
Food Safety Modernization Act

The Impact of the Produce Rule

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Southern Legislative Conference

Food Safety Modernization Act Webinar



Produce Safety Proposed Rule

- **The Extent of this Rule....**
 - Establishes science-based minimum standards for the safe production and harvesting of produce
 - The most significant revision to food safety law in this country since 1938:
 - 1,000 pages
 - 500 scientific, economic and industry references
 - Over 110 FDA questions
- **Page 3537 of the Federal Register....**



Produce Safety Proposed Rule

Covered Produce

almonds, apples, apricots, aprium, asian pear, avocados, babaco, bamboo shoots, bananas, Belgian endive, blackberries, blueberries, broccoli, cabbage, cantaloupe, carambola, carrots, cauliflower, celery, cherries, citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cucumbers, curly endive, garlic, grapes, green beans, guava, herbs (such as basil, chives, cilantro, mint, oregano, and parsley), honeydew, kiwifruit, lettuce, mangos, other melons (such as canary, crenshaw and persian), mushrooms, nectarine, onions, papaya, passion fruit, peaches, pears, peas, peppers (such as bell and hot), pineapple, plums, plumcot, radish, raspberries, red currant, scallions, snow peas, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), tomatoes, walnuts, watercress, and watermelon

Exempt Produce

arrowhead, arrowroot, artichokes, asparagus, beets, black-eyed peas, bok choy, brussels sprouts, chick-peas, 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.

Produce Safety Proposed Rule

- **Which categories of produce are covered?**
 - Produce defined as a fruit and vegetables
 - Includes mushrooms, sprouts, herbs and tree nuts
 - Does not include grains
- **What is not covered**
 - Produce rarely consumed raw
 - Produce used for personal consumption
 - Produce that is subjected to processing or manufacturing (requires registration under food facilities)

Produce Safety Proposed Rule

- **Which farms are covered?**
 - Domestic and foreign farms that grow, harvest, pack, or hold covered produce with an average food sales during the previous 3-year period or \$25,000 (US dollars) or more.
 - Farms of “mixed-type” type of facilities
- **Farms with a “qualified exemption”**
 - Farms with average food sales of less than \$500,000 that sells primarily to consumers and located within a 275 mile radius of customers.
 - \$25,000 Exemption

Produce Safety Proposed Rule

- **Which hazards are covered?**
 - Worker Training and Health and Hygiene
 - Agricultural Water
 - Biological Soil Amendments
 - Domesticated and Wild Animals
 - Equipment, tools, and Buildings
 - Sprouts
- **Focused on indentified routes of microbial contamination**
- **Considers risk posed by practices, commodities**

Produce Safety Proposed Rule

- **Alternatives are Permitted**
 - Science based alternatives that are equivalent are permitted related to water and biological soil amendments of animal origin
- **Variances Provide Flexibility**
 - U.S. State or Foreign country may petition FDA for a variance from some or all provisions if deemed necessary in light of growing conditions
- **Recordkeeping Required**
 - Required that certain standards are being met (agriculture water testing results)

Produce Safety Proposed Rule

- **Compliance Dates**

- 60-days after publishing of **final** rule

- **Staggered Implementation**

- Very Small Farms (\$25,000 to \$250,000)

- Four years after compliance date
- water six years

- Small Farms (\$250,000 to \$500,000)

- Three years after effective dates
- water five years

- Other Covered Farms

- Two years after effective date
- water four years



Produce Safety Proposed Rule

- **Industry Key Issues to Consider**

- We oppose the concept of producers of any size should be “exempt” from the basic rule
- We are also concerned about produce commodities being *wholly exempt* from the rule
- The exemption list should be addressed as part of Guidance rather than regulation
- Alternative list is too restrictive
- Rule is inadequate for petitioning for variances
- Clearer definitions and “bright line” on what constitutes a farm and food facility
- Segregation of processed and fresh produce under rule

Thank You!

Questions and Discussion

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