

## FDA Issues COVID-19 Food Safety Guidance for Food Manufacturers

Maintaining the integrity and safety of the domestic food supply is a key concern for all Americans. Especially during the public health emergency brought on by the 2019 novel coronavirus (COVID-19), food processors and manufacturers must continue to be vigilant in protecting the health and safety of their workers and the foods they produce and distribute. In light of the COVID-19 pandemic, the U.S. Food and Drug Administration (FDA) has announced several steps to adjust the regulatory burden on manufacturers. Continued attention to food safety practices remains critically important to preserving public safety and health.

The update below provides a summary of recent FDA pronouncements and actions, as well as some guidance to help ensure the safety of food products and mitigate any risks of spreading disease through the food supply chain. Considering and addressing the impact of COVID-19 on these operations will not only help meet regulatory obligations and keep customers and others in the supply chain safe, it will also help respond to customer inquiries about the safety of the food they purchase.

### FDA Actions

The FDA announced several new policies in recent days and held a teleconference on March 18, 2020. Here are the current FDA positions and new policies in response to COVID-19:

- **No Evidence of Food or Food Packaging Transmission.** The FDA stated there is no evidence that the virus has been spread through food or food packaging. The agency distinguishes SARS-CoV-2, the virus that causes the disease COVID-19, from norovirus and other foodborne pathogens. Specifically, the virus behind COVID-19 is a respiratory virus. Nonetheless, the agency acknowledges that there is at least some risk of transmission of the virus through surface contact. Additional food safety considerations to address the risk of transmission through surface contact on food or packaging are discussed below.
- **Food Industry Is Critical Infrastructure for National Security Purposes.** The FDA stated that the food industry is considered critical infrastructure by the U.S. Department of Homeland Security, and it will work with FEMA and other agencies to minimize disruption in the supply of food.
- **FDA Will Temporarily Limit Inspections and Audits.** Specifically, the FDA will limit the following:
  - Domestic, routine surveillance inspections will largely be suspended, and the FDA will look for other ways to achieve its mission without conducting on-site inspections. Only for-cause or "mission-critical" on-site inspections will be carried out, including: (1) inspections in connection with a foodborne illness outbreak; (2) a Class I recall; or (3) a product suspected to be associated with COVID-19. In most cases, these inspections will be pre-announced.
  - The FDA is suspending certain food supplier verification activities. Where manufacturers' food safety plans or foreign supplier verification programs require on-site audits of food suppliers to verify their food safety practices, the FDA will not enforce such requirements when travel to such facilities is restricted by a government travel restriction or travel advisory. Manufacturers are still required to employ other appropriate supplier verification methods, such as sampling and testing or a review of food safety records, and should update their food safety plan or foreign supplier verification program to incorporate these alternative activities.

- **FDA Recommends Certain Steps if an Employee Has a Confirmed Case of COVID-19.** If an employee is confirmed to have COVID-19, companies should inform employees of possible exposure but respect confidentiality and follow CDC guidance, as well as consult local health agencies and redouble cleaning and sanitizing practices. **The FDA stated that the presence of a sick employee does not require product to be recalled or held.** Additional guidance on addressing employee health issues is provided below.

## Impact of COVID-19 on Food Safety Plans and Preventive Controls

The FDA's Current Good Manufacturing Practice (CGMP) rules require manufacturers to reassess their food safety plans and the adequacy of their preventive controls when they become aware of new potential hazards. The CGMP rules also require manufacturers to exclude from their operations persons who have, or appear to have, an illness by which there is a reasonable possibility of food, food contact surfaces, or food packaging materials becoming contaminated.

Even though the FDA is not aware of cases where the virus causing COVID-19 has been transmitted through food or food packaging, the agency did acknowledge there is a risk of transmission of the disease through surface contact. Food manufacturers should update their food safety plans to assess and address potential hazards from the transmission of the virus on food or food packaging. Assessing these risks requires answers to several questions, which may or may not be available at this time. The process to reassess food safety plans should be ongoing and such plans should incorporate additional information about the virus as it becomes known.

Here are some tips and considerations for updating food safety plans to help keep food products safe:

- **Focus on Employee Health Practices.** All reasonable steps should be taken to instruct employees on the safest health practices to reduce the spread of COVID-19 and to provide the information and supplies people need to protect themselves and others. Limiting the spread of the disease is the most important thing to do to protect employees and their families and communities. It also will help to limit the potential contact of the virus with the food and packaging. [Here](#) are some tips we've prepared for addressing employee health issues as well as legal considerations.
- **Take Steps to Mitigate Risks of Potentially Sick Employees.** Asymptomatic transmission is an especially pernicious feature of the current public health pandemic. It is possible that some employees might have the virus but exhibit no symptoms. As such, in addition to generally promoting and supporting employee health practices, **assess the risk of an infected employee transmitting the virus to food or packaging during the manufacturing process.** This requires assessing the likelihood of the virus surviving on food or packaging from the point of possible transmission through preparation and packaging of finished product. **Evaluate and implement process controls that could further mitigate that risk,** such as the following:
  - Verify existing or new "kill steps," such as cooking the food
  - Add more frequent, additional, or different sanitation steps for equipment, utensils, food contact surfaces, etc.
  - Install barriers to keep employees at a certain distance of exposed product, especially at critical steps
  - To the extent feasible, maximize automation and minimize human intervention
- **Assess Preventive Controls for Finished Product.** If there is a chance the virus would survive the process into a finished, packaged product, **consider whether any additional "kill steps" could be taken to mitigate that risk, such as:**
  - Could the finished product be sanitized to kill the virus on packaging?
  - Would holding the finished product for a period of time before shipping kill the virus?

- Would additional instructions to customers be appropriate to further mitigate any risks of exposure by contact?
- **Consider the Handling and Shipping of the Finished Product.** Assess the risk of exposure from handling during the storage and shipping of the finished product and implement steps to minimize those risks.
- **Document Efforts.** Finally, be sure to document the efforts undertaken to reassess food safety plans in light of this potential threat. Keep records documenting the consideration of potential hazards in light of the best scientific information available. Also document the preventive controls that were considered, when and why they were implemented, and why other controls were rejected.

## Conclusion

We know that food safety has always been a high priority of food manufacturers. The FDA has stated there is no evidence that the virus behind COVID-19 has been spread through food or food packaging. Even so, taking additional steps to ensure that the product does not create a risk of transmitting the virus via surface contact will protect customers, further ensure the safety of our food supply system, and help maintain and build company reputations for safety and care.

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