

Background

More than a decade ago, the Clinton Administration identified the safety of fresh produce (fruits and vegetables intended to be eaten raw) as a priority for action in its first-ever, national “Food Safety Initiative.”¹ Since that time, the Food and Drug Administration (FDA), the federal agency responsible for produce safety, has followed a voluntary approach in addressing the problem, opting for guidance documents² and letters to growers³ over mandatory regulations that would establish enforceable safety standards. This approach has not succeeded: during the intervening period, foodborne-illness outbreaks linked to fresh produce have persisted. According to one source, from 1990 through 2005, at least 713 foodborne-illness outbreaks have been linked to produce items.⁴ In recent years, two high-profile outbreaks have captured public attention: in 2006, an *E. coli* O157:H7 outbreak, resulting in 3 deaths and nearly 200 illnesses, was traced to bagged spinach,⁵ and just this past summer, *Salmonella* Saintpaul-tainted peppers (and perhaps tomatoes) made more than 1,400 people sick.⁶

In response to the continuing concern about produce safety and the federal government’s failure to adopt binding regulations, grower groups, trade associations, and retailers have all put into place their own sets of guidelines and safety standards

Guidelines Compared

In comparing broad guidelines intended to apply to the entire range of fresh fruits and vegetables with commodity-specific guides (for leafy greens and tomatoes), we acknowledge that there is a certain “mixing of apples and oranges.” Nevertheless, we believe this comparison is instructive. There are

aimed at the primary safety concern, which is the microbial contamination of fresh fruits and vegetables.⁷ These guidelines, generally known as “Good Agricultural Practices” (or GAPs), address issues such as water quality, manure use, worker hygiene, and animal control, all of which can be avenues for contamination. Controlling contamination at its source is critical when you are dealing with fresh produce. Thorough cooking can kill most pathogens in food; however, because fresh fruits and some vegetables are typically eaten raw, there is no intervening “kill step.”

Given diminished consumer confidence in the safety of fresh produce, the burden on growers of meeting competing produce-safety standards, and the significant financial impact of foodborne-illness outbreaks on growers and retailers,⁸ there is currently substantial support for FDA’s adoption of mandatory produce-safety regulations.⁹

To inform the policy debate, PSP has analyzed six different sets of produce-safety standards or guidelines and produced a side-by-side comparison of select provisions. In addition to the four areas noted above, the chart also includes provisions relating to the growing and harvesting of produce that address the condition of the field as well as field sanitation.

many different views on the approach FDA should take in drafting federal regulations governing produce safety and therefore, a consideration of all different approaches to produce safety-standards (e.g. general provisions and commodity-specific requirements) is warranted.

The following guidelines represent a wide range of “authors:” in addition to FDA, they include an international organization, a private-sector certifying body, a group of large retail buyers, a group of growers, and a state government:

- *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (FDA 1998 Guidance)*: issued by FDA in 1998, it contains voluntary guidelines related to microbial food-safety hazards and good agricultural and management practices.¹⁰
- *Code of Hygienic Practice for Fresh Fruits and Vegetables (Codex Provisions)*: adopted in 2003 by the Codex Alimentarius Commission, a body established in 1963 by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) to develop food standards and guidelines.¹¹
- *Food Safety Leadership Council On-Farm Produce Standards (FSLC Standards)*, issued in 2007 by a group of large retailers/customers.¹²
- *GLOBALGAP Standards*: adopted in 2007, it is a single integrated standard with modular applications for different product groups.

Key Findings of the Comparison

A key finding of the PSP comparison is that FDA’s 1998 Guidance is woefully out of date; many private standards currently include more stringent standards. Some of the important issues not addressed in the existing FDA Guidance are:

- microbial standards and a sampling and testing protocol for irrigation water;
- consideration of the prior use of a growing field;

The standards considered in this comparison include those that apply to all farms, to all crop-based operations, and those that apply only to growers of fruits and vegetables).¹³

- *Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens (June 13, 2008 edition) (Leafy Greens Guide)*: this is the most recent version of the standards that are followed by the growers who have signed the California Leafy Green Products Handler Marketing Agreement.¹⁴
- *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain* (Edition 1.0) and the *Tomato Best Practices Manual (Florida Tomato Rule)*: these two documents were incorporated into the Florida Tomato Rule, which implements legislation passed in the State of Florida in 2008.¹⁵

Some of these provisions are mandatory (the Florida Tomato Rule and the Leafy Green Guide for those growers that enter into the agreement) while the others are voluntary. Many of the headings in the chart attempt to reflect this distinction. In places where a particular guideline does not exactly reflect a heading, an explanatory footnote is included.

- microbial standards and a sampling and testing protocol for manure composting;
- the proximity of growing fields to Concentrated Animal Feeding Operations (“CAFOs”); and
- prohibition of smoking, eating, or spitting in growing areas.

While FDA recently issued a notice seeking comments on how its 1998 Guide could be improved,¹⁶ there is no deadline for issuing a revised guide.

Other key findings of the comparison include the following:

- Four of the guides (GLOBALGAP Standards, FSLC Standards, Leafy Greens Guide, and Florida Tomato Rule) include microbial standards for irrigation water and set some specific direction for regular, periodic sampling and testing.
- Three of the documents (FDA 1998 Guidance, FSLC Standards, and Leafy Greens Guide) prohibit the growing of produce on flooded land.
- Two of the standards (Codex Provisions and GLOBALGAP Standards) apparently allow the use of raw manure on growing fields
- Two of the guides (FSLC Standards and Leafy Greens Guide) include specific standards for the composting of manure and manure-containing soil amendments and set a specific sampling and testing protocol.
- Four of the documents (FDA 1998 Guidance, Codex Provisions, FSLC Standards and Leafy Greens Guide) address the need to store manure away from growing fields, but they do so in general terms and do not specify a set distance requirement.
- All of the guides, except one (GLOBALGAP Standards), contain provisions relating to animal control, but each one takes a different approach.
- Two of the standards (FSLC Standards and Leafy Greens Guide) contain a provision setting a minimum distance between growing fields and CAFOs.
- While all six guidelines address the proximity of toilets to field workers, some use very general language, while others set a specific distance (e.g., either within ¼ mile or 500 meters of all workers).
- Two of the guidelines (FSLC Standards and Leafy Greens Guide) require that growers have a policy addressing disposition of produce that has come into contact with blood or bodily fluids, with the FSLC Standards expressly requiring destruction of the product.
- While all of the guidelines state that harvesting equipment/tools should be sanitized or disinfected, only one (Leafy Greens Guide) expressly requires that the sanitation procedure be verified.
- Only two of the guidelines (FDA 1998 Guidance and Codex Provisions) include a specific provision directing that damaged harvesting containers be disposed of.

GAP Provisions Included in the Chart

AGRICULTURAL WATER

Sets or recommends specific microbial standards for irrigation water

Water is used at numerous points in the growing and harvesting of fresh produce. The likelihood of water being the source of microbial contamination depends on a number of factors: of particular importance is whether the water comes into contact with the edible portion of the produce.¹⁷

In order to determine whether water is suitable for use in irrigation, four of the six guidelines set specific microbial standards. Both the FSLC Standards and the Leafy Greens Guide set generic *E. coli* standards for well water and surface water (which are different). By contrast, the Florida Tomato Rule requires that irrigation water meet the U.S. Environmental Protection Agency (EPA) standard for recreational water, and that foliar application of water at the time of harvest meet the EPA standard for potable water. GLOBALGAP applies WHO guidelines to treated sewage water used by irrigation, while possibly polluted water must comply with either WHO guidelines or local standards.

Specifies regular, periodic water sampling and microbial testing

The Leafy Green Guide provides the most detailed information on the protocol to follow when sampling and testing for microbial contamination is required, setting out different procedures depending on whether the application is foliar or non-foliar, and whether or not the water comes in contact with the edible portion of the fruit. Both the FSLC Standards and the Florida Tomato Rule contain some information on microbial testing of agricultural water: the FSLC sets testing frequencies for well and surface water, while the Florida regulations simply direct that ground water be tested at least annually and surface water, at least quarterly.

Two other guidelines set more general standards: the GLOBALGAP Standards states that the frequency of a water analysis should depend on the risk assessment and the characteristics of the particular crop. The Codex Provisions simply state that “where necessary,” growers should have their water tested for microbial contaminants.

Only the FDA 1998 Guidance minimizes the importance of regular microbial sampling and testing of agricultural water, stating that “[m]icrobial testing of agricultural water may be of limited usefulness.” However it does continue that “appropriate microbiological testing may be useful for confirming water quality concerns in extreme situations (e.g., polluted water source) and in assessing the effectiveness of certain control programs (e.g. clean-up of well water).”¹⁸

Assess impact of adjacent land on water quality

Growers should evaluate the impact on their growing fields of surrounding land uses because this land could be a source of contamination, especially after a heavy rainfall.¹⁹ Four of the six guidelines mention the need to assess the impact of adjacent land on water quality. FDA states that growers should be “aware of current and historical use of land” and that operators “should consider what affects their portion of the watershed.” The FSLC Standards direct growers to conduct a risk assessment to “review surrounding land use impact on water quality,” while the Leafy Greens Guide directs growers to evaluate all adjacent land and waterways for “possible sources of pathogens.” In the section on water quality, the Florida Tomato Rule notes that consideration should be given to a number of factors that may have an impact on water quality, including what activities occur or conditions exist on adjacent land.

GROWING FIELD

Consider prior use of growing field

Prior use of a growing field—for example, as a landfill—may be relevant to the safety of produce being grown in it.²⁰ Only the FDA Guidance fails to mention consideration of the prior use of the growing field as having an impact on the safety of the fresh produce grown in it. All of the other guides mention the need to take into account prior use and the FSLC goes the farthest, specifically requiring that a soil analysis be done if the field has been used in the past for other than growing produce.

Prohibits growing on flooded land

Only three of the six guidelines prohibit the growing of produce on flooded land. FDA addressed this issue in a more recent letter to

growers (in 2005),²¹ not in the 1998 Guidance. The FSLC Standards exclude tree crops and stone fruit from the prohibition on harvesting produce grown on flooded fields. These standards contain the most stringent provisions, requiring that there be documented testing results prior to replanting to ensure that soil meets EPA and other regulatory standards. The Leafy Green Guide prohibits harvesting within 30 feet of flooding but notes that a risk analysis may dictate a greater buffer distance. It also states that the time interval before planting can commence following the receding of floodwaters is 60 days, provided that the soil has sufficient time to dry out, and further provides that appropriate soil testing can be used to shorten this period.

MANURE

Prohibits use of raw manure

Raw manure or incompletely treated manure can be a potent source of microbial contamination.²² Four of the guidelines strongly recommend against or prohibit the use of raw manure or products containing raw manure; in fact the Leafy Greens Guide specifies that if raw manure has been applied to fields, a grower must wait one year prior to growing these commodities. By contrast, two of the guidelines do not prohibit the use of raw manure on growing fields. The Codex Provisions allow its use only if “appropriate corrective actions” are taken to reduce microbial contaminants, but no standards or specific actions are mentioned. GLOBALGAP does not mention raw manure and only prohibits the use of raw human sewage sludge on growing fields.

Sets specific standard for composting manure

Only two of the guides include specific standards for the composting of manure and manure-containing soil amendments. The FSLC Standards set a level for generic *E. coli* and require a negative test result for *Salmonella*, *E. coli* O157:H7, and *Shigella*, while the Leafy Greens Guide sets levels for fecal coliforms, *Salmonella* and *E. coli* O157:H7. The FDA Guidance, the Codex Provisions, and the GLOBALGAP Standards do not contain any such specifications. The Florida Tomato Rule addresses the issue in a general manner, providing that “only properly composed manures are allowed.”

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MANURE

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Requires or recommends sampling and testing

Only the FSLC Standards and the Leafy Greens Guide set specific sampling and testing requirements; the former simply requires growers to create a compost monitoring plan that outlines sample collection procedures while the latter prescribes the sampling procedure (a 12-point sampling plan with a composite sample and the testing of each lot before it is applied to a production field).

Store and treat manure away from growing fields

This particular provision is aimed at eliminating the possibility that run-off from a manure storage area could contaminate growing fields. The FDA Guidance and the Codex Provisions address this issue, but they do so in general terms (manure storage should be situated “as far as practicable” or “avoid locating in proximity to production”). By contrast, the FSLC Standards provide that, in general, manure should be stored and treated at least 400 feet from the edge of crops.

ANIMAL CONTROL

Excludes animals from growing areas

The presence of domestic or wild animals—and in particular, their feces—in the growing fields can lead to contamination of produce.²³ Only the GLOBALGAP Standards fail to address this issue; the remaining five guidelines all contain provisions relating to animal control, but each takes a different approach. The FSLC Standards and the Leafy Greens Guide both speak in terms of animals of “significant public health concern” or of “significant risk.” The FDA Guidance and the Florida Tomato Rule address domestic and wild animals separately, noting that domestic animals “should be excluded” from growing fields, and that steps should be taken (such as the creation of buffer

zones) “to deter or redirect” or “discourage” wildlife (which in the Florida regulations is specified as reptiles, amphibians, and rodents.)

Requires set distance from CAFOs

Only the FSLC Standards and the Leafy Green Guide contain provisions that set a minimum distance between growing fields and Concentrated Animal Feeding Operations (or “CAFOs”), facilities that generate significant amounts of manure that may contain harmful pathogens. The FSLC Standards set the minimum distance at one mile from the end of a row of crops, while the Leafy Greens Guide sets an interim distance of 400 feet from the edge of the crop.

WORKER HEALTH AND HYGIENE

Prohibits smoking, eating, spitting, gum chewing in growing areas

Workers in the field who do not follow proper hygiene—fail to use toilet or handwashing facilities, spit in the growing area, come to work sick—can easily contaminate the produce they are handling.²⁴ All of the guidelines except for the FDA Guidance address this issue, with the FSLC Standards using the strongest language, providing that “eating, drinking, chewing gum/tobacco, candy, and smoking are prohibited in the growing area.”

Specifies location of toilets

All six guidelines address the proper placement of toilets to ensure they are easily accessible to workers in the field, with the most general language

used in the Codex Provisions (facilities should be located “in close proximity to the fields”) and the Leafy Greens Guide (“field sanitary program should address the placement of field sanitation units”). The FDA 1998 Guidance, the FSLC Standards and the Florida Tomato Rule all require toilets to be within ¼ mile of all workers (which is the standard set in regulations of the U.S. Occupational Safety and Hazard Administration). GLOBALGAP sets the distance at 500 meters.

Requires destruction of product that comes in contact with blood or bodily fluids

Only the FSLC Standards require that growers destroy any produce that has come into contact with blood or bodily fluids.

FIELD SANITATION

Sanitize or disinfect harvesting equipment and test/verify efficacy of sanitation

All of the guidelines included in the chart state that harvesting equipment/tools should be sanitized or disinfected but only the Leafy Greens Guide expressly requires that the sanitation process/procedure should be verified.

Dispose of damaged harvest containers

Only the FDA Guidance and the Codex Provisions expressly state that damaged harvesting containers that are no longer “cleanable” or can no longer be kept “in a hygienic condition” should be discarded. The remaining four guidelines do not include such a specific provision.

Notes

- ¹ The White House, Office of the Press Secretary, Memorandum for the Secretary of Health and Human Service and the Secretary of Agriculture, Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables (1997), available at <http://www.foodsafety.gov/~dms/fs-wh2.html>.
- ² See HHS, FDA, CFSAN, Guidance for Industry, Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (1998) (*FDA 1998 Guide*), available at <http://www.cfsan.fda.gov/~dms/prodguid.html>; HHS, FDA, Guidance for Industry, Guide to Minimize Microbial Food Safety Hazards for Fresh-Cut Fruits and Vegetables, 2008, available at <http://www.cfsan.fda.gov/~dms/prodgui4.html>.
- ³ See HHS, FDA, CFSAN, Office of Plant and Dairy Foods, Letter To Firms that Grow, Pack, or Ship Fresh Lettuce and Fresh Tomatoes (2004), available at <http://www.cfsan.fda.gov/~dms/prodltr.html>; HHS, FDA, CFSAN, Office of Plant and Dairy Foods, Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce (2005), available at <http://www.cfsan.fda.gov/~dms/prodltr2.html>.
- ⁴ Caroline Smith DeWaal and Farida Bhuiya, *Outbreaks by the Numbers: Fruits and Vegetables 1990-2005*, Center for Science and the Public Interest, 5, available at <http://www.cspinet.org/foodsafety/IAFPPoster.pdf>.
- ⁵ See *Ongoing Multistate Outbreak of Escherichia coli serotype O157:H7 Infections Associated with Consumption of Fresh Spinach—United States, September 2006*, MMWR, 55(38); 1045-1046 (Sept. 29, 2006), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5538a4.htm>.
- ⁶ See *Outbreak of Salmonella Serotype Saintpaul Infections Associated with Multiple Raw Produce Items—United States, 2008*, MMWR, 57(34); 929-934 (Aug. 29, 2008), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5734a1.htm>.
- ⁷ A number of different pathogens—such as *E. coli* O157:H7, various strains of *Salmonella*, and *Cyclospora*—have been associated with fresh fruits and vegetables. For more information, see HHS, FDA, USDA, CFSAN, Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables, Appendix B (2008), available at <http://www.cfsan.fda.gov/~dms/prodgui4.html>; and FDA, CFSAN “Foodborne Pathogenic Microorganisms and Natural Toxins Handbook, Bad Bug Book” (2008), available at <http://www.cfsan.fda.gov/~mow/intro.html>.
- ⁸ Estimates of the economic cost to that industry in Florida alone have been more than \$100 million and in Georgia close to \$14 million. Reginald L. Brown testifying before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *The Recent Salmonella Outbreak: Lessons Learned and Consequences to Industry and Public Health*, 110th Cong. 2nd sess., July 31, 2008. http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.073108.Brown-Testimony.pdf; *FDA tomato alert costly to Georgia producers Southeast Farm Press*, September 4, 2008, available at <http://southeastfarmpress.com/vegetables-tobacco/salmonella-warning-0905/index.html>.
- ⁹ See, e.g. *United Fresh, PMA Endorse Common Produce Safety Principles* (May 25, 2007), available at http://www.unitedfresh.org/news/338/United_Fresh_PMA_Endorse_Common_Produce_Safety_Principles?page=338&title=United_Fresh_PMA_Endorse_Common_Produce_Safety_Principles&content_type=news.
- ¹⁰ Available at <http://www.cfsan.fda.gov/~dms/prodguid.html>.
- ¹¹ Available at www.codexalimentarius.net/download/standards/10200/cxp_053e.pdf.
- ¹² Available at <http://www.perishablepundit.com/DailyPundit/PunditImages/FSLC-On-FarmStandards-11-2007.pdf>. Members of the FSLC included Avendra, Darden, Disney, McDonald’s, Publix, and Walmart, While the FSLC Standards were criticized by growers’ organizations, it is our understanding that they are being used by some third-party auditors in their auditing of produce suppliers for retailers.
- ¹³ Available at http://www.globalgap.org/cms/front_content.php?idcat=3.
- ¹⁴ Available at http://www.caleafygreens.ca.gov/members/documents/LGMAAcceptedGAPs06.13.08_001.pdf. (*Leafy Greens Guide*).
- ¹⁵ Available at <http://www.cfsan.fda.gov/~acrobot/tomatsup.pdf> and <http://www.doacs.state.fl.us/fs/ TomatoBestPractices.pdf>. A more recent edition of the commodity-specific guide for tomatoes has been published but, as of the date of publication, it had not been officially incorporated into the Florida regulation.
- ¹⁶ See 73 Fed. Reg 51306 (2008) available at <http://edocket.access.gpo.gov/2008/pdf/E8-20187.pdf>.
- ¹⁷ *FDA 1998 Guide* at 9–10.
- ¹⁸ *Id.* at 12–13.
- ¹⁹ *Id.* at 11.
- ²⁰ *Leafy Greens Guide* at 13.
- ²¹ HHS, FDA, CFSAN, Office of Plant and Dairy Foods, Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce (2005), available at <http://www.cfsan.fda.gov/~dms/prodltr2.html>.
- ²² *FDA 1998 Guide* at 19.
- ²³ *Id.* at 24.
- ²⁴ *Id.* at 26.