

FDA Proposed Rule on Produce Safety



**FDA FOOD SAFETY
MODERNIZATION ACT**

Michigan State Listening Session
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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

Food Safety Plan Questions (Examples)

- Should we require that some or all covered farms perform operational assessments and/or develop a food safety plan?
- What criteria should be employed to determine which farms should be subjected to such a requirement?

Who Would be Covered?

- Farms that grow, harvest, pack or hold most produce in raw or natural state (raw agricultural commodities)
- Farms and “farm” portions of mixed-type facilities
- Domestic and imported produce
- Farms with annual sales > \$25,000 per year
- Limitations on coverage are proposed

Covered Produce

- “Produce” defined as fruits and vegetables
- Produce includes mushrooms, sprouts, herbs and tree nuts
- Produce does not include grains
- Some limitations on covered produce

Limitations on Coverage

- Produce for personal or on-farm consumption
- Produce not a 'raw agricultural commodity'
- Certain produce rarely consumed raw
- Produce that will receive commercial processing with a "kill-step"
- Farms with sales of \leq \$25,000 per year
- Qualified exemption

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

Regulatory Questions (Examples)

- Should specific commodities or categories be excluded based on relative risk data?
- Can commodity characteristics be used as a basis to consider a commodity-specific approach?
- Comments on Qualitative Assessment of Risk

Agricultural Water

- Agricultural water must be safe and of adequate sanitary quality for intended use
- Inspection of water system
- Reinspect system, make changes, test water OR treat water
- Specific criteria for quality of water for certain purposes and analytical testing
- Alternatives permitted that provide same level of public health protection

Agricultural Water-more detail

- Specific requirements for the quality of water used for specified purposes and follow-up action when water does not meet the quality standards.
 - 235 CFU generic *E. coli* standard (direct contact with covered produce other than sprouts during growing)
 - 0 detectable generic *E. coli* standard (highest risk uses)

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?

Biological Soil Amendments of Animal Origin

- May contaminate produce with pathogens; requirements include:
 - Definitions for determining their status as treated or untreated
 - Standards for handling, conveying and storing
 - Treatment methods, application methods, and application intervals
- Alternatives permitted that provide same level of public health protection

Biological Soil Amendments of Animal Origin-more detail

- Microbial standards for treatment processes
 - More stringent and less stringent standards
- Application requirements
 - Relate to whether there is contact with produce during and after application
- Minimum application intervals
 - Time from application to harvest

Worker Health and Hygiene

- Pathogens may be transmitted from person to food
- Requirements include:
 - Training
 - Preventing contamination by ill persons
 - Hygienic practices (toilet facilities; hand washing)
 - Visitors must be aware of policies and have access to toilet and hand washing facilities

Equipment, Tools, Buildings and Sanitation

- Requirements include:
 - Equipment/tools-designed and constructed to allow adequate cleaning and maintenance
 - Food contact surfaces of equipment and tools must be inspected, maintained, and cleaned and sanitized as necessary
 - Buildings-designed and constructed to allow adequate cleaning and reduce potential for contamination
 - Buildings must have adequate, reasonably accessible toilet and hand washing facilities

Domesticated/Wild Animals

- Requirements apply if there is a reasonable probability that animals will contaminate covered produce and include:
 - Wait an adequate amount of time between grazing and harvesting
 - If working animals used in a planted growing area, take measures to prevent pathogens from being introduced onto produce
 - Monitor for animal intrusion and if observed, evaluate for harvest (no harvesting of visibly contaminated covered produce)

Environment Questions (Examples)

- To what extent have farmers taken action to exclude wildlife from outdoor produce growing areas?
- What measures are being used for these purposes?
 - e.g. construction of fences or other physical barriers, chemical deterrents, or other mechanisms around growing areas to exclude wildlife?

Environment Questions (Examples-cont.)

- Has the implementation of measures to prevent animal intrusion negatively impacted habitat for rare or declining aquatic or terrestrial wildlife species or migratory birds?
 - Please provide examples

Requirements for Sprouts

- Warm, moist, and nutrient-rich conditions are ideal conditions for pathogen growth
- Requirements include:
 - Building and sanitation requirements
 - Treating seed before sprouting
 - Testing spent sprout irrigation water (or sprouts, in some cases) for certain pathogens
 - Monitoring the growing, harvesting, packing, and holding environment for *Listeria* species or *Listeria monocytogenes*

Environmental Monitoring Questions (Examples) (other than sprouts)

- Should we require any or all covered farms that wash and pack produce, or that only pack produce, to perform environmental testing for *L. monocytogenes* or *Listeria spp.*?
- What criteria should be employed to determine which farms should be subject to such a requirement?

Growing, Harvesting, Packing and Holding Activities

- Proposal includes science-based, minimum standards related to growing, harvesting, packing and holding
- Requirements include:
 - Separating covered and excluded produce; sanitizing food contact surfaces as necessary
 - Not distributing covered produce that drops to the ground before harvest unless it receives commercial processing
 - Food-packing material appropriate for use

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.

Recordkeeping Required But Not Burdensome

- The proposed rule would require certain records, for example, to document that certain standards are being met
 - Agricultural water testing results
- Records already kept for other purposes need not be duplicated

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

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

Registration Question

Should we require that covered farms, as described in proposed Sec.112.4(a), register with FDA?

How to Comment on the Proposed Rules

- www.regulations.gov
- Link to rules on www.fda.gov/fsma
- Comments are due by May 16, 2013 (120 days)
- Comment periods on major FSMA proposals will be coordinated to enable comment on how the rules can best work together.



Rulemaking Process: It Doesn't Happen Overnight

1. FDA proposes rule and requests comments
2. FDA considers comments and considers revising rule
3. FDA issues final rule setting dates for companies to comply



We are here