



Guidance for Industry

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

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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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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

The Food and Drug Administration (FDA or the Agency) is concerned about positive sample findings for human pathogens in fresh cilantro and recommends that this produce industry segment take action to enhance the safety of these products.

Since 2004, FDA has confirmed the presence of *Salmonella* species (*Salmonella* spp.) in 28 samples of fresh cilantro that was in, or entering into, commerce. The samples of fresh cilantro were of both U.S. and non-U.S. origin.

Salmonella spp. is a human pathogen that can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Healthy persons infected with *Salmonella* spp. often experience fever, diarrhea (which may be bloody), nausea, vomiting, and abdominal pain. In rare circumstances, infection with *Salmonella* spp. can result in the organism getting into the blood stream and producing more severe illnesses such as arterial infections (i.e., infected aneurysms), endocarditis, and arthritis.

Fresh cilantro is commonly consumed in its raw state without processing or cooking to adequately reduce human pathogens. The manner in which it is grown, harvested, sorted, packed, and shipped is crucial to ensure that the potential for microbial contamination is minimized, thereby reducing the potential risk of illness to consumers.

In 1998, FDA issued a "Guide to Minimize Microbial Food Safety Hazards for Fruits and Vegetables." (Ref. 3: the GAPs Guide). The GAPs Guide recommends good agricultural practices (GAPs) and good manufacturing practices (GMPs) that growers, harvesters, sorters, packers, and shippers can use to address risk factors common to the growing, harvesting, washing, sorting, packing, and transporting of fresh fruits and vegetables and thereby minimize food safety hazards potentially associated with fresh produce.

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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We partnered with the fresh produce industry in the U.S. and abroad since that time to promote the adoption of these recommendations and to advance the scientific knowledge applicable to enhancing the safety of fresh fruits and vegetables. In addition, in 2001, FDA made available a report prepared for the Agency under contract by the Institute for Food Technologists (Ref. 4). This report summarizes scientific research relating to the various methods of eliminating or reducing pathogens, while maintaining fresh attributes on whole and fresh-cut produce.

Under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 342(a)(1)), a food is deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health. Under section 402(a)(4) of the FD&C Act (21 U.S.C. § 342(a)(4)), a food is deemed to be adulterated if it is produced under insanitary conditions whereby it may be rendered injurious to health. FDA may take enforcement action where food has tested positive for *Salmonella* spp. (Refs. 1 and 2). Prohibitions applicable to adulterated food are contained in section 301 (21 U.S.C. § 331) of the FD&C Act. Consequences for violations of the FD&C Act may include seizure, injunction, and criminal prosecution (See, e.g., sections 302, 303 and 304 of the FD&C Act (21 U.S.C. §§ 332, 333 and 334)).

The Agency intends to continue to monitor the safety of fresh produce, including fresh cilantro, whether produced domestically or abroad, and to continue to encourage the use of GAPs and GMPs. FDA intends to take appropriate enforcement action against firms and farms that distribute adulterated fresh produce or grow or pack fresh produce under insanitary conditions.

During the past decade, FDA has taken steps to inform several segments of the fresh produce industry about safety concerns relative to a particular commodity (i.e., lettuce, tomatoes, and sprouts) and to recommend that the applicable market segment review their current operations in the context of the GAPs Guide, as well as other available information regarding adequately reducing pathogens in or on fresh produce (Refs. 5-7). We encouraged these firms to assess hazards unique to the production of the applicable commodity and to develop commodity-specific preventive control strategies that would identify potential hazards that may be specific to that commodity. Several industry segments have taken steps to address our concerns and recommendations (see, e.g., Refs. 8-9). In addition, FDA has issued for public comment draft commodity-specific guidance for melons, leafy greens (including lettuce) and tomatoes (Refs. 10-12).

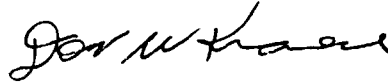
Likewise, in view of continued positive findings for *Salmonella* spp. in fresh cilantro, FDA recommends that firms in the fresh cilantro industry review their current operations in the context of the GAPs Guide, as well as other available information regarding adequately reducing pathogens in or on fresh produce. We further encourage these firms to assess hazards unique to the production of cilantro and to develop commodity-specific preventive control strategies that would identify potential hazards that may be specific to fresh cilantro. Since the available

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information concerning some of the recent positive findings for *Salmonella* spp. does not definitively identify the point of origin of the contamination, we recommend that firms take these steps for all points from the farm through distribution.

The Agency is ready to provide technical assistance to the industry.

Sincerely,



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

References

1. FDA. 2010. Compliance Policy Guide Sec. 527.300, Dairy Products - Microbial Contaminants and Alkaline Phosphatase Activity.
2. FDA. 1995. Compliance Policy Guide Sec 555.300, Foods, Except Dairy Products - Adulteration with Salmonella (CPG 7120.20).
3. FDA. 1998. Guide to Minimize Microbial Food Safety Hazards for Fruits and Vegetables.
4. Institute of Food Technologists. 2001. Analysis and Evaluation of Preventive Control Measures for the Control and Reduction/Elimination of Microbial Hazards on Fresh and Fresh-Cut Produce.
5. FDA. 2004. Letter to Firms that Grow, Pack, or Ship Fresh Lettuce and Fresh Tomatoes.
6. FDA. 2005. Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce.
7. FDA. 2009. Letter to Seed Suppliers, Distributors, and Sprouters.
8. International Fresh-Cut Produce Association, Produce Marketing Association, United Fresh Fruit and Vegetable Association, Western Growers. Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain - 1st Edition.
9. Commodity specific Food Safety Guidelines for the Production, Harvest, Post-Harvest, and Valued-Added Unit Operations of Green Onions
10. FDA. 2009. Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons; Draft Guidance.
11. FDA. 2009. Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Tomatoes; Draft Guidance.
12. FDA. 2009. Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens; Draft Guidance.