



SPOTLIGHT

What the FDA Requires for Food Safety During the COVID-19 Pandemic

By Shook Of Counsel [John Johnson](#)

The U.S. Food and Drug Administration’s (FDA) regulatory requirements for food companies, including manufacturers and importers, remain largely unchanged during the COVID-19 outbreak. However, COVID-19 is disrupting plant operations and supply-chains, which companies must be mindful of as they continue to function within the regulatory requirements:

- Food safety remains FDA’s top priority. The agency is continuing to work with companies to implement food recalls, and FDA will conduct mission critical, for-cause inspections when necessary.
- Monitor email inboxes for a message from an FDA investigator indicating that the agency is requesting records to conduct a remote inspection. FDA has indicated that these remote inspections will start for food importers to determine their compliance with the Foreign Supplier Verification Program (FSVP).
- Current Good Manufacturing Practices (cGMPs), Food Safety Plans, Hazard Analysis Critical Control Points (HACCP) Plans and FSVP must continue to be implemented. In doing so, companies must remember to:
 - Continue implementing their personnel hygiene and plant sanitation procedures, which may need to be modified or made more frequent. Because COVID-19 does not appear transmitted by food or food packaging, FDA does not have specific guidance on controlling for COVID-19 but instead refers companies to other resources: Centers for Disease Control and Prevention (CDC), Occupational Safety and Health Administration (OSHA) and Food and Beverage Issues Alliance.

SHARE WITH [TWITTER](#) | [LINKEDIN](#)

SUBSCRIBE

PDF ARCHIVES

Shook offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

For additional information about Shook’s capabilities, please contact



Mark Anstoetter
816.559.2497
manstoetter@shb.com

- Conduct a hazard analysis for changes made and, if necessary, conduct validation and verification and amend the applicable plan and supporting records. Document appropriately throughout these processes.
- Recognize FDA’s policy acknowledging that an onsite audit of an ingredient supplier or a foreign supplier is not possible or advisable during the COVID-19 outbreak so a company may select an alternative verification activity during the crisis. If selected, a company must document its reliance on this policy and then follow the regulations for conducting the selected verification activity.

- When selecting an alternative or temporary supplier, a company must remember to either approve the supplier according to its normal procedures or follow its program for using an unapproved supplier.
- When conducting a hazard analysis for an alternative or temporary supplier for a food or alternative ingredients, thoroughly inspect the formulation (including sub-ingredients) against the regulations, product labels and product specification sheets. Never assume the alternative food is identical to the previous one; the alternative may contain a different ingredient that affects the food’s compliance. A company must look out for:
 - Major Food Allergens or ingredients derived from them; the Major Food Allergens are milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat and soybeans.
 - Other allergens or sensitivity ingredients, such as sulfites, Yellow No. 5 and carmine/cochineal extract.
 - Non-permitted ingredients, such as cyclamates and unapproved colorants (e.g., Ponceau 4R, Green S or lutein).

The need for safe food is a constant and is arguably even more important during the COVID-19 outbreak. It is imperative for a company to vigilantly implement the requirements to seek to avoid the need for a food recall and possibly FDA compliance activities.



LEGISLATION, REGULATIONS & STANDARDS

WHO, Governments Issue Advice on Food Safety During COVID-19 Pandemic

The World Health Organization (WHO) has issued “[COVID-19 and food safety: guidance for food businesses](#),” which provides information on the risks of transmission of COVID-19 in the food and beverage industry. “It is highly unlikely that people can contract COVID-19 from food or food packaging,” the guidance states. “Coronaviruses cannot multiply in food; they need an



M. Katie Gates Calderon
816.559.2419
kgcalderon@shb.com



Lindsey Heinz
816.559.2681
lheinze@shb.com



James P. Muehlberger
816.559.2372
jmuehlberger@shb.com

ABOUT SHOOK

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

Shook attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility

animal or human host to multiply.” Instead, it urges industry to “reinforce personal hygiene measures and provide refresher training on food hygiene principles to eliminate or reduce the risk of food surfaces and food packaging materials becoming contaminated with the virus from food workers.” The guidance provides specifics on hygiene standards, such as open food displays and the use of disposable gloves.

The U.S. Food and Drug Administration has also provided several resources for food and beverage companies, including a list of [frequently asked questions](#). The website features regularly updated questions on a number of issues, such as food-supply problems and shortages on hand sanitizer and related products. The European Commission issued a similar [resource](#) with questions and answers.

inspections, subject to FDA, USDA and FTC regulation.



FDA Warns CBD Sellers for COVID-19 Claims

The U.S. Food and Drug Administration has urged several sellers of products with cannabidiol (CBD) to stop marketing their products as able to treat or prevent COVID-19. The letters, sent by the Center for Drug Evaluation and Research (CDER), emphasize that “FDA is taking urgent measures to protect consumers from certain products that, without approval or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people.” The targeted CBD Sellers—including [Indigo Naturals](#), [Native Roots Hemp](#), [CBD Online Store](#) and [Nova Botanix LTD](#)—market their products with claims ranging from “boosting the immune system” to providing stress relief “when everyone else is panicking.” The letters urge the companies to respond within 48 hours to a CDER COVID-19 Task Force email address.

California to Provide Food Industry Employees with Paid Sick Leave

California Governor Gavin Newsom has [announced](#) that the state will provide workers in the food sector—including farmworkers and employees at grocery stores and fast food restaurants—with two weeks of paid sick leave. The order aims to “fill[] a gap left by federal relief that had provided similar paid leave benefits for employers with fewer than 500 workers,” according to the announcement. The Executive Order also “provides health and safety standards to increase worker and customer protection by permitting workers at food facilities to wash their hands every 30 minutes, or as needed, to increase proper sanitation measures.”

LITIGATION

Second Circuit Affirms “Angus Beef” Challenge Dismissal

The U.S. Court of Appeals for the Second Circuit has affirmed a lower court’s dismissal of a putative class action alleging Dunkin’ Brands Inc. misled consumers about the cuts of meat in its “Angus” line of products. *Chen v. Dunkin’ Brands Inc.*, No. 18-3087 (2nd Cir., entered March 31, 2020). The plaintiffs argued that Dunkin marketed its products as containing “Angus Steak” despite containing ground beef patties rather than “an ‘intact’ piece of meat.” The appeals court first affirmed the dismissal of several plaintiffs on jurisdictional grounds before considering the merits of the argument.

The complaint “identified three Dunkin Donuts television advertisements, providing descriptions along with video links, and alleged that the advertisements were deceptive in their use of the word ‘steak,’” the court noted. “All three advertisements, however, conclude with multiple zoomed-in images that clearly depict the ‘steak’ in the Products as a beef patty.” The court turned to Merriam-Webster to determine that “while the word ‘steak’ can refer to ‘a slice of meat,’ it is also defined as ‘ground beef prepared for cooking or for serving in the manner of steak” and noted that chopped steak, hamburger steak and Salisbury steak are examples of the latter definition.

“[I]t is true that literally accurate statements can still be misleading,” the court noted, but “context is crucial.” Dunkin’s Angus products “are marketed as grab-and-go products that can be consumed in hand, without the need for a fork and knife,” the court concluded. “A reasonable consumer purchasing one of the Products from Dunkin Donuts in that context would not be misled into thinking she was purchasing an ‘unadulterated piece of meat.’”

Marijuana Dispensaries Challenge Executive Order Closing Recreational-Use Stores

Several dispensaries of recreational marijuana in Massachusetts have filed a lawsuit alleging that Governor Charlie Baker exceeded his authority by classifying recreational-use marijuana retail

establishments as non-essential while declaring medical-marijuana dispensaries and liquor stores as essential during a statewide shutdown to combat the spread of COVID-19.

CommCan Inc. v. Baker, No. 2084CV00808 (Mass. Super. Ct., filed April 8, 2020). The complaint asserts that Massachusetts “seems to be the only state that has deemed medical marijuana essential but adult-use/recreational marijuana non-essential” and argues that California, Colorado, Illinois, Nevada and Washington classified both types of establishment as essential.

The plaintiffs also include a Nantucket recreational-use dispensary and a war veteran who obtains marijuana from the dispensary for medical purposes because the nearest medical dispensary is more than an hour away. The court has reportedly denied an initial request for a preliminary injunction on the executive order.

Humane Society Challenges USDA Pandemic Standards for Bird Flu Mitigation

The Humane Society of the United States (HSUS) has filed a lawsuit arguing that a 2015 assessment issued by the U.S. Department of Agriculture (USDA) “ignores the most logical alternative” in determining the national approach to combating avian influenza in poultry-production facilities. *Humane Society of U.S. v. USDA*, No. 20-3258 (C.D. Cal., W. Div., filed April 8, 2020). HSUS argues that USDA failed to adequately detail alternatives to its approach to a bird flu pandemic and instead chose as the “preferred alternative” a practice that includes shutting down a facility’s ventilation system, allegedly resulting in the birds inside suffocating and “essentially cook[ing] the conscious birds to a protracted, and unnecessarily torturous death.” HSUS seeks a declaration that USDA’s action was arbitrary and capricious and an abuse of discretion.

Farmworker Labor Unions Sue Washington for Inadequate COVID-19 Protections

Multiple labor unions have reportedly filed a lawsuit alleging that Washington’s Departments of Health and Labor & Industries failed to provide guidance that would protect farmworkers from increased risks of COVID-19 infection. The unions seek an injunction that would require the agencies to expedite oversight through emergency rulemaking. “Lack of enforceable rules

regarding social distancing, protective face masks, access to soap and water, and to environmental cleaning allows conditions to continue in which virus can spread easily and quickly,” the complaint states, according to *Bloomberg*.

SHB.COM

ATLANTA | BOSTON | CHICAGO | DENVER | HOUSTON | KANSAS CITY | LONDON
LOS ANGELES | MIAMI | ORANGE COUNTY | PHILADELPHIA | SAN FRANCISCO
SEATTLE | TAMPA | WASHINGTON, D.C.

The choice of a lawyer is an important decision and should not be based solely upon advertisements.

© Shook, Hardy & Bacon L.L.P. All rights reserved.

[Unsubscribe](#) | [Forward to a Colleague](#) | [Privacy Notice](#)