FSMA
FDA's Supplemental Proposed Rules

Robert Hahn
Olsson Frank Weeda Terman Matz PC

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Four Supplemental Proposed Rules

- Produce Safety
- Preventive Controls for Human Food
- Preventive Controls for Animal Food
- Foreign Supplier Verification Programs

Produce Safety

- Narrows coverage
  - Farm or farm mixed-type facility exempt if average annual sales of produce of $25,000 or less

Produce Safety

- Clarifies line between “farm” and “facility,” so that fewer entities subject to both rules
  - Farm may engage in field coring (“harvesting”)
  - Farm may engage in activities incidental to “packing” (e.g., sorting, grading)
  - Farm may engage in activities incidental to “holding” (e.g., fumigating, weighing, mixing lots of same RAC)
  - Farm may pack RACs grown on another farm not under the same ownership

Produce Safety

- Clarifies line between “farm” and “facility” (cont’d)
  - Farm may engage in “manufacturing/processing” food, provided that:
    - All such food is consumed on that farm or another farm under the same ownership;
    - Such activities consist only of packaging and labeling of RACs; or
    - Such activities consist only of drying/dehydrating RACs to create a different commodity, and packaging and labeling of the dried commodity.

Produce Safety

- Agricultural water standard
  - Would apply EPA 2012 recreational water quality criteria (RWQC)
  - Allow producers to meet standard by leaving time interval between last irrigation and harvest, using a specific die-off rate of 0.5 log per day (or another rate supported by scientific data)
  - Allow producers to meet standard by leaving an appropriate time interval between harvest and end of storage, using appropriate die-off rate and/or removal rate (for activities such as commercial washing)

Produce Safety

- Biological soil amendments
  - Remove 45-day minimum application interval for composted manure
  - Reconsider 9-month minimum application interval for raw manure
    - FDA is deferring a decision on the appropriate interval pending further actions: research, risk assessment, and steps to encourage produce growers to transition to use of compost
    - FDA unlikely to object to compliance with NOP

Produce Safety

- Animal encroachment
  - Clarify that regulations do not require “taking” of threatened or endangered species in violation of Endangered Species Act
  - Clarify that regulations do not require exclusion of animals from outdoor growing areas, or destruction of animal habitat, or clearing borders
  - BUT, if animal intrusion does occur, producer still must evaluate whether covered produce may be harvested

Preventive Controls for Human Food

- "Farm" definition
  - Expands activities a "farm" may conduct without becoming a "facility" subject to FDA registration and preventive controls
  - FDA requests comments on current requirement that a "farm" be "in one general physical location"
  - FDA intends to add to list of on-farm low-risk activity/food combinations (that are exempt when conducted by a small or very small business)

PC's for Human Food

- Exemption for facilities solely engaged in storage of RACs (other than fruits and vegetables) for further distribution or processing
  - Would include facilities that engage in activities incidental to "packing" and "holding"
  - Such as: fumigating, grading, weighing, drying, blending lots, applying preservatives to protect against mold

PC's for Human Food

- Definition of "very small business"
  - Define as less than $1 million in total annual sales of human food, adjusted for inflation
  - A "very small business" is a "qualified facility" subject to modified requirements
  - A "very small business" has 3 years after publication of final rule to comply

PC's for Human Food

- Hazard analysis
  - Must consider economically motivated adulteration (if there is a pattern of EMA of that food in the past)
  - Must consider environmental pathogens (only for RTE foods exposed to the environment prior to packaging if packaged food will not receive a treatment to control the environmental pathogen)

PC's for Human Food

- Environmental monitoring
  - A verification activity
  - Testing for an environmental pathogen (or appropriate indicator organism)
  - Would be required only if contamination of a RTE food with an environmental pathogen is identified as a significant hazard (i.e., RTE food is exposed to an environmental pathogen prior to packaging and packaged food will not receive a treatment to control the pathogen)

PC's for Human Food

- Product testing
  - A verification activity
  - Testing for a pathogen (or appropriate indicator organism) or "other hazard"
  - Would be required only if appropriate in light of the facility, the food, and the nature of the preventive control
    - FDA appears to leave this determination to the facility

PC's for Human Food

- Supplier controls
  - A preventive control
  - Require receiving facility to implement supplier control program for raw materials and ingredients for which it has identified a significant hazard
    - "Receiving facility" defined as a facility that receives raw materials or ingredients and manufactures/processes them

PC's for Human Food

- Supplier verification activities
  - Onsite audits of supplier;
  - Sampling/testing of raw material or ingredient (by either receiving facility or supplier);
  - Review of supplier's food safety records; or
  - Other appropriate verification activities.
- Instead of onsite audit, receiving facility may rely on inspection of supplier by FDA or foreign food safety authority recognized by FDA as comparable or equivalent

PC's for Human Food

- Supplier verification activities (cont'd)
  - BUT, if SAHCODHA hazard identified, receiving facility must conduct annual onsite audits, unless it documents determination that other verification activities (or less frequent onsite audits) will provide adequate assurance that hazard is controlled

PC's for Human Food

- Supplier verification activities (cont'd)
  - Alternative verification activities would apply where the supplier is a farm or a "qualified facility"
  - Supplier must have written procedures to ensure all raw materials and ingredients received from approved suppliers. BUT, where necessary, may receive from unapproved suppliers on a temporary basis, provided perform adequate verification activities prior to acceptance.

PC's for Human Food

- Exclusions from Current Good Manufacturing Practice (CGMP) regulations
  - "Farms";
  - Activities of farm mixed-type facilities with the definition of "farm";
  - Holding or transportation of RACs;
  - Hulling, shelling, and drying of nuts (but not roasting or other manufacturing/processing); and
  - Fishing vessels not required to register with FDA.

THANK YOU

QUESTIONS?