FOOD SAFETY MODERNIZATION ACT (FSMA): PRODUCE RULE

how does it impact you

The final rule on produce safety.
WHAT IS THE PRODUCE RULE?

The FDA Food Safety Modernization Act (FSMA) Produce Safety rule is now final, and the earliest compliance dates for some farms begin one year after the effective date of the final rule. The rule establishes, for the first time, science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. This final rule will support the FDA’s efforts to act quickly in response to food-related emergencies and will help the FDA to use its inspectional resources more efficiently.

The definition of “farm” and related terms were revised in the final Preventive Controls for Human Foods Rule, and the same definition of those terms are used in this rule to establish produce standards. Operations whose only activities are within the farm definition are not required to register with the FDA as food facilities and thus are not subject to the preventive controls regulations. The standards of FSMA are based on a foundation of Good Agricultural Practices (GAP). The rule is divided into several parts.

1) AGRICULTURAL WATER: Farmers would ensure that water is safe and of adequate sanitary quality, and with inspection and periodic testing requirements.

2) BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN: The rule specifies types of treatment, methods of application, and time intervals between application of certain soil amendments — including manure and composted manure — and crop harvest.

3) DOMESTICATED & WILD ANIMALS: With respect to domesticated animals, certain measures, such as waiting periods between grazing and crop harvest, if there is a reasonable probability of contamination. Farmers must monitor for wildlife intrusion and not harvest produce visibly contaminated with animal feces.

4) TRAINING: Training for supervisors and farm personnel who handle produce covered by the rule.

5) HEALTH AND HYGIENE: Farm personnel have to follow hygienic practices, including hand washing, not working when sick, and maintaining personal cleanliness.

6) EQUIPMENT, TOOLS, AND BUILDINGS: Requirements for equipment and tools that come into contact with produce, as well as for buildings and other facilities.

7) SPROUTS: Separate standards for sprout production, including treatment of seed before sprouting and testing of spent irrigation water for pathogens.

COVERED PRODUCE INCLUDES THE FOLLOWING EXAMPLES:

1) almonds, apples, apricots, apricot pits, Artichokes-globe-type, Asian pears, avocados, bananas, Belgian endive, blackberries, blueberries, boysenberries, Brazil nuts, broccoli, Brussels sprouts, burro grass, Chinese cabbages, cantaloupe, cantaloupe seeds, carrots, cauliflower, celery, celery root, chestnuts, cherries (sweet), chestnuts, chicory, citrus, cowpea beans, cress, garden lettuce, lychees, macadamia nuts, mangoes, melons, okra, peanuts, horseradish, lentils, ginger, hazelnuts, dates, eggplants, figs, sweet; cranberries, beans; collards; corn, cocoa beans; coffee beans-coffeebird; com; sweet; cranberries; dates; eggplants; figs; garlic; giant sunflower; horseradish; lentils; olive; peanuts; pecans; peppermint; potatoes; pumpkins; squash; broccoli; sweet potatoes; and water chestnuts

2) Mixes of intact fruits and vegetables (such as fruit baskets)

2) Produce that is not a raw agricultural commodity

1) Rarely consumed raw: almonds, apricots, apricot pits, Artichokes-globe-type, Asian pears, avocados, bananas, blackberries, blueberries, boysenberries, Brazil nuts, broccoli, Brussels sprouts, burro grass, Chinese cabbages, cantaloupe, cantaloupe seeds, carrots, cauliflower, celery, celery root, chestnuts, cherries (sweet), chestnuts, chicory, citrus, cowpea beans, cress, garden lettuce, lychees, macadamia nuts, mangoes, melons, okra, peanuts, horseradish, lentils, ginger, hazelnuts, dates, eggplants, figs, sweet; cranberries, beans; collards; corn, cocoa beans; coffee beans-coffeebird; com; sweet; cranberries; dates; eggplants; figs; garlic; giant sunflower; horseradish; lentils; olive; peanuts; pecans; peppermint; potatoes; pumpkins; squash; broccoli; sweet potatoes; and water chestnuts

2) Produce that is not a raw agricultural commodity

3) Produce that is not

THE PRODUCE RULE:

Covering fruits and vegetables that are rarely consumed raw and mixtures of intact fruits and vegetables grown and handled under the same management as other fruits and vegetables grown on the farm or another farm under the same management.
HOW DOES THE RULE APPLY TO YOU?

If you grow, harvest, pack, or hold produce, you may be subject to part or all of the Produce Rule. Check out this chart to see how the rule applies to you.

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Does your farm grow, harvest, pack or hold produce?

- **YES**
  - Your farm is NOT covered by this rule.

Does your farm on average (in the previous three years) have $25k* or less in annual produce sales?

- **YES**
  - Your farm is NOT covered by this rule.

Is your produce one of the commodities that FDA has identified as rarely consumed raw?

- **YES**
  - This product is NOT covered by this rule.

Is your produce for personal/on-farm consumption?

- **YES**
  - This product is NOT covered by this rule.

Is your produce intended for commercial processing that adequately reduces pathogens (for example, commercial processing with a “kill step”)?

- **YES**
  - This product is eligible for exemption from the rule, provided you make certain statements in documents accompanying the produce, obtain certain written assurances, and keep certain documentation as per sections 112.2(b)(2) through (b)(6).

Does your farm on average (in the previous three years) as per Section 112.5:

  - have< $500k* annual food sales, AND
  - a majority of the food (by value) sold directly to “qualified end-users:?

- **YES**
  - This product is eligible for exemption from the rule, your farm is eligible for a qualified exemption from the rules, which means that you must comply with certain modified requirements and keep certain documentation as per Sections 112.6 and 112.7.

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CLARIFICATION OF COMPLIANCE DATES

<table>
<thead>
<tr>
<th>BUSINESS SIZE</th>
<th>SPROUTS</th>
<th>MOST PRODUCE</th>
<th>WATER RELATED</th>
<th>QUALIFIED EXEMPTION LABELING REQUIREMENT</th>
<th>RETENTION OF RECORDS SUPPORTING A QUALIFIED EXEMPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALL OTHER BUSINESSES (&gt;500K)*</td>
<td>1/26/17</td>
<td>1/26/18</td>
<td>1/26/22</td>
<td>1/1/2020</td>
<td>1/26/16</td>
</tr>
<tr>
<td>SMALL BUSINESSES (&gt;250K-500K)*</td>
<td>1/26/18</td>
<td>1/28/19</td>
<td>1/26/23</td>
<td>1/1/2020</td>
<td>1/26/16</td>
</tr>
<tr>
<td>VERY SMALL BUSINESSES (&gt;25K-250K)*</td>
<td>1/28/19</td>
<td>1/27/20</td>
<td>1/26/24</td>
<td>1/1/2020</td>
<td>1/26/16</td>
</tr>
</tbody>
</table>

*Sales are adjusted for inflation annually.  **Track changes to water compliance rule at www.fda.gov/fsma.
FOR ADDITIONAL RESOURCES, TOOLS, & INFORMATION

- FDA'S FOOD SAFETY MODERNIZATION ACT
  www.fda.gov/FSMA
- USDA
  www.ams.usda.gov/services/auditing/gap-ghp
- PRODUCE SAFETY ALLIANCE
  www.producesafetyalliance.cornell.edu
- NATIONAL SUSTAINABLE AGRICULTURE COALITION
  www.sustainableagriculture.net
- NATIONAL GOOD FOOD NETWORK
  ngfn.org/resources
- ILLINOIS EXTENSION
  web.extension.illinois.edu/smallfarm/foodsafety.html
- FAMILY FARMED
  onfarmfoodSafety.org
- SAFE QUALITY FOOD INSTITUTE
  www.sqfi.com/suppliers/fsma-resources-page
- NORTH CENTRAL SARE
  www.northcentralsare.org

Visit www.ilfb.org/livelocal or call 309-557-2155 for more information.