



Guidance for Industry

Letter to Firms that Grow, Harvest, Sort, Pack, Process, or Ship Fresh Cantaloupe

*Additional copies are available from:
Office of Food Safety
Produce Safety Staff, HFS-317
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
(Tel) 240-402-1700
<http://www.cfsan.fda.gov/guidance.html>*

You may submit written comments regarding this guidance at any time. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the title of the guidance document.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
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The Food and Drug Administration (FDA or the Agency) is issuing this letter to firms that grow, harvest, sort, pack, process, or ship fresh cantaloupe to enhance awareness regarding the Agency's recommended best practices for preventing contamination of fresh produce with pathogens, including *Listeria monocytogenes*. *L. monocytogenes* is a bacterium that can contaminate foods and cause a mild non-invasive illness (called listerial gastroenteritis) or a severe, sometimes life-threatening, illness (called invasive listeriosis). Persons who have the greatest risk of experiencing listeriosis after consuming foods contaminated with *L. monocytogenes* are fetuses and neonates who are infected after the mother is exposed to *L. monocytogenes* during pregnancy, the elderly, and persons with weakened immune systems. Invasive listeriosis is characterized by a high case-fatality rate, ranging from 20 percent to 30 percent (Ref. 1).

FDA is issuing this guidance in response to a multi-state foodborne illness outbreak of listeriosis associated with consumption of fresh, whole cantaloupe (Ref. 2). As of October 25, 2011, the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services had reported 139 confirmed illnesses and 29 confirmed deaths associated with consumption of the implicated cantaloupe. More information about FDA's investigation of this outbreak is available in a warning letter that FDA issued to the farm whose cantaloupes were implicated in the outbreak, on October 18, 2011 (Ref. 3), and in a report setting forth factors that potentially contributed to the contamination the cantaloupes, which FDA published on our website on October 19, 2011 (Refs. 3 and 4).

In light of this multi-state outbreak of listeriosis associated with consumption of cantaloupe, which CDC has stated is the first listeriosis outbreak associated with melon (Ref. 2), the Agency believes that it is prudent to encourage members of the cantaloupe industry to review their current operations in the context of a number of FDA guidances and draft guidances that are

¹ This guidance has been prepared by the Produce Safety Staff in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

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generally relevant to preventing contamination of fresh cantaloupe with human pathogens. The FDA document that is most relevant to food safety hazards associated with melons is FDA's draft guidance to industry titled "Guide to Minimize Microbial Food Safety Hazards of Melons" (Ref. 5; the Draft Melon Guide). The Draft Melon Guide supplements FDA's guidances entitled "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" (Ref. 6; the GAPs Guide) and "Guide to Minimize Microbial Food Safety Hazards for Fresh-cut Fruits and Vegetables" (Ref. 7; the Fresh-cut Guide). Additionally, the Agency recommends that the cantaloupe industry consider the recommendations in FDA's draft guidance to industry titled "Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat Foods," to the extent those recommendations are relevant to the specific practices used in the fresh cantaloupe industry (Ref. 1).

The Agency recognizes that many in the cantaloupe industry have taken actions to address food safety issues associated with growing, handling, processing, and distribution of fresh whole and fresh-cut cantaloupe. This includes the industry-led development of the "Commodity Specific Food Safety Guidelines for the Melon Supply Chain" that FDA utilized in its development of the Agency's Draft Melon Guide (Refs. 5 and 8). The Agency applauds these efforts and other cantaloupe industry efforts that are aimed at enhancing cantaloupe safety.

The Agency continues to stand ready to provide technical assistance to the fresh produce industry.

Sincerely,



Michael M. Landa
Acting Director
Center for Food Safety
and Applied Nutrition

References

1. FDA. 2008. [Guidance for Industry: Control of Listeria Monocytogenes in Refrigerated or Frozen Ready-to-Eat Foods; Draft Guidance.](#)
2. [Multistate Outbreak of Listeriosis Linked to Whole Cantaloupes from Jensen Farms, Colorado](#)
3. FDA. 2011. Warning Letter to Jensen Farms. Accessed online on Oct 20th, 2011 at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm276249.htm>
4. FDA. 2011. Environmental Assessment: Factors Potentially Contributing to the Contamination of Fresh Whole Cantaloupe Implicated in a Multi-State Outbreak of Listeriosis. Accessed online on Oct 20th, 2011 at <http://www.fda.gov/Food/FoodSafety/FoodborneIllness/ucm276247.htm>
5. FDA. 2009. [Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons; Draft Guidance.](#)

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5. FDA. 2009. [Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons; Draft Guidance.](#)
 6. FDA. 1998. [Guide to Minimize Microbial Food Safety Hazards for Fruits and Vegetables.](#)
 7. FDA. 2008. [Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables.](#)
 8. Fleming, P., Pool, W., and Gorny, J., Eds; "Commodity Specific Food Safety Guidelines for the Melon Supply Chain," (1st edition); Produce Marketing Association and United Fresh Produce Association; November 7, 2005. Accessed online on Oct 3rd, 2011 at <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/FruitsVegetablesJuices/GuidanceComplianceRegulatoryInformation/ucm168609.htm>
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