COVID-19 FAQs for the U.S. Food Industry

March 19, 2020

Dear clients,

We hope that you are well and keeping safe during this challenging time. During the past few weeks, we have received many questions regarding how to overcome or avoid challenges that are created by the current COVID-19 pandemic. Below, we provide our thoughts and responses to some of the most frequently asked questions.

Please note that our guidance is current as of the published date, and it may change as the situation develops. We are staying abreast of developments and participating in government briefings in real time, such as the FDA briefing held for food stakeholders on March 18, 2020.

Please note that this document is not a substitute for legal advice. To speak with a Reed Smith FDA lawyer concerning any issue related to COVID-19, please contact us using the information provided below. We look forward to speaking with you.

1. What do I do first to prepare my company for COVID-19?

COVID-19 will affect food companies' operations in many different ways, and the severity of its impact will differ for each company. While we discuss in the below parts certain issues related to recalls, current Good Manufacturing Practices, and supply chain disruptions, this cannot account for all issues that your company might encounter.

Our recommendation is for a company's management to form a preparedness committee that considers and plans for different scenarios of how COVID-19 can affect its operations, and that analyzes where the company is most vulnerable. Considering these scenarios in advance and planning for them will allow measured, efficient and coordinated responses should your company be impacted by COVID-19. Note that the COVID-19 response is primarily being managed at the local and state levels and each jurisdiction's requirements vary. Tracking the requirements of the jurisdictions in which you operate will help streamline your response to an issue when it arises.

2. Generally speaking, what actions has FDA taken and what statements has the agency made regarding COVID-19?

FDA has issued temporary policies in response to the burden and challenges posed by the spread of COVID-19. Citing difficulties with and warnings against travel, FDA recently announced temporary enforcement discretion for FSMA's on-site supplier audit requirements relating to preventive control rules and foreign supplier verification programs, as long as other appropriate supplier verification methods are in place. In addition, FDA plans to limit unannounced inspections and will focus its announced inspections on facilities with public health concerns. The agency also stated that it is postponing inspections of foreign food facilities until April 2020 due to travel advisories and restrictions from the U.S. and foreign governments, and to protect the health of FDA employees. Please note, however, that FDA may strengthen its oversight in other areas, such as imports, to ensure the safety of food that is imported from overseas.

FDA is providing to food manufacturers and other stakeholders regular updates and recommendations via publications and telephone briefings. The Agency has stated that there is no evidence that indicates that COVID-19 transmissions can result from domestically produced or imported food. Citing Centers for Disease Control and Prevention recommendations, it also recommends continued implementation of hygienic practices at work (in any case, a requirement under FDA cGMP requirements), and that employees who are ill stay at home.

3. If an employee tests positive for COVID-19, and the employee was involved in manufacturing, processing, packaging, or other preparation of the food, must all food that was potentially exposed to the employee be recalled?

Generally speaking, no. FDA has stated that, "there is currently no evidence to support the transmission of COVID-19 associated with food or food packaging" and it further stated that it expects that recalls will not be necessary. The agency confirmed this position during the FDA briefing held for food stakeholders on March 18, 2020.

However, it is possible that an in-depth review may become required if the facts indicate that the food or food packaging materials can pose a serious risk to consumers. FDA can order a recall if it determines that the products

have a reasonable probability of being misbranded or adulterated (that is, injurious to consumers), and if the food products will cause "serious adverse health consequences or death to humans or animals" (often shortened to "SAHCODHA"). If the facts indicate, for example, that the food or food packaging has been somehow contaminated with COVID-19 and can cause SAHCODHA, a recall may be required.

As stated above, the answer will be no in most cases and FDA agrees. However, certain facts may need to be analyzed for the company to reach a conclusion, including the employee's role in the food production process, the timing and duration of the employee's sickness, processing steps, and potential updates about the ability of the virus to survive on food or food packaging. Indeed FDA left open the possibility of the virus surviving on various surfaces (e.g., food packaging materials). Please note that various state and local laws and regulations could also apply, including a potential reporting obligation to the state or local health departments.

4. Are there any current Good Manufacturing Practices (cGMP) requirements that are relevant to COVID-19?

Yes. FDA's cGMP regulations include disease control requirements, where "[a]ny person who . . . is shown to have, or appears to have, an illness . . . or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated" must be excluded from operations. In addition, the management must take any other "necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances . . . ." 21 C.F.R. 110.10.

The scope and breadth of the cGMP regulations (and others) mean that they may not be limited necessarily to pathogens such as Salmonella, Listeria, or E. coli. In fact, FDA appears to be applying the cGMP requirements to COVID-19, stating that "facilities are required to control any risks that might be associated with workers who are ill **regardless of the type of virus or bacteria**."

Considering risks to productivity and potential liability to the company, we would recommend implementing at least basic procedures to ensure that employees showing symptoms are identified and excluded from food processing or manufacturing operations. Such measures will ensure that the company employees remain safe, and that the company remains compliant with the cGMP requirements.

If you have any questions concerning labor and employment law, as many companies do, please see our colleagues' article summarizing guidance to frequently asked questions.

5. Can I market food or dietary supplements that claim to be effective for preventing COVID-19?

No. FDA's prohibition against unlawful marketing of food as having therapeutic or preventive effects against diseases remains in place. In fact, FDA and the FTC already sent warning letters to companies that market products that claim to treat or prevent COVID-19. The agencies are likely to continue to take actions against such violations because such violations may distract the public from taking proper measures and following legitimate procedures for prevention and treatment of COVID-19; FDA considers such products "to be a threat to the public health."

6. What food safety issues must I be thinking of now?

We recommend revisiting and confirming the company's compliance with food safety requirements. For example, consumers have been purchasing greater quantities of food than is typical in response to the spread of COVID-19. Depending on the type of food and amount purchased, customers may be holding some of this food for an extended period of time (e.g., canned food).

Given this change in purchasing habits, companies may consider reviewing the production logs again to ensure that the food processing was conducted in accordance with the specifications and set procedures (e.g., scheduled process filings for canned foods), and that there are no concerns with such food being stored for an extended period of time. In addition, though not an FDA requirement, you might also consider confirming that the scientific basis behind expiration dates remains valid.

FDA is also recommending frequent washing and sanitizing of all food contact surfaces and utensils, including the frequent cleaning and sanitizing of counters and condiment containers. How COVID-19 affects each company will differ, but we recommend revisiting and confirming compliance with various food safety requirements.

7. What are some considerations with regard to the supply chain?

Modern food supply chains involve many parties that both receive and send products to the downstream party; in fact, unless a company is either the farm (the beginning of a supply chain) or the grocery chain (retail), most companies will have both suppliers and customers to which they send products. The situation involving COVID-19 may potentially cause disruptions to the supply chain, and such disruptions could result in an inability to meet production or delivery deadlines.

Companies should take multi-dimensional approaches in preventing or minimizing such disruptions. For example, companies should consider diversifying or otherwise increasing the inventory of key ingredients to ensure that the production schedule and the ability to meet deadlines are not impacted, even if a supplier fails to deliver.

Disruptions could also be caused by employees in a factory becoming infected with COVID-19. To prevent this, companies may consider increasing the spacing among employees, re-designing the movement routes, minimizing the likelihood of transmission during breaks or meals, or otherwise increasing the frequency of workplace cleaning. FDA is closely monitoring the food supply chain for any shortages and states to be in regular contact with food manufacturers and grocery stores.

Finally, we understand that supply chain disruptions can also cause contractual disputes. For information regarding contractual issues and force majeure clauses, please see our colleagues' writing here.

We will continue to monitor the situation and provide updates as necessary. Please let us know if you have any questions. We are here to help you with preparation and readiness during this very challenging time.

Questions?

Cori Annapolen Goldberg
Partner
New York
+1 212 549 0378
cgoldberg@reedsmith.com

Sung W. Park
Senior Associate
New York / Washington, D.C.
+1 202 414 9262
spark@reedsmith.com