



**What Do I Need to Know About The
Produce Safety Rule?**

Produce Safety Rule – What Should I Know?



- **Present overview of FDA's proposed "Produce Rule"**
- **Understanding of key areas**
- **What things you need to know...**

1. Does it Apply to Me?

- **Farms that grow produce domestically.**
- **Applies to produce *imported* to the U.S.**
- **Covers growing, harvesting, packing or holding produce**
- **Commodity list in the rule. Also includes mixes of produce and tree nuts.**

1. Does it Apply to Me?

- **Produce rarely consumed raw is excluded, e.g.**
 - artichokes, potatoes, etc.
 - If the commodity is to be processed to address microbial contamination (i.e. reduce microorganisms to extent sufficient to prevent illness), you may also be exempt

1. Does it Apply to Me?

- **Exempt if you grow for personal or on-farm consumption.**
- **Very small farms**
 - (under \$25,000 a year in sales) and farms with sales of less than \$500,000, where half of those sales are to consumers or to nearby restaurants or retail are exempt from some or all of the new law's provisions.

2. What Does The Rule Cover

- **“take appropriate measures to minimize the risk of serious health consequences and to take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable health hazards”.**
- **Covers Microbial Hazards Only**

2. What Does The Rule Cover



- **FDA proposes safety standards/documentation for compliance in 6 areas:**
 - **Worker training, health, and hygiene**
 - **Agricultural water that contacts produce**
 - **Biological soil amendments**
 - **Domesticated and wild animals in the growing area**
 - **Equipment, tools, and building sanitation**
 - **Specific sprout standards**

3. What Else?

- **Does not require a farm to conduct operational risk assessments or have a written food safety plan**
- **no product testing requirements (except for sprouts).**
 - However, FDA does ask for comments in this area
- **Rules consistent with USDA NOP**

4. What Commodity's are covered?

- **Only one mentioned is sprouts**
 - Not commodity by commodity

4. What Commodity's are covered?

- **FDA would take a risk-based approach as opposed to a commodity approach**
 - Commodity characteristics, product use, method of production, etc.
 - Risk-based approach evident within each of the six areas; e.g. agricultural water testing based on source, soil amendment application intervals based on type, etc.

5. Compliance Dates

- **Proposals and have no legal effect until finalized.**
- **Timelines:**
 - **After FDA receives all of the comments, they will begin to draft the final rule.**
 - **That will take months, perhaps even a year or more.**

5. Compliance Dates

- **Timelines:**

- When that final regulation is published, the clock will start on when farms must be in compliance.
 - For larger farms - 2 years.
 - Small businesses - 3 years
 - Very small businesses - 4 years

6. Records and Recordkeeping

- **6 areas to demonstrate compliance with the requirements.**
 - Soil amendments
 - Agricultural water
 - Worker training and health
 - Domesticated animals and animal intrusion
 - Building, equipment and sanitation management
 - Sprout production

7. More Records?

- **Records must include basic information**
- **Records must be accurate, legible, indelible, signed, and dated.**
- **Store records for 2 years**

7. More Records?

- **Records available to FDA - they do not have to be submitted to FDA as a matter of routine**
- **Farms are still excluded from the “one up/one back” trace back requirements**

8. Alternative Standards

- **Alternative Standards**

- Requirements for testing and subsequent actions for agricultural water
- Composting treatment processes
- Minimum application intervals for untreated soil amendments,
- composted amendments and compost teas

8. Alternative Standards

- **Adequate scientific data**

- Data must be documented/kept in your records.
- It is not entirely certain what would qualify as “adequate scientific data”.
- Alternative practice must provide same level of public health protection
- There has been work done by scientific experts to define protocols to follow to gain exemptions

9. Personnel Requirements?

- **Training for produce handlers**
 - Principles of food hygiene and safety
 - Importance of personal hygiene
 - FDA standards
- **Harvesters**
 - When not to harvest due to a hazard
 - On corrective actions when hazards observed

9. Personnel Requirements?

- **Training for produce handlers**
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- **Harvesters**
 - When not to harvest due to a hazard
 - On corrective actions when hazards observed
- **Visitors**

10. What about Water?

- **Agricultural water** –
 - any water used in the growing, harvest, packing of produce where the water is reasonably likely to contact the produce
- **Inspect and Maintain Water System**
- **Discontinue Use if not safe**

10. What about Water?

- **Water testing - No generic E.coli**
 - Sprouts
 - Direct contact with produce
 - Used for hand washing
- **Can be used:**
 - Growing activities <235 CFU

10. What about Water?

- **Water testing**

- Beginning of each growing season
- Every three months during season
- Surface Water tested 7-30 days depending on the source

11. What About Soil Amendments?

- **Handled, transported and stored to prevent contamination of:**
 - Products
 - Food Contact Surfaces and work areas
 - Water sources and distribution systems
 - Other SA in storage
- **Treatment Validation**
- **Application Intervals**

12. Anything Else?

- **Domesticated and Wild Animals**
- **Production Standards**
- **Equipment , buildings and Sanitation**

12. Anything Else?

- **Sprouts – seed, growing, testing, etc.**
- **Analytical methods – AOAC, FDA BAM, Water and Waste Water Methods of American Public Health Association or equivalent**

13. What Do I Do Now?

- **Stay informed – Just proposals**
- **Read the Summaries**
- **Conduct a GAP audit.**