

FDA Proposed Rule on Produce Safety



**FDA FOOD SAFETY
MODERNIZATION ACT**

Key Principles

- Considers risk posed by practices, commodities, conditions
- Science- and Risk-based
 - Identified routes of microbial contamination
 - Excludes certain produce rarely consumed raw
 - Excludes produce to be commercially processed with a “kill-step”
- Flexible
 - Additional time for small farms to comply
 - Variances
 - Alternatives for some provisions

21 CFR Part 112

Standards for the Growing, Harvesting,
Packing and Holding of Produce for Human
Consumption

Regulatory Framework

- Framework considers many factors associated with produce farming community
 - Examples include diversity of operations and broad range of crops and practices
- Proposing integrated approach that draws on past experiences
 - Examples include CGMPs, HACCP, shell egg regulation

Qualitative Assessment of Risk Reflects Science Behind Rule

- Draft qualitative assessment of risk helps to inform proposed rule
- Provides a scientific evaluation of potential adverse health effects resulting from human exposure to hazards in produce
- Available for public comment as part of the proposed rule

Integrated Approach

- Would cover all produce commodities except those that pose little or no risk of foodborne illness
- Would apply the most stringent requirements to agricultural practices that pose the greatest likelihood of contamination of the produce, regardless of the covered produce commodity

Standards for Produce Safety

Focus on 5 identified routes of microbial contamination

1. Agricultural water
2. Biological soil amendments of animal origin
3. Worker health and hygiene
4. Equipment, tools, buildings and sanitation
5. Domesticated and wild animals

Other requirements

- Sprouts
- Growing, harvesting, packing and holding

Agricultural Water

- **“Agricultural water”**: Water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food-contact surfaces
- Agricultural water must be safe and of adequate sanitary quality for its intended use
- Inspection of agricultural water system

Agricultural Water- more detail

- Specific criteria for quality of water used for certain purposes, and analytical testing
 - 235 CFU generic *E. coli* per 100 ml standard
 - For direct contact with covered produce (other than sprouts) during growing
 - Alternatives permitted that provide same level of public health protection
 - 0 detectable generic *E. coli* standard
 - For highest risk uses

Agricultural Water – more detail

- **No requirements to test when:**
 - Farm receives water from a Public Water System or a public water supply that meets microbial requirements; or
 - Farm treats the water in a manner that is in accordance with the proposed rule's requirements for water treatment
- **Frequency of testing of untreated surface water**
 - Where runoff into the containment is minimized: test at least 1x/month during growing season
 - Where runoff into the source is likely: test every 7 days during growing season
- **Frequency of testing of other agricultural water**
 - Test at the beginning of each growing season and every 3 months thereafter during the growing season

Agricultural water – more detail

- Follow-up action required:
 - When a farm determines or has reason to believe that its agricultural water is not safe and of adequate sanitary quality for its intended use; or
 - When water tested does not meet microbial standards
 - Then, before the farm may use the same water source again, it would be required to either:
 - Re-inspect agricultural water system, identify conditions likely to introduce pathogens to produce or food-contact surfaces, make changes, & retest water; OR
 - Treat the water in a manner that is in accordance with the proposed rule's requirements for water treatment

Agricultural Water Questions (Examples)

- Are the microbial standards specified in these provisions appropriate for the specified intended uses?
 - For example, are the microbial standards appropriately tailored to uses such as direct application of irrigation water?
- Are there any alternative options not considered in the proposed rule?

Alternatives Permitted

- Farms may establish alternatives to certain requirements related to water and biological soil amendments of animal origin
- Alternatives must be scientifically established to provide the same amount of protection as the requirement in the proposed rule without increasing the risk of adulteration

Variations Provide Flexibility

- A state or foreign country may petition FDA for a variance from some or all provisions if deemed necessary in light of local growing conditions.
- Practices under the variance would need to provide the same level of public health protection as the proposed rule without increasing the risk of adulteration.

Compliance Dates Staggered

- **Effective Date:** 60 days after final rule is published

Compliance Dates

- **Very small farms**
 - Average annual value of food sold $> \$25,000$ and $\leq \$250,000$
 - Four years after the effective date to comply
 - For some water requirements, six years

Compliance Dates

- **Small farms**

- Average annual value of food sold $>$ \$250,000 and \leq \$500,000
- Would have three years after the effective date to comply
- Would have five years for some water requirements

- **Other covered farms**

- Other covered businesses would have to comply two years after the effective date
- Would have four years for some water requirements

Comments

- Received approximately 1,050 as of 7/26
- Several comments supporting the rule
- Major Categories
 - Implementation of the rule
 - Scope exclusions
 - Biological Soil Amendments
 - Agricultural Water

Stakeholder issues regarding Agricultural Water Standard

- Principally opposed to water standards
- Confusion about standards
- Standards are not appropriate
- Questions about alternatives and variances

Discussion

- Flexibility of agricultural water provision area
- Considerations for determining the adequacy of scientific data
- Equivalent level of public health protection
- Submitting comments to the docket

Utilization of Information

- Finalization of the Rule
- Guidance development
- Education/ outreach
- Further research