

Proposed Rules under the FDA Food Safety Modernization Act

Don Kraemer

U.S. Food and Drug Administration

FDA FOOD SAFETY
MODERNIZATION ACT



Agenda

- Introductory Comments
- Proposed Rule on Produce Safety
- Proposed Rule on Preventive Controls for Human Food
- Technical Assistance

Five Proposed Rules Establish Food Safety Framework

- Produce Safety Standards - Published Jan. 2013
- Preventive Controls for Human Food - Published Jan. 2013
- Foreign Supplier Verification Program – Published July 2013
- Accredited Third Party Certification – Published July 2013
- Preventive Controls for Animal Food



Key Aspects of Proposals

- Confirm industry's role in food safety
- Risk-based and flexible
 - Burden commensurate with risk
- Address small business issues
 - Additional time for small farms, businesses, to comply
- Consistency with Codex standards
- Extensive government, stakeholder Input

Produce

FDA Proposed Rule on Produce Safety



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 regulatory experiences
 - Examples include Good Manufacturing Practice Regulation, HACCP Regulation, Shell Egg Regulation
 - Ensuring that measures are no more trade restrictive than necessary to achieve ALOP

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
- Estimated number of covered farms:

U.S.: 40,496; Foreign: 14,927

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
- Farms with sales of \leq \$25,000 per year
- Qualified exemption and modified requirements

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 activities

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

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 an equivalent level of protection as the requirement in the proposed rule without increasing the risk of adulteration

Variances Provide Flexibility

- A U.S. state or foreign country may petition FDA for a variance from some or all provisions
- Practices under the variance would need to provide an equivalent and appropriate 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
 - Example: agricultural water testing results
- Records already kept for other purposes need not be duplicated

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

Preventive Controls for Human Food



Summary of Requirements

- Hazard Analysis and Risk-Based Preventive Controls
 - Each facility would be required to implement a written food safety plan that focuses on preventing hazards in foods
- Updated Good Manufacturing Practices

Who would be Covered?

- Facilities that manufacture, process, pack or hold human food
- In general, facilities required to register with FDA under sec. 415 of the FD&C Act
- Applies to domestic and imported food
- Some exemptions and modified requirements are being proposed
- Estimated number of covered facilities:
U.S.: 97,646; Foreign: 109,190

Hazard Analysis and Risk-Based Preventive Controls

Human PC



Preventive Controls Required

- Process controls
- Food allergen controls
- Sanitation controls
- Recall plan
- In addition, seeking comment on supplier approval and verification program

Verification Required

- Validation
- Calibration
- Review of records
- In addition, seeking comment on review of complaints, finished product and environmental testing

Updated Good Manufacturing Practices

- Protection against allergen cross-contact
- Certain provisions containing recommendations would be deleted
- Comments requested on mandating training and whether rule should require, rather than recommend, certain provisions

Exemptions and Modified Requirements from Preventive Controls -1

- “Qualified” facilities:
 - Very small businesses (3 definitions being proposed—less than \$250,000, less than \$500,000 and less than \$1 million in total annual sales)
 - OR
 - Food sales averaging less than \$500,000 per year during the last three years AND
 - Sales to qualified end users must exceed sales to others

Exemptions and Modified Requirements from Preventive Controls - 2

- Foods subject to low-acid canned food regulations (microbiological hazards only)
- Foods subject to HACCP (seafood and juice)
- Dietary supplements
- Alcoholic beverages

Exemptions and Modified Requirements from Preventive Controls - 3

- Facilities, such as warehouses, that only store packaged foods that are not exposed to the environment
 - Certain packaged food for which refrigeration is required for safety must have temperature controls, monitoring, verification and records

Exemptions and Modified Requirements from Preventive Controls - 4

- Certain storage facilities such as grain elevators and warehouses that store only raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing are exempt from hazard analysis and risk-based preventive controls.
 - Also exempt with respect to CGMPs

Farm-Related Exemptions

- Activities within the definition of “farm,” including farm activities that are covered by the proposed produce rule
- Certain low-risk manufacturing/processing, packing and holding activities conducted by small/very small businesses on farms for specific foods

Risk Assessment

- Draft qualitative risk assessment announced in a separate notice of availability
- Addresses activities outside the farm definition conducted in a facility co-located on a farm.

Effective and Compliance Dates

Effective date:

60 days after the final rule is published

Compliance Dates

- **Small Businesses**—a business employing fewer than 500 persons would have two years after publication.

Compliance Dates (cont.)

- **Very Small Businesses**—a business having less than \$250,000 (or alternatively \$500,000 or \$1 million) in total annual sales of food would have three years after publication to comply.
 - Very small businesses are considered “qualified” facilities and subject to modified requirements
- **Other Businesses**—a business that does not qualify for exemptions would have one year after publication of the final rule to comply.

Education and Technical Assistance

- Alliances
 - Produce Safety
 - Preventive Controls
 - Sprouts Safety
- Joint Institute for Food Safety and Applied Nutrition (JIFSAN)
- Guidance documents
- National technical assistance network

