

# Supplemental Proposed Produce Safety Rule



**FDA FOOD SAFETY  
MODERNIZATION ACT**

# Background

- FDA issued proposed rule on Jan. 16, 2013
  - Standards for growing, harvesting, packing, and holding of produce
- Stakeholder Input
  - 3 Public meetings; various outreach efforts
  - Comment period closed on Nov. 22, 2013
  - Over 15,000 comments received
- Limited re-opening of docket (prior to final)
  - Describe FDA's current thinking on certain specific issues
  - Seek public comment on new/revised provisions

# Issues Addressed in Supplemental Proposed Rule

- Use of raw manure
- Agricultural water
  - Microbial quality standard for water used during growing by direct application
  - Frequency of testing
- Potential impact on wildlife and animal habitat
- Withdrawal of qualified exemption
- Farms excluded from coverage
- Packing or holding of own or others' RACs

# Use of Raw Manure

- Proposed
  - Minimum time interval of 9 months between application and harvest
  - General safe harbor for all crops, soils, regions
  - Acknowledged need for additional science
  - NOP standard of 90/120 days based on organic crop practices, not scientific evidence
- Public Comments – various concerns, incl.
  - Negative impact on soil ecology
  - Disruption to current cropping cycles
  - Economic concerns

# Use of Raw Manure

- FDA Action in Supplemental Proposed Rule
  - Reiterate importance of quantitative standard and FDA's recognition of composting as less risky
  - Remove 9-mo interval and defer decision while working with USDA, stakeholders to:
    - initiate and complete a risk assessment
    - establish and implement a robust research agenda
    - help develop infrastructure to transition to composting
  - Commit to re-opening docket after completion of a risk assessment
  - Indicate no objection to NOP standard in interim
  - Eliminate time interval restriction for compost use

# Agricultural Water – Microbial Quality Standard

- Proposed for water used during growing by direct application
  - Geometric mean of no more than 126 CFU generic *E. coli*/100 mL
  - Single sample maximum of 235 CFU generic *E. coli* /100 mL
  - Based on analysis underlying EPA's recreational water quality criteria, supported by quantitative risk assessments

# Agricultural Water – Microbial Quality Standard

- Public Comments –concerns incl.
  - More restrictive than necessary to protect public health;
  - Not appropriate for all commodities;
  - Many water sources do not meet standard;
  - Provisions for alternatives insufficient

# Agricultural Water – Microbial Quality Standard

- FDA Action in Supplemental Proposed Rule  
Updated standard for water used during growing by direct application :
  - Geometric mean of no more than 126 CFU generic *E. coli* /100 mL
  - Statistical Threshold Value (STV) (approximates the 90<sup>th</sup> percentile) not to exceed 410 CFU generic *E. coli* /100 mL



# Agricultural Water – Microbial Quality Standard

- FDA Action in Supplemental Proposed Rule  
Updated standard for water used during growing by direct application :
  - New provisions to achieve the microbial quality standard after accounting for microbial die-off, removal:
    - Apply time interval in days between last irrigation and harvest using 0.5 log/day reduction rate (or other appropriate alternative rate); and/or
    - Apply time interval in days between harvest and end of storage using an appropriate reduction rate (e.g., removal during commercial washing or natural die-off during extended storage)

# Agricultural Water – Frequency of Testing

- Proposed – Begin testing at the start of growing season:
  - For untreated, unprotected surface water, test every 7 days during growing season
  - For untreated ground water, test every 3 months during growing season
- Public Comments – various concerns, incl.
  - Cost associated with testing (with little return in public health benefits)
  - Variability in surface water quality

# Agricultural Water – Frequency of Testing

- FDA Action in Supplemental Proposed Rule
  - Tiered approach to testing untreated surface water used during growing by direct application method:
    - Baseline survey of water quality profile, during time period(s) as close as practical to harvest (over 2 years) to determine appropriate use
    - Annual verification survey to verify water quality
    - Re-establish water quality profile once every 10 years using annual data (or sooner, if necessary)

# Agricultural Water – Frequency of Testing

- FDA Action in Supplemental Proposed Rule
  - Tiered approach to testing untreated ground water
    - Baseline testing 4 times during growing season or year
    - Annual verification testing once during growing season or year

# Potential Impact on Wildlife and Animal Habitat

- Proposed
  - Various standards for domesticated and wild animals, incl.
    - Evaluate whether produce can be safely harvested if evidence of animal intrusion
    - Take all measures reasonably necessary to identify and not harvest contaminated produce
- Public Comments
  - Negative environmental effects (fencing, clearing of farm borders, effects on endangered or threatened species)

# Impact on Wildlife and Animal Habitat

Produce  
Revised

- FDA Action in Supplemental Proposed Rule
  - Codify previous preamble text
  - New codified provision (developed in consultation with FWS) to state:

Regulation does not authorize “taking” of endangered or threatened species; or require measures to destroy animal habitat or exclude animals from outdoor growing areas

# Withdrawal of Qualified Exemption

Produce  
Revised

- Proposed
  - Certain procedures for withdrawal of qualified exemption (“Tester” exempt farms)
- Public Comments
  - Clarify circumstances under which FDA would withdraw the exemption
  - Provide for intermediate steps prior to withdrawal
  - Provide for reinstatement of qualified exemption that is withdrawn

# Withdrawal of Qualified Exemption

Produce  
Revised

- FDA Action in Supplemental Proposed Rule
  - Clarify that before withdrawing an exemption we may consider other steps (e.g., warning letter, injunction) and the actions taken by the farm to correct the problem
  - Explicitly provide for notification and opportunity for farm to respond before determining to withdraw an exemption
  - Provide process for reinstatement of exemption that has been withdrawn



# Farms Excluded from Coverage

- Proposed
  - Rule would not cover farms that have an average annual value of *food* sold during the previous three-year period of \$25,000 or less
- FDA Action in Supplemental Proposed Rule
  - Rule would not cover farms that have an average annual value of *produce* sold during the previous three-year period of \$25,000 or less

# Farms Excluded from Coverage

- FDA Action in Supplemental Proposed Rule
  - Per the supplemental proposed rule, rule would result in exclusion of 4.0% of covered produce acres and 3.1% of produce acres (i.e., exclusion of additional 2.1% of produce acres compared to previous proposal)
  - Such farms not covered by produce rule would continue to be subject to adulteration provisions of FD&C Act

# Farms Excluded from Coverage

- FDA Action in Supplemental Proposed Rule
  - Corresponding changes to definitions of small business and very small business farms (which would be covered, but under extended compliance periods)

# Packing and Holding of Own and Others' RACs

- Original Proposal
  - Different requirements would apply when a farm packs/holds its own RACs than when it packs/holds others RACs or packs off farm
- Public Comments – various issues, incl.
  - No differences in risk associated with whose produce is packed or where it is packed
  - Packing/holding of RACs is inherently a farm activity

# Packing and Holding of Own and Others' RACs

- FDA Action in Supplemental Proposed Rule (also corresponds to FDA action in Preventive Controls rule)
  - Modify the farm definition so it would include establishments that pack or hold food that is grown or raised on another farm whether or not under the same ownership
    - Moves coverage of on-farm packing and holding of another's produce out of the PC rule and into the produce rule because now considered a farming activity

# Regulatory Impact Analysis

Produce  
Revised

- Estimate 35,503 farms will be covered
  - As opposed to 40,211 previously
- New, lower cost of microbial quality standard and testing requirements for agricultural water

	Benefits	Domestic Costs	Foreign Costs	Total Costs (Domestic + Foreign)	Net Benefits
<b>Original</b>	\$1,037.78	\$459.56	\$170.62	\$630.22	\$407.56
<b>Supplemental Proposed Rule</b>	\$930.00	\$386.23	\$143.39	\$529.62	\$400.37
<b>Difference</b>	-\$107.78	-\$73.33	-\$27.23	-\$100.60	-\$7.19

# Website to Submit Comments:

[www.regulations.gov/#!submitComment;D=FDA-2011-N-0921-0973](http://www.regulations.gov/#!submitComment;D=FDA-2011-N-0921-0973)

# QUESTIONS/DISCUSSION