

August 26, 2019

Dear Papaya Growers, Harvesters, Packers, Distributors, Exporters, Importers, and Retailers:

As we write this letter, the U.S. Food and Drug Administration (FDA or the agency) and other public health agencies are investigating an outbreak of *Salmonella* Uganda infections tied to the consumption of whole, fresh papaya. As of this date, more than 70 people in eight states have gotten sick, according to the Centers for Disease Control and Prevention.

Since 2011, FDA has noted a pattern of recurrent outbreaks tied to consumption of imported papayas from Mexico. Because of these outbreaks, hundreds of people have fallen ill and two have died. FDA is greatly concerned about recurring outbreaks.

As Mexico is the largest supplier of papaya to U.S. consumers, we are actively engaged with our regulatory counterparts in the Mexican government in investigating this current outbreak and are working together to prevent any future outbreaks related to contaminated papaya.

FDA has a duty to protect consumers from contaminated food, a commitment at the heart of our public health mission and one that we take very seriously. In pursuit of this goal, FDA sets standards for the safe growing, harvesting, packing, processing and holding of produce sold in the United States, including papaya, no matter where in the world it is grown.

Industry stakeholders have the primary responsibility to ensure that foods they bring to market are safe for consumers to eat and serve their families. We urge all segments of the papaya industry to review their operations and make all necessary changes to strengthen public health safeguards.

Working together, we must end these outbreaks.

Safety Is an Ongoing Concern

FDA is aware of eight outbreaks since 2011 caused by *Salmonella* serotypes that have been tied to consumption of imported fresh papaya. While the 2019 outbreak is ongoing, the first seven outbreaks account for almost 500 reported cases of illness, more than 100 hospitalizations and two deaths. The pattern of recurrent outbreaks we have observed since 2011, including the 2019 illnesses, have involved *Salmonella* infections traced back to or suspected of being associated with papaya growing operations in Mexico. (*For a breakdown of outbreaks and illnesses, see the chart at the end of this letter.*)

Fresh papayas are most often eaten raw, without undergoing a process to eliminate potential microbial hazards. Therefore, the way they are grown, harvested, packed, held, processed and distributed is crucial to minimizing the risk of contamination with human pathogens.

In response to this most recent *Salmonella* Uganda outbreak, FDA deployed an inspection team to the packing house and farm that supplied papayas linked to people who got sick. The findings of those visits will be made public when FDA's investigation is complete, consistent with our regular procedures. To further our prevention efforts, FDA is collaborating with our counterparts in the Mexican government regarding this current outbreak through the agency's Latin America Office.

Regulatory Requirements and Industry Responsibility

The recurring nature of these outbreaks is a clear indication that more must be done within the papaya industry to protect its customers and to meet legal obligations.

The U.S. Federal Food, Drug and Cosmetic Act prohibits food producers from introducing, or delivering for introduction, into interstate commerce adulterated foods that are potentially harmful to consumers.

Additionally, there are new requirements under the FDA Food Safety Modernization Act (FSMA). The Produce Safety Rule¹ (under FSMA sets science and risk-based minimum standards for domestic and foreign farms for the safe growing, harvesting, packing and holding of covered produce, which includes papaya. Unless not covered due to farm size or eligible for an exemption due to other factors, all growers of covered produce, including papaya growers in Mexico and other nations, are covered by the rule.

Another FSMA rule, the Foreign Supplier Verification Program², makes importers responsible for verifying that the foods they bring into the United States, including papaya, have been produced in a manner that meets applicable U.S. safety standards (e.g. the Produce Safety Rule).

Call to Action

To meet food safety requirements and follow best practices to provide the public with safe foods, we are asking the papaya industry to:

- assess the factors that make crops vulnerable to contamination. If a foodborne pathogen is identified in the crop or growing environment, a root cause analysis should be performed to determine the likely source of contamination. Procedures and practices that minimize that risk must be implemented.
- examine the use and monitoring of water used to grow, spray (pesticides, fungicides), move, rinse or wax crops to identify and minimize risks from potential hazards.
- adopt tools and practices needed to enhance traceability. Papayas are a perishable commodity, and traceability information should facilitate the rapid tracking of involved product to expedite its removal from commerce, prevent additional consumer exposures, and properly focus any recall actions.
- fund and actively engage in food safety research to identify the potential sources and

¹ <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety>

² <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-foreign-supplier-verification-programs-fsvp-importers-food-humans-and-animals>

routes of microbial pathogens and develop data-driven and risk-based preventive controls.

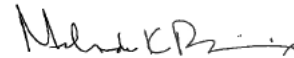
We recognize that we are in this together. Rest assured that the FDA intends to use all the tools and enforcement powers we have available to further strengthen safeguards and prevent contaminated papayas from being imported into the U.S. Those tools include education, outreach, training, enforcement, and research activities designed to support farmers' efforts to keep their crops safe for consumers.

However, we can't do this alone and believe that more must be done by industry as repeated outbreaks are unacceptable from a public health perspective. We look forward to working with you to reach our shared goal of ensuring a safe food supply for consumers.

Sincerely,



Frank Yiannas
Deputy Commissioner for Food Policy
and Response



Melinda K. Plaisier
Associate Commissioner
for Regulatory Affairs

CC:

ProPapaya, the National Papaya Board of Mexico
Fresh Produce Association of the Americas
Texas International Produce Association
Produce Marketing Association
United Fresh Produce Association
Food Marketing Institute
Associated Wholesale Grocers
International Foodservice Distributors Association
National Grocers Association
National Restaurant Association
Grocery Manufacturers Association
Florida Fruit & Vegetable Growers Association
California Fresh Fruit Association
Western Growers
American Association of Exporters and Importers
Express Association of America
National Customs Brokers and Forwarders Association

Foodborne Illness Outbreaks Tied to Papayas

Foodborne illness outbreaks of Salmonellosis by serotype, associated with whole, fresh papayas as the confirmed or suspected food vehicle.

Outbreak	Year	<i>Salmonella</i> serotype(s)	Confirmed Cases	Hospitalizations	Deaths attributable to <i>Salmonella</i>
1	2011	Agona	99	0	0
2	2012	Agona <i>suspected</i>	25	5	0
3	2017	Anatum	20	5	1
4	2017	Braenderup <i>suspected</i>	55	18	0
5	2017	Outbreak #5 Serotypes: Thompson, Kiambu, Agona, Gaminara, Senftenberg	213	68	1
6	2017	Urbana	7	4	0
7	2017	Newport & Infantis	4	2	0
8	2019	Uganda	71	27	0
Total			494	129	2