20740-3835

Note: Please do not mail products to this address.

Contacting Us About FSMA

The FDA Food Safety Modernization Act (FSMA), the most sweeping reform of our food safety laws in more than 70 years, was signed into law by President Obama on January 4, 2011.

It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it.

[Learn about How to Contact FDA About FSMA.](#)



<https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/businesses-employers.html>

Coronavirus Disease 2019 (COVID-19)

CDC > Coronavirus Disease 2019 (COVID-19) > Schools, Workplaces & Community Locations



Coronavirus Disease 2019 (COVID-19)

- How to Prepare +
- Symptoms & Testing +
- Are You at Higher Risk for Severe Illness? +
- If You Are Sick or Caring for Someone +
- Frequently Asked Questions
- Travel +
- Cases & Latest Updates +
- Schools, Workplaces & Community Locations** +
- Healthcare Professionals +
- Healthcare Facilities +
- Health Departments +
- Laboratories +
- Communication Resources +

Resources for Businesses and Employers

Plan, prepare, and respond to coronavirus disease 2019



Interim Guidance for Businesses and Employers



Cleaning and Disinfection Recommendations

OSHA/HHS Guidance

- [Guidance on Preparing Workplaces for COVID-19](#)



COVID-19-Related Disruptions to the Food Supply Chain and Government Response

Non-Performance and Force Majeure

- Major transportation and logistics providers struggling to meet contractual obligations in light of disruptions caused by the COVID-19 pandemic
- Some major providers have invoked force majeure already; others are expected to follow
 - *E.g.*, DHL declaration on March 19th

Border Closures by CBP

- The northern and southern U.S. borders closed to non-essential traffic, as of March 21
- “Lawful cross-border trade” not intended to be affected
- A U.S. suspension on travel from some EU countries is in effect, but (despite some confusing indications from President Trump during an initial press briefing) this currently does not include commercial trade from EU

State “Stay At Home” Orders and Restrictions

- Trump administration has rejected reports of any planned nationwide closure or curfew
 - If anything, the administration is considering relaxing CDC guidelines encouraging businesses to institute flexible work-from-home policies
 - Trump tweet on Sunday evening
- Rapidly evolving situation, on a state-by-state basis, with multiple states imposing state-at-home orders
 - CA Executive Order (N-33-20)
 - NY Executive Order (No. 202.6)
 - IL Executive Order (No. 8)
 - NJ Executive Order (No. 107)
 - OH Department of Public Health (Director’s Stay at Home Order)

Recent Federal Guidance on “Critical Infrastructure”

- On March 19th, Department of Homeland Security (DHS), Cybersecurity and Infrastructure Security Agency (CISA), issued guidance to states and localities about who should be considered “critical infrastructure workers”
- “Food and Agriculture” is one of the primary categories on the initial list
 - 14 subcategories identified, such as “food manufacturer employees”
 - Other primary categories include Healthcare/Public Health, Law Enforcement, Energy, Transportation & Logistics, Public Works, and Chemicals, among others
- Intended “to be overly inclusive reflecting the diversity of industries across the United States”
- Advisory guidance, not binding on states or localities
 - Guidance will continue to evolve
 - States will likely refine the scope of the federal guidance – potentially narrowing the list overall but adding some additional businesses/sectors

Product Exclusions on China Imports Subject to Tariffs

- As of March 18th, Trump administration is rejecting calls for broad tariff relief or tariff exclusions in response to COVID-19 pandemic
- Nevertheless, as indicated by the recent exclusions, there may be limited tariff relief for much-needed medical equipment, pharmaceuticals, and supplies.
 - Food products are not currently expected to be part of this
- On March 25th, USTR is expected to announced that it will begin taking requests, on a rolling basis, for removal of China tariffs on “medical-care products” that will help combat the COVID-19 pandemic
 - This includes medical products on any of the four lists/tranches (Lists 1–4)
- In addition, on March 17th, USTR announced another round of exclusions for goods subject to List 4 (7.5% additional tariffs). Many of the exclusions are focused on medical devices and equipment
- USTR also announced that, as of March 25th, it is extending certain exclusions another 12 months, for certain goods subject to List 1 (25% additional tariffs)
 - This included, among other things, certain breast pumps, water filtering equipment, and UV water purifiers

Near-Term Recommendations

- Situation is and will remain highly fluid – keep a close watch on international, federal, state and local developments
 - U.S. and trading partners’ continued attempts to restrict the spread
 - Border closings, trade restrictions, new rules, *etc.*
 - “Shelter-in-Place” announcements
 - Curfews – what they may mean for “Critical Infrastructure” and “Essential Business Services”
- Review business agreements with service providers – determine whether you consider force majeure or be prepared (as much as possible) if others invoke
- Reach-out to government contacts to remain up-to-date
- Consider stakeholder associations that can help with information flow
- Confer with counsel regarding developments, impact, and assessments
- Remain safe – practice social distancing, follow government announcements

Upcoming Webinars

- **Cybersecurity Considerations for Telework, March 23, 2020**

The novel coronavirus has forced industry, government, and academia to quickly adapt to teleworking and teleconferencing situations, and in their haste to implement changes, many employers may not consider the privacy and cybersecurity implications of their telework policies. Join the Cybersecurity Coalition and NIST for a webinar on "Cybersecurity Considerations for Telework."

- **Contract Performance and Frustration in Coronavirus's New Normal — Performing the Impossible and Impractical in Key Jurisdictions, March 24, 2020**

Join us as we discuss force majeure, impracticability, and impossibility doctrines under state law as they relate to the coronavirus and performance of contracts in the current environment.

- **Consumer Financial Services Legal and Regulatory Update: COVID-19, March 25, 2020**

Join members of Venable's Consumer Financial Services Practice Group as they address the latest on the evolving legal and regulatory landscape, and ways to manage key compliance risks, related to the fallout from the COVID-19 pandemic.

COVID-19 Resources

www.venable.com/covid-19

Questions?



Ashley Craig
202.344.4351
awcraig@Venable.com



Todd Halpern
202.344.4152
thhalpern.@Venable.com



Claudia Lewis
202.344.4359
calewis@Venable.com



© 2020 Venable LLP.

This document is published by the law firm Venable LLP. It is not intended to provide legal advice or opinion. Such advice may only be given when related to specific fact situations that Venable has accepted an engagement as counsel to address.

VENABLE LLP