The FDA Guidelines on Fresh Cut Produce: Nonbinding Recommendations, Or a Mechanism for Establishing Civil Liability for Food-borne Illnesses?

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# TABLE OF CONTENTS

- Guarding Against Contamination During the Production and Harvesting of Fresh Fruits and Vegetables. ...............2
- Guarding Against Contamination by Workers Processing Fresh Cut Produce.........................................................3
- Ensuring that the Processing Facility and Available Equipment do not Become a Source of Contamination.........3
- Sanitizing the Processing Facility to Prevent Contamination ..................................................................................4
- Preventing Contamination While Packaging and Storing Fresh Cut Produce...........................................................5
- Encouraging Recordkeeping of Compliance with the Guidelines and Developing a Plan for a Product Recall in the Event of Contamination. .........................................................................................................................6
- Encouraging Retail Sectors Providing Fresh Cut Produce to the Consuming Public to Require Compliance with the Guidelines. ........................................................................................................................................6
- Industry Response to the Guidelines and Their Role in Civil Litigation Related to Food-Borne Illnesses. ...............7

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While Americans’ increased consumption of fresh produce in recent years has caused a rapid growth spurt in the fresh cut sector of the produce industry, such growth has brought with it an increased risk and number of outbreaks of food-borne illnesses associated with the consumption of fresh produce.\(^2\) Ready-to-eat fresh vegetables, fruits, and prepared salads, for example, have a high risk of contamination because they are generally grown in a natural environment, such as a field or orchard, and are often consumed raw without cooking or other treatments to reduce or eliminate present pathogens.\(^2\) Given these conditions, an official from the Food and Drug Administration (hereinafter, “FDA”), the governmental agency charged with protecting the public health and ensuring the safety of food products,\(^3\) recently acknowledged that the “FDA does not expect fresh produce to be a sterile item.”\(^4\)

In the past ten years, seventy-two food-borne illness outbreaks were associated with fresh produce with spinach, tomatoes, and green onions being the most recent culprits.\(^5\) While the specific causes of these various outbreaks remain under investigation,\(^6\) the manner in which these “ready to eat” products are grown, harvested, packed, processed, and distributed has become critical to minimizing microbial contamination and reducing consumers’ risk of illness.\(^7\) The FDA has identified several possible factors that contribute to the contamination of fresh produce including the exposure of fresh produce to poor water quality, manure used for fertilizer, workers with poor hygiene, and domesticated and wild farm animals.\(^8\)

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1 Shin, Anny, Produce Growers Balk at Calls for Regulation, THE WASHINGTON POST, Dec. 11, 2006 (stating that The Center for Science in the Public reports that American are now more likely to get sick from eating contaminated produce than from any other food item).

2 Statement of Robert E. Brackett, Ph.D., Director Center for Food Safety and Applied Nutrition, Food and Drug Administration, before the Committee on Health, Education, Labor, and Pensions, United States Senate (hereinafter, “Brackett Statement”), at 1 (Nov. 15, 2006), available at: http://www.fda.gov/ola/2006/foodsafety1115.html (last visited, March 25, 2007). See also Shin, Anny, supra note 1 (noting that unlike meat, which can be rid of bacteria through proper cooking, produce is meant to be consumed raw and without any “kill step” as food safety experts refer to it).

3 Id. (this document also notes that the FDA regulates all foods consumed by the public with the exception of meat, poultry, and processed egg products, which are regulated by the Department of Agriculture and works in conjunction with the Centers for Disease Control, which conducts surveillance and outbreak investigation and routinely monitors specific illnesses attributable to the food supply).


5 See, Corbett Dooren, Jennifer, FDA Aims to Reduce Produce-Borne Illness, THE WALL STREET JOURNAL (Mar. 13, 2007); Shin, Anny, supra, note 1 (stating that a total of 71 cases associated with the fall, 2006 outbreak in Delaware, New Jersey, New York, Pennsylvania, and South Carolina, were reported to the Centers for Disease Control).

6 See U.S. Food and Drug Administration, Questions & Answers Taco Bell E. Coli 0157:H7 Lettuce Outbreak, supra note 5 (noting that the FDA continues its work with state health agencies and the CDC to determine the cause of the recent spinach/lettuce contamination); accord Fox, Maggie, FDA Offers Hints to Make Baggaged Produce Safer, Science News (March 12, 2007) available at: http://www/sciam.com/article.cfm (last visited March 15, 2007) (noting the FDA has admitted it is not clear as to the source of contamination of lettuce, tomatoes, and other produce).

7 See Brackett Statement, supra note 2.

8 Id.
In March, 2007, the FDA issued guidelines entitled “A Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables”9 (hereinafter, “the Guidelines”). Although the Guidelines are nonbinding, open for public comment, and subject to approval by the Office of Management and Budget,10 they represent the FDA’s current thinking on the topic of food safety.11 The Guidelines beg the question of whether they are truly advisory and nonbinding, or will become a mechanism for establishing civil liability on the part of all in the chain of distribution from farm to table for food-borne illnesses.

One should not be deceived by the Guidelines’ nonbonding nature and, instead, should use them as effective risk management tools to prevent food-borne illnesses and subsequent litigation. In terms of food-related litigation, the Guidelines may be used as a sword by the plaintiffs’ bar seeking to hold all entities in the chain of fresh cut produce production and distribution liable for food-borne illnesses, while processors, distributors, and sellers of fresh cut produce who may find themselves defending against product liability claims may use compliance with the Guidelines as a shield against civil liability. What follows is an overview of the Guidelines and suggestions for producers, processors, and distributors, including restaurants, hotels, and grocery stores to ensure compliance, help defend against potential lawsuits, and participate in the ongoing regulatory process of this rapidly growing industry, which for now, is essentially being asked to police itself.

The recent FDA guidelines cover fresh-cut fruits and vegetables that have been minimally processed and altered by peeling, slicing, chopping, shredding, coring, or trimming, with or without washing or other treatment, before they are packaged for use by consumers and/or retail establishments.12 Examples of such fresh-cut produce include shredded lettuce, sliced tomatoes, salad mixes, peeled baby carrots, broccoli and cauliflower florets, cut celery stalks, shredded cabbage, cut melon, sliced pineapple, and sectioned grapefruit.13 The FDA promulgated these guidelines to encourage fresh-cut produce processors to take a proactive role in minimizing microbial food safety hazards by establishing a control program to build safety into processing operations by addressing personnel health and hygiene, training, building and equipment, sanitation operations, produce production, product specification, storage, transport, and recordkeeping.14 To enhance these efforts, the FDA recommends that processors encourage the adoption of safe practices by their partners throughout the supply chain, including produce growers, packers, distributors, transporters, importers, exporters, retailers, food service operators, and consumers.15

Guarding Against Contamination During the Production and Harvesting of Fresh Fruits and Vegetables.

Given that fresh produce may become contaminated at any point along the farm to table continuum, the Guidelines start at the beginning of the chain of distribution, namely, the production and harvesting of fresh fruits and vegetables. The Guidelines suggest that fresh cut produce processors become aware of the conditions under which their products are grown, harvested, packed, and transported as each step in the process presents an opportunity for contamination. Such contamination may occur via contact with untreated manure used in soil and/or by contaminated water during growth, infected workers, unclean containers and tools used in harvesting and packing, and/or unclean floors and walls of a vehicle used in transport. The following are a few of the FDA’s

10 Corbett Dooren, Jennifer, supra note 5.
11 See FDA Guidelines, supra note 9, at p. 4.
12 Id.
13 Id.
14 Id.
15 Id.
recommendations for ensuring that incoming fresh produce is safe and suitable for processing into a fresh cut product:

- Become aware of the practices of suppliers (i.e., growers, packers, coolers, and transporters);
- Have a knowledgeable food safety expert evaluate suppliers’ practices;
- Accept produce from suppliers who use the Guidelines or other appropriate practices from the farm to the processing facility; and
- Establish a mechanism to verify the use of food safety practices by suppliers (for example, require a supplier’s letter of certification or guarantee).

**Guarding Against Contamination by Workers Processing Fresh Cut Produce**

After production and harvesting, the next potential source of contamination lies with the personnel processing fresh cut produce. Here, the Guidelines focus on worker health, hygiene, and training. The following are some of the FDA’s suggestions:

- Establish a company policy requiring employees to report any active case of illness before beginning work;
- Train supervisors to know the typical signs and symptoms of infectious disease such as vomiting, nausea, diarrhea, and abdominal cramps. Employees displaying these symptoms should be excluded from any operations expected to result in contaminating fresh produce or food contact surfaces (such as cutting boards and utensils) until the medical condition is resolved;
- Maintain an adequate supply of bandages to protect cuts and wounds and, for workers along a processing line, use a bandage detectible by a metal detector so that the facility will know when a bandage has fallen into a processing line and can take corrective action;
- Require workers to wash their hands frequently and maintain overall personal cleanliness;
- Wash and sanitize non-disposable gloves before beginning work and change such gloves whenever contamination is a possibility;
- Require workers to refrain from eating, using tobacco, chewing gum, or spitting in or around food processing areas;
- Train employees at the beginning of and throughout their employment (annually, at a minimum) on practices for production, maintenance, quality assurance and control, worker health and hygiene, employee roles and responsibilities, and sanitation principles and practices.16

**Ensuring that the Processing Facility and Available Equipment do not Become a Source of Contamination.**

The next potential source of contamination is the processing facility, its structures, (such as walls, ceilings, floors, windows, doors, vents, and drains) and available equipment. The FDA suggests that processing facilities be designed to:

- Limit access to the facility and its processing areas by pests such as insects, birds, and rodents by closing all exterior doors and entrances when not in use and ensuring an adequate seal when such doors, entrances, windows, and other openings are closed;

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16 The FDA suggests that employees be trained at their work station, in small groups, covering only one topic at a time targeting food safety concerns specific to that work station for 10-15 minutes per session followed by a refresher or follow-up session for reinforcement. The guidelines also suggest posting multilingual signs and pictorial representations of practices covered in the training and documenting all training in terms of the topics covered and employees completing it. For information on such training, materials, and examples, see the FDA Guidelines, *supra* note 9, at 10-13 and visit: [http://www.nal.usda.gov/foodborne/index.html](http://www.nal.usda.gov/foodborne/index.html); [http://www.fightbac.org/main.cfm](http://www.fightbac.org/main.cfm); and [http://www.foodsafety.gov](http://www.foodsafety.gov).
• Provide adequate space for operations, ensure adequate drainage of processing and wash water, and use food contact surfaces that are easy to clean and maintain;

• Use floor flumes with caution due to the potential for water aerosol contamination of the room air and equipment surfaces and refrain from using floor flumes for transfer from the produce cooling and packing operation into or across an area housing fresh cut produce operations;

• Design pipelines to avoid pipe and wall condensation from becoming a source of contamination and design collection areas for waste stream water to prevent product and equipment contamination;

• Use protective guards over light fixtures to prevent broken glass from falling into a product;

• Avoid wood construction materials wherever possible. Materials such as plastic or stainless steel are preferable for use in processing areas because they reduce the risk of microbial harborage and cross-contamination of final products;

• Design the facility so that incoming raw products never cross paths or commingle with finished fresh-cut produce products;¹⁷

• Minimize the number of entrances and exits to the processing area;

• Use an air filtration system for central air distribution and airflow that is counter to product flow so that filtered air moves from the cleanest areas (such as areas used for packaging and finished product storage) to less clean areas (such as receiving areas);

• Use equipment with smooth, non-absorbent, sealed, and easily cleanable food surfaces that drain freely and are made of durable, non-corrosive materials; elevate food-contact surfaces sufficiently above the floor to prevent contamination from floor splashes; and install stationary equipment away from floor drains to prevent contamination; and

• Establish a preventative maintenance program for all equipment that includes periodic examination, an action plan should refrigeration or disinfectant systems malfunction, and all maintenance and calibration suggested by the manufacturer.

Sanitizing the Processing Facility to Prevent Contamination

Since pathogenic microorganisms may be found on floors, in drains, and on surfaces of sorting, grading, processing, and packaging equipment, sanitization practices become essential to reducing and eliminating microbial contamination. To that end, the FDA suggests that fresh cut processors consider: establishing sanitation standard operating procedures including a regular schedule for cleaning all equipment, storage areas, production areas, air systems, and water storage areas;¹⁸ cleaning, sanitizing, and storing toxic chemicals at the appropriate temperature and in a manner that prevents cross-contamination with food, food contact surfaces and food packaging materials; implementing a pest control program throughout the facility to eliminate rodents, birds, and insects that harbor pathogens; monitoring air quality in areas where fresh and fresh cut produce are exposed; maintaining and inspecting water systems; and establishing an environmental monitoring program to prevent cross-contamination. Some of the more specific recommendations in these areas include:

¹⁷ See FDA Guidelines, supra note 9, at p. 15 (suggesting, among other things, to place restrooms in an area apart from the processing area; store in-process and raw produce materials in different rooms, establish dedicated cold rooms for raw product and processed product; have a microbiology lab that opens into an area other than a processing area, and place hand washing and sanitization facilities throughout to facilitate regular and appropriate use by all employees).

¹⁸ See FDA Guidelines, supra note 9, at p. 18, Figure 4 (providing an example of a processing plant environmental sanitation schedule).
• Use water of an adequate quality for cleaning and sanitizing at temperatures appropriate for any chemicals used;
• Use window screens, screen doors, and weather stripping for all doors and air fans to prevent entry by rodents and maintain a map identifying by numbered locations all rodent traps and bait boxes used inside and outside the facility;
• Ensure that changing and hand washing facilities and restrooms do not open directly into processing areas and have doors equipped with self-closing mechanisms;
• Use negative air pressures in raw product areas, microbiology labs, and rest rooms to keep air from these areas from flowing to processing areas, and maintain positive air pressure in processing and packaging areas;
• Protect sources of water and ice from contamination, regularly test well water if used, routinely maintain and inspect any water charcoal filtering systems, and ensure that the volume, temperature, and pressure of water is adequate for all operational and clean up demands; and
• Perform environmental sampling and monitoring on all food contact and non-food contact surfaces (such as drains).

Preventing Contamination While Packaging and Storing Fresh Cut Produce

Next, the Guidelines address control measures to prepare, process, package, and store fresh-cut produce. Food processors should develop specifications and controls for all ingredients and components that are necessary for the production of a safe finished product. Fresh produce should be inspected upon receipt at the processing facility for contamination during the loading, transport, and unloading processes and damaged or decomposed produce and all extraneous matter such as soil, debris, and pests should be removed. Finished fresh-cut product should be stored and transported under conditions that will protect the food from physical, chemical, and microbiological contamination, free and away from raw whole produce, and should be transported in sanitary vehicles at appropriate temperatures. Specific recommendations in these areas include, but are not limited to:

• Transport produce from the field to the processing, packaging, or cooling facility as soon as practical after harvest and inspect delivery vehicles, cartons, and other packaging materials for cleanliness;
• Retain information about all incoming ingredients, such as the identity of the grower or supplier and date of harvest and link this information with processing records;
• Wash and remove as much dirt as possible from incoming produce and maintain water quality so that it does not become a source of contamination;
• Include the ice used on fresh or fresh cut produce in routine water quality testing;
• Store fresh cut produce at appropriate temperatures to reduce the potential for microbial growth;
• Prevent condensate and defrost water from evaporator-type cooling systems (such as vacuum cooling and cold storage) from dripping onto fresh and fresh cut produce;
• Regularly inspect and keep all refrigeration units in good operating condition;
• Use an inventory system that ensures first-in, first-out use and shipment of raw materials and finished products;
• Where appropriate, remove as much excess water as possible from processed produce through draining methods such as spin drying;
• Reject damaged or contaminated packaging materials and store all packaging materials so that they are away from pests, dirt, cleaning chemicals, and water condensation from overhead equipment;

19 See id. (noting that the FDA’s 1998 “Guide to Minimize Microbial Food Safety Hazards in Fresh Fruits and Vegetables,” provides useful guidance to facilities reviewing primary production practices).
• Label all finished fresh cut produce with recommended storage instructions (such as “Keep Refrigerated”) and temperatures;
• Ensure that any “use by” date on the product package is validated by studies of the product with respect to microbiological safety and keep records of these studies;
• Transport finished products at appropriate temperatures in refrigeration vehicles designed to uniformly circulate cold air and ship such products on a first in, first out basis to minimize storage time; and
• Load and unload fresh-cut produce in a manner that minimizes the potential for damage and microbial contamination.

Encouraging Recordkeeping of Compliance with the Guidelines and Developing a Plan for a Product Recall in the Event of Contamination.

The FDA suggests that up to date and appropriate records be maintained with respect to the above practices. Such records ensure the consistency of processing operations and product safety, are more reliable than human memory, aide in a trace-back investigation to determine the source of contamination, and provide useful documentation in terms of risk management and litigation defense. While the FDA recommends that such records be maintained at the processing facility for at least six months after the date the product was prepared unless a longer retention time is required by law, it is advisable to keep such records for a longer period of time and in accordance with any established record (in paper and/or electronic form) retention policies.20 Such records to be kept with respect to food processing pertain, but are not limited to:

• Employee training;
• Temperature control;
• Water quality, supply, treatment, and monitoring;
• Equipment monitoring, maintenance, and calibration;
• Sanitation and pest control;
• Product processing and distribution;
• Corrective action;
• Inspection (of incoming product, facility, and production areas); and
• Microbiological contamination (such as with respect to food surfaces and equipment).

The FDA also recommends that fresh cut processors establish and maintain a written contingency plan for use in initiating and carrying out a produce recall in the event of contamination. Such a plan should include the names of responsible contact personnel, methods to identify, locate, and control recalled products and investigate other possibly affected products, and procedures for monitoring a recall’s effectiveness. The use of package and date codes can help link product packages with production times, equipment, and raw ingredient sources thereby facilitating the recovery of products during a recall.

Encouraging Retail Sectors Providing Fresh Cut Produce to the Consuming Public to Require Compliance with the Guidelines.

Finally, the Guidelines encourage produce growers and packers, fresh cut produce processors, and shippers to work with retail sectors to develop technologies that allow for the identification of fresh-cut produce from the farm to the processing facility, on to the retailer, and finally, the consumer. Although the Guidelines do not yet

20 Note that in most states, the statute of limitations on personal injury claims is two years.
address food service suppliers, restaurants, and supermarkets, the Guidelines contemplate and it would be advisable for such entities to require their suppliers to produce documentation of steps taken to comply with the Guidelines and keep similar records as to supply, distribution, and inspection upon receipt of fresh and fresh cut produce for sale to the ultimate consuming public. Buyers of fresh cut produce should consider requiring producers and suppliers to provide self or third party audit verification of commodity-specific industry guidelines already in existence for melons, lettuce, and leafy greens. Additional industry specific guidelines with respect to green onions and herbs are reported to be in progress.

Some entities further up the production and distribution chain acted to require evidence of compliance even before the FDA Guidelines were issued. For example, in October, 2006, executives at eight supermarket chains and distributors including Safeway, Sysco, Wegmans, and Kroger sent a letter to growers and packers demanding that they develop a food safety program for lettuce and other leafy greens. The Food Marketing Institute, which represents large retailers and wholesalers, and the National Restaurant Association were also reported to be developing separate guidelines prior to the FDA’s action on the subject.

Industry Response to the Guidelines and Their Role in Civil Litigation Related to Food-Borne Illnesses.

Although these Guidelines mark the first time the FDA has formally advised produce processors to adopt a system of safety checks similar to those used in the meat industry, consumer advocates, produce growers, and food handlers have suggested that the agency go further to prevent and guard against food-borne illnesses. At a recent public hearing held by the FDA to address problems, challenges, and progress in the area of food safety, a director of the West Coast office of the Consumers Union called for greater government oversight of the fresh produce industry and expressed doubts with leaving the industry in charge of developing good agricultural practices. The director of the FDA’s Food Safety and Security Staff defended the Guidelines as a risk-based


22 See Department of Health and Human Services, Food and Drug Administration, Safety of Fresh Produce; Public Hearings; Request for Comments, 72 F.R. 8750 (Feb. 27, 2007).

23 Shin, Anny, supra note 1.

24 Id.

25 See Bailey, Brandon, Critics Attack FDA’s Guidelines for Cut Produce, Call Them Weak, SAN HOSE MERCURY NEWS, Mar. 13, 2007 (noting that one consumer advocate called the Guidelines “too little, too late,” because they are only advisory and that California produce growers are drafting a more detailed set of guidelines for spinach, lettuce, and other leafy greens); Alonso-Zaldivar, Ricardo, Federal Rules for Vegetables are Weaker Than for Meat, LOS ANGELES TIMES, Sept. 22, 2006 (noting that while safety guidelines for fresh produce are broadly supported by the agricultural industry, there is no system for assuring that they are followed by every grower, processor, and shipper); Engel, Mary, Spinach Warning Lifted, But Worries Remain, LOS ANGELES TIMES, Sept. 30, 2006 (quoting the Deputy Director for Prevention Services at California’s Department of Health Services in saying that to date, the voluntary process had not resulted in prevented outbreaks).

approach that focuses on prevention of food-borne illnesses and rapid responses when outbreaks occur.\textsuperscript{27} The director noted that while regulations are always an option for food safety, the Guidelines are easier to change with developments in science and should be given a chance to work.\textsuperscript{28}

The Guidelines are by no means the last word on the subject of fresh cut produce. Additional public hearings are scheduled in which all those in the chain of distribution of fresh cut produce have been invited to participate.\textsuperscript{29}

In addition to such hearings, the Guidelines may be tested and interpreted in the courts in the context of product liability claims arising from food borne illnesses. For example, soon after the FDA’s announcement, in the fall of 2006, that fresh spinach was contaminated by \textit{E. coli}, a proposed class action and three personal injury complaints for strict liability, breach of warranty, and negligence were filed against Natural Selection Foods and the Dole Food Company stemming from the growing, harvesting, packaging, supplying, marketing, and distribution of fresh spinach.\textsuperscript{30} The proposed class is defined as anyone in the United States who purchased contaminated spinach that was usable but went unused at the time of the FDA announcement, and the class members seek recovery of sums they paid for spinach they could not use.\textsuperscript{31} Had the Guidelines been in place prior to the \textit{E. coli} outbreak, Plaintiffs’ attorneys would undoubtedly be citing to them as evidence, and arguing that they should be conclusive proof, of the standard of care required of producers, processors, and all involved in the chain of distribution of fresh produce. Prior cases support the notion that FDA guidelines provide at least some evidence of due or reasonable care and, thus, the current Guidelines could very well become the standard to which such defendants in food related products liability cases are held.\textsuperscript{32} On that note, however, the Guidelines, if implicated and compliance therewith properly and fully recorded, can also serve as a means of defending producers, processors, and all involved in the chain of distribution of fresh produce from liability for food-borne illnesses caused by contaminated fresh produce.\textsuperscript{33}

In the end, the Guidelines are both nonbinding recommendations by the government agency charged with ensuring food safety and, at the very least, a mechanism for demonstrating reasonable conduct or lack thereof in civil litigation. Thus, those in the fresh cut produce industry and distribution chain should not be lured into a false sense of security by the FDA’s designation of the Guidelines as voluntary and non-binding. Judges and juries will likely apply those same Guidelines to aid in their determination of reasonable care and what was once thought to be a voluntary and recommended practice, if ignored, may soon become a basis for high exposure and liability for food-borne illnesses caused by contaminated fresh cut produce. Thus, the best practice is to review and implement the Guidelines in the near future as doing so will avoid contaminated fresh cut produce and reduce the risk and occurrences of resulting food-borne illnesses and civil liability.

\textsuperscript{27} See id.  
\textsuperscript{28} Id.  
\textsuperscript{29} See Department of Health and Human Services, Food and Drug Administration, Safety of Fresh Produce; Public Hearings; Request for Comments, supra note 21 (announcing public hearings on the recently announced Guidelines).  
\textsuperscript{30} See Mealey’s Litigation Report: Food Liability, Class Complaint, Personal Injury Allegations Follow Announcement of E. coli Outbreak in Fresh Spinach.  
\textsuperscript{31} See id.  
\textsuperscript{33} See Feldman v. Lederle Labs, 608 A.2d 356 (N.J. Super. 1992) judgment aff’d as modified on other grounds, 625 A.2d 1066 (N.J. 1993) (noting that efforts to comply with FDA regulations could be considered evidence of the defendant’s reasonableness).