



Vegetables and Pulses Outlook: Special Article

The Food Safety Modernization Act and the Produce Rule*

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In January 2011, President Obama signed the Food Safety Modernization Act (FSMA) into law. Part of this legislation requires the U.S. Food and Drug Administration (FDA) to develop mandatory microbial food safety practices for produce growers. On January 16, 2013, FDA published the proposed rule regulating produce—Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption—commonly known as the produce rule (*Federal Register*, 2013a). The produce rule establishes science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities for which FDA has determined such standards minimize the risk of serious adverse health consequences or death. While the proposed produce rule is the focus of this article, it is not the only part of FSMA that will affect the produce industry. Some produce operations may fall under the proposed preventive control rule (published at the same time as the produce rule) (*Federal Register*, 2013b). Additional rules that may apply to produce are not yet published.

From Voluntary to Mandatory Practices

A series of high-profile foodborne illness outbreaks in the mid-1990s, traced back to fresh raspberries and spring mix, first focused attention on microbial contamination of produce (Calvin, 2003). In 1998, FDA published a voluntary guidance document on good agricultural practices (GAPs) titled *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* to help producers reduce the risk of microbial contamination. For fresh and fresh-cut produce there is no effective microbial elimination step such as pasteurization for milk; as a result, GAPs focus on reducing the risk of microbial contamination but do not eliminate the risk.

Use of GAPs became standard industry procedure for some, but not all, growers. In 2004, after more outbreaks, FDA met with the produce industry to encourage them

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to develop voluntary commodity-specific good agricultural practices (CSGs) that targeted specific risk factors for individual commodities with a history of problems. Some CSGs developed into voluntary or mandatory food safety programs, most often for industries that had experienced foodborne illness outbreaks traced to their commodity. A few examples demonstrate the variety of tools industry groups have used to accomplish this task.

After the 2006 foodborne illness outbreak linked to California spinach, the California leafy greens industry developed the California Leafy Greens Marketing Agreement (Calvin, 2007). Although membership is voluntary, members must comply with food safety metrics and face audits to remain certified as members. The agreement uses California Department of Food and Agriculture (CDFA) auditors licensed and trained by USDA's Agricultural Marketing Service (AMS). Most California leafy greens handlers belong to the marketing agreement but foodborne illness outbreaks linked to California leafy greens have continued to occur. Arizona has a similar marketing agreement for leafy greens. Leafy greens operations in other States often choose to produce in accordance with the California Leafy Greens Marketing Agreement metrics. In 2009, several organizations proposed a national leafy greens marketing agreement. In 2011, based on evidence received at a public hearing, AMS published a proposed rule recommending establishment of a national marketing agreement and invited public comment. Now the industry waits for AMS to decide how or whether to proceed with an agreement.

California cantaloupe growers, who faced market backlash from outbreaks linked to cantaloupe in other States in 2011 and 2012, voted in 2012 to add food safety requirements to an existing State marketing order. A marketing order, unlike an agreement, is mandatory for all operations in the defined region. The industry expects the marketing order to be in operation in May for the beginning of the 2013 season. Recent outbreaks were linked to Colorado, North Carolina, and Indiana—areas with much smaller cantaloupe production than California. In 2012, the cantaloupe producers in the Rocky Ford region of Colorado formed the Rocky Ford Cantaloupe Growers Association. A condition of membership is a mandatory GAPs audit conducted by Colorado Department of Agriculture auditors licensed and trained by AMS. This organization, which is limited to growers in the Rocky Ford area, has 18 grower members. In 2013, growers started the Eastern Cantaloupe Growers Association which is open to any growers from east of the Rocky Mountains to the east coast. Individual growers apply for membership showing they have complied with the specific food safety standards of the organization and agreeing to one unannounced audit during the season from an approved third-party auditor. Both the Rocky Ford Growers Association and the Eastern Cantaloupe Growers Associations formed as voluntary trade associations, bypassing marketing orders and agreements.

About the time FDA identified tomatoes as one of the commodities that needed CSGs (2004), Florida tomato growers tried to include food safety in their existing Federal marketing order. After discussions with AMS, the Florida tomato industry eventually turned to State statutes to make the food safety standards mandatory beginning in 2007 (*Federal Register*, 2013a, p. 3514). California tomato farmers tried to include food safety practices in their existing State marketing order but did not receive CDFA approval. In 2007, a group of growers, representing about 90 percent of California fresh-market tomato production, started a cooperative that requires that participants employ GAPs with audits conducted by CDFA auditors licensed and trained by AMS.

There are no current statistics on use of GAPs or other food safety practices in the United States. Growers could adopt higher food safety standards to minimize their own business risks, to respond to buyer demands, or to participate in industry food safety programs. Those who were proactive in adopting food safety practices may not face many additional requirements with FSMA; others may face substantial new requirements.

Despite organized efforts over the last two decades to reduce the risk of foodborne illness in produce, the latest research from the Centers for Disease Control and Prevention found that 46 percent of foodborne illnesses in the period 1998-2008 were attributed to produce (Painter et al, 2013). Of course, these data do not reflect more recent activities to improve food safety. Continued outbreaks linked to produce put pressure on Congress to do more about this problem.

Even when the final mandatory produce rule is in operation, voluntary or mandatory industry programs may still fill a need. A grower organization may impose tougher standards based on the consensus of the industry while FDA

might have to wait for scientific evidence to show that a more aggressive standard has merit. With large industry and government investment, however, new research is quickly becoming available. Grower organizations are nimble and can quickly require new practices as new risks or solutions appear; government regulations tend to require far more coordination, legal review, and public scrutiny, so therefore take much longer to develop. Many of the grower programs include mandatory annual audits; FDA will not be able to inspect all farms every year under FSMA. The proposed rule states “With a community as large and diverse as the produce farming industry, it is not reasonable to expect that industry-wide compliance can be gained primarily through inspection and enforcement, though, of course, inspection and enforcement must be a component of our efforts. Inspections will, of necessity, be targeted to those farms that present the greatest risk (*Federal Register*, 2013a, p. 3609).” The rule then states that rigorous audits under the national or regional marketing agreements can be an important tool for fostering compliance, as can nonregulatory audits initiated by growers, packers, and buyers. Grower organizations may want to continue their programs with mandatory annual audits to minimize the risk to the industry. Also, retail and foodservice buyers might prefer the mandatory annual audits the industry food safety programs provide.

FSMA Product Coverage

The proposed produce rule applies to most raw produce (fruit and vegetables, including mushrooms, sprouts, peanuts, tree nuts, and herbs) for human consumption. Produce not covered by the rule include:

- Certain specified produce commodities that are rarely consumed raw.¹
- Produce that is not a raw agricultural commodity (RAC). A RAC is defined as “any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.” A head of lettuce packed in the field for sale is a RAC. If a head of lettuce is processed into a bagged salad it is a processed product, not a RAC. Processed products for off-farm use fall under other FDA regulations. The proposed produce rule applies to activities within the “farm” definition. It states “A farm that chooses to transform its RACs into processed foods should be considered to have chosen to expand its business beyond the traditional business of a farm.”
- Produce that qualifies under the exemption for products that receive commercial processing that adequately reduces the presence of microorganisms of public health significance—although documentation is still required.
- Produce used only for personal or on-farm consumption.

FSMA Farm Coverage

All farms in the United States that grow, harvest, pack, or hold produce are covered with the following exemptions:

- Produce from farms that have an average annual value of food sold during the previous 3-year period of \$25,000 or less.
- A qualified exemption for farms with food sales averaging less than \$500,000 per year during the last 3 years AND the farm sales to qualified end-users must exceed sales to others (the Tester Amendment). Qualified end users are the direct consumer (an individual, not a business) of the food or a restaurant or retail food establishment that is located in the same State as the farm or not more than 275 miles away. But even those that qualify for the exemption must comply with certain labeling requirements. Also, FDA can withdraw the qualified exemption.

¹ Commodities exempted under the proposed rule are: arrowhead, arrowroot, artichokes, asparagus, beets, black-eyed peas, bok choy, Brussels sprouts, chickpeas, collard greens, crabapples, cranberries, eggplant, figs, ginger root, kale, kidney beans, lentils, lima beans, okra, parsnips, peanuts, pinto beans, plantains, potatoes, pumpkin, rhubarb, rutabaga, sugarbeet, sweet corn, sweet potatoes, taro, turnips, water chestnuts, winter squash (acorn and butternut squash), and yams.

FSMA Food Safety Practices Covered

The produce rule focuses on prevention of microbial contamination of produce, not product testing, except for sprouts in certain conditions. Some of the major food safety practices that are addressed in the proposed rule include standards directed to:

- Personnel qualifications and training
- Health and hygiene
- Agricultural water
- Biological soil amendments of animal origin and human waste
- Domesticated and wild animals
- Growing, harvesting, packing and holding activities
- Equipment, tools, buildings, and sanitation
- Sprouts

See the proposed produce rule and FSMA web page for complete details on the specific food safety practices (*Federal Register*, 2013a; U.S. FDA, 2013).

From Proposed Rule to Final Rule and Implementation

Now that the proposed rule has been published, the public has until May 16, 2013 to provide comments (FDA has received several requests to extend the comment period). In addition, FDA is holding listening sessions to hear public comments. After the May deadline, FDA will consider the comments and decide whether revisions are needed. Once FDA issues a final rule, it becomes effective 60 days later but producers would not have to comply immediately with the new rule. Most farms would have 2 years to comply. For the produce rule, FDA defines small farms as those with more than \$250,000 but not more than \$500,000 in food sales (on a rolling basis, average annual monetary value of food sold during the previous 3-year period); these farms would have 3 years to comply.² FDA defines very small farms as those with more than \$25,000 but no more than \$250,000 in food sales; these farms would have 4 years to comply. All farms, regardless of size, would have 2 additional years to comply with some of the water requirements of the produce rule. FDA is sponsoring training activities to help farms come into compliance. The Produce Safety Alliance was established under a cooperative agreement between FDA, USDA, and Cornell University to improve understanding and implementation of GAPs with curriculum development and training. There is also a Sprouts Safety Alliance.

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² USDA defines a small farm as one with a gross cash farm income of less than \$250,000 (Hoppe, MacDonald, and Korb, 2010).

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