Produce Safety Educators
Monthly Meeting #13
October 20th, 2014
2PM EDT
Instructions

• All participants are muted.

• There will be time for questions and answers at the end of each presentation and at the end of the meeting.
  – To ask a question or make a comment, please ‘raise your hand’ using the small button on the right hand panel
  – We may not get around to all comments/questions, BUT you may leave additional comments in the comment box to be compiled after the session

• This session will be recorded and shared via the listserv after the call.
Agenda

• Proposed FSMA Supplemental Overviews
  • Foreign Supplier Verification Program
    ▪ Mr. Brian Pendleton, J.D. – Senior Policy Advisor, FDA

• Produce Safety
  ▪ Dr. Samir Assar – Produce Safety Staff Director, FDA

• Preventive Controls for Human Food
  ▪ Dr. Mickey Parish – Senior Advisor, Office of Food Safety

• Additional FDA Staff Members Present:
  – Ms. Joy Johanson and Dr. Michael Mahovic, Consumer Safety Officers Produce Safety Staff; Ms. Scarlett Salem, Produce Safety Staff; Dr. Rita Nalubola, Senior Policy Advisor in the Office of Policy; Ms. Kruti Ravaliya, ORISE Fellow

• Question & Answer Session
Revised Proposed Rule on Foreign Supplier Verification Programs

http://www.fda.gov/fsma
Background

• FSMA Sec. 301 (FDCA 805) requires importers to have foreign supplier verification programs (FSVPs) and FDA to issue regulations

• FDA issued the proposed rule on FSVPs for importers of food for humans and animals on July 29, 2013
FSVP Proposed Rule

• Proposed requirements on:
  – Personnel (qualified individual)
  – Compliance status review
  – Hazard analysis
  – Foreign supplier verification activities
  – Complaints, investigations, corrective actions
  – FSVP reassessment
  – Identification of importer at entry
Proposed Rule (cont.)

• Modified requirements for:
  – Dietary supplements
  – Very small importers and food from very small foreign suppliers
  – Food from suppliers in countries with food safety systems recognized as comparable or determined to be equivalent
Stakeholder Input

• Two public meetings
• Webinars and other outreach
• Approximately 325 comments received
Supplemental Notice

• FDA published a supplemental notice of proposed rulemaking (SNPRM) on FSVP on Sept. 29, 2014

• Announcing changes to proposed rule in response to comments and to align FSVP with newly proposed supplier program provisions in proposed rules on preventive controls (PC)
Issues in Supplemental Notice

- Importers subject to proposed PC supplier program requirements
- Hazard analysis
- Risk evaluation
- Supplier verification activities
- Definitions of “very small importer” and “very small foreign supplier”
Importers with PC Supplier Programs

• Original Proposed Rule:
  – If all hazards are controlled by importer or its customer, only need to document annually that hazards are being controlled (if controlled by customer, obtain written assurance)
  – But we noted our intent to align FSVP with any PC supplier verification provisions to avoid imposing redundant requirements
Importers with PC Supplier Programs

• Comments:
  – Generally agreed with proposal and with avoiding imposing redundant requirements on importers who also are facilities that would be subject to PC supplier verification requirements
Importers with PC Supplier Programs

• Revisions in SNPRM:
  – Importers that have supplier programs in compliance with PC supplier program provisions would be deemed in compliance with most FSVP requirements
  – If importer’s customer is in compliance with PC supplier program provisions, importer would annually obtain written assurance
Hazard Analysis

• Original Proposed Rule:
  – Consider hazards “reasonably likely to occur” (RLTO) in an imported food

• Comments:
  – RLTO standard inappropriate due to use in determination of HACCP critical control points; should consider “known or reasonably foreseeable hazards”
Hazard Analysis

• Revision in SNPRM:
  – Importer would be required to determine whether any “known or reasonably foreseeable hazards” are “significant” (knowledgeable person would, based on a hazard analysis, establish controls to significantly minimize or prevent and components to manage those controls)
Hazard Analysis (cont.)

• Original Proposed Rule:
  – Importer must consider hazards that may occur naturally or may be unintentionally introduced
  – Requested comment on whether importers should consider hazards intentionally introduced for economic reasons (economically motivated adulteration – EMA)

• Comments:
  – Mixed views on inclusion of EMA
Hazard Analysis (cont.)

• Revision in SNPRM:
  – Importers would be required to consider hazards that may be intentionally introduced for economic gain
  – Some EMAs should be regarded as known or reasonably foreseeable hazards in certain foods (e.g., melamine in pet food)
Risk Evaluation

• Original Proposed Rule:
  – In addition to hazard analysis, importers would be required to conduct food and supplier compliance status review
  – Would include review of warning letters, import alerts, and import certification requirements
Risk Evaluation

• Comments:
  – Should take holistic approach, considering risks inherent in food and risks associated with suppliers, including supplier history of performance and response to problems
  – Agreement that these documents often are relevant, but perceived over-emphasis on compliance failures
  – Concerns about availability of information
Risk Evaluation

• Revision in SNPRM:
  – In addition to hazard analysis, importer would be required to consider supplier-related risks in determining appropriate supplier verification activities
  – Importer would be required to promptly reevaluate risks when it becomes aware of new information about risks
Supplier Verification Activities

• Original Proposed Rule:
  – Maintain written list of approved suppliers

• Comments:
  – List would pose logistical or administrative challenges
  – Some suggested importers be required to have system that ensures use of approved suppliers
Supplier Verification Activities

• Revised in SNPRM:
  – Importer would need to establish and follow written procedures to ensure use of suppliers approved on the basis of the risk evaluation
  – When necessary and appropriate, importer may use unapproved supplier if importer subjects the food to adequate verification activities
Verification Activities (cont.)

- Original Proposed Rule:
  - Two alternatives for supplier verification activity requirements
    - Option 1: Mandatory annual onsite auditing in certain circumstances
    - Option 2: Importer has flexibility to select from among specified activities
Verification Activities (cont.)

• Comments:
  – Option 1 supporters
    • Greater protection for consumers
    • Most rigorous method for most serious risks
    • Option 2 incentivizes use of lower-cost methods
  – Option 2 supporters
    • More flexible and risk-based
    • Aligns with industry practice
    • Allows better allocation of resources
Verification Activities (cont.)

- Revision in SNPRM:
  - Importer to determine appropriate verification activities (and frequency) based on risk evaluation
  - When there is a serious hazard controlled by foreign supplier, importer would need to obtain annual onsite audit unless it determined that other activities and/or less frequent auditing are appropriate
Verification Activities (cont.)

• Revision in SNPRM (cont.):
  – If foreign supplier is a farm not subject to the produce safety regulations, verification would entail obtaining written assurance every 2 years that the supplier produces food consistent with the FD&C Act
Documentation of Verification

• Original Proposed Rule:
  – Did not specify documentation that would be required for different types of verification activities

• Comments:
  – Opposed to applying third-party auditing provisions to FSVP audits
  – Opposed to making audit reports available to FDA
Documentation of Verification

• Revision in SNPRM:
  – For audits, full reports would not be required; importer would be required to document procedures, dates, conclusions, corrective actions, and use of qualified auditor
  – Basic requirements specified for sampling and testing, record review
Very Small Importers

• Original Proposed Rule:
  – Defined “very small importer” and “very small foreign supplier” as having annual food sales of no more than $500,000

• Comments:
  – Some suggest a higher ceiling (e.g., $1 million or $2 million)
  – Some oppose any modified requirements for very small firms
Very Small Importers

• Revision in SNPRM:
  – Increase proposed annual food sales ceiling to $1 million consistent with change to PC definition of “very small business”
  – Request comment on how to take into account definition of “very small business” in PC for animal food regulations (< $2.5 million in annual sales) and exclusion from Produce Safety regulations of farms with sales of no more than $25,000
Regulatory Impact Analysis

- Revisions to the proposed rule result in cost reduction:

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Questions and Discussion
Supplemental Proposed Produce Safety Rule
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

• Re-opening the 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 irrigation water
  - Frequency of testing
- 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 in irrigation and crop protection
  - 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

- 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 in irrigation & crop protection:
– Geometric mean of no more than 126 CFU generic *E. coli* /100 mL
– Statistical Threshold Value (STV) (approximately 90%) not to exceed 410 CFU generic *E. coli* /100 mL
– For water that does not meet microbial standard, alternate options are provided to account for microbial die-off:
  • 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
  – For untreated, unprotected surface water, every 7 days depending on source
  – For untreated ground water, begin testing at the start of growing season and 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
  – Proposed testing frequency for water used in irrigation and crop protection
  – Tiered approach to testing untreated surface water:
    • Baseline survey of water quality profile near periods of harvest (over 2 years) to determine appropriate use
    • Annual verification survey to verify water quality
    • Re-establish baseline water quality once every 10 years using annual data (or sooner, if necessary)
  – Tiered approach to testing untreated ground water
    • Baseline testing 4 times during growing season or year
    • Annual testing once during growing season or year
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

• 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

- **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

• 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
  - 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

• **Issue**
  – 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

• 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

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QUESTIONS/DISCUSSION
Preventive Controls for Human Food Facilities
Supplemental Proposal
Background

- FDA issued proposed rule on Jan. 16, 2013
  - Proposed Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food
- Stakeholder Input
  - 3 Public meetings; various outreach efforts
  - Comment period closed on Nov. 22, 2013
  - Approximately 8,000 comments received
- Re-opened the docket Sept. 29, 2014
  - Describe FDA’s current thinking on certain specific issues
  - Seek public comment on new/revised provisions
Issues Addressed in Supplement

• Packing and holding of own and others’ RACs (farm definition)
• Definition of holding
• Definition of very small business
• Framework for hazard analysis/ preventive controls
• Product testing/ environmental monitoring
• Supplier program
• Economically motivated adulteration
• Withdrawal of exemption
Packing and Holding of Own and Others’ RACs

• **Issue**
  – 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
  – Would modify the farm definition so it would include facilities 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 food out of the PC rule (because now considered a farming activity) and into the produce rule because now considered a farming activity
On-farm vs. Off-farm Packinghouses

- Subject to different rules due to statute
- Reasonable to expect similar controls at both types of packinghouses
  - CGMP requirements for off-farm PHs would be analogous to those for on-farm
  - Off-farm PH food safety plan would focus on preventive controls similar to those required of on-farm PHs under the produce safety standards
Drying/Dehydrating RACs

• Drying to create a distinct commodity results in a processed food (e.g., raisins)
• For some commodities, this is akin to harvesting activities traditionally conducted on RACs
• Revised farm definition includes this activity, provided no additional manufacturing/processing is conducted
Other Farm-Definition Issues

• Field coring listed as a harvesting activity within the farm definition
• Request comments on “one general physical location” provision in the farm definition
• RAC exemption does not apply to drying/dehydrating of RACs to create a distinct commodity
Definition of Holding - RACs

- **Proposed**
  - Exemption for facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing (e.g., grain elevators)

- **Public Comments**
  - Unless we clarify that activities incidental to holding (e.g., drying, screening, fumigating, and blending) are within that definition, few grain elevators would qualify for the exemption
Definition of Holding – Packaged Food

• **Proposed**
  – Exemption for facilities that are solely engaged in the storage of packaged food not exposed to the environment

• **Public Comments**
  – Unless we clarify that activities incidental to holding (e.g., holding non-food items, break down pallets, assemble variety packs) are within that definition, few warehouses would qualify for the exemption
Definition of Holding

• **FDA Action in Supplemental Proposed Rule**
  – Modified the definition of holding to include activities performed incidental to storage of a food (e.g., for the safe or effective storage of that food and activities performed as a practical necessity for distribution of that food (such as blending the same RAC and breaking down pallets)) but not include any activities that would transform a RAC into a processed food
Very Small Business

• **Proposed**
  – Three options based on total annual sales of food, adjusted for inflation: Option 1, $250,000; Option 2, $500,000; and Option 3, $1,000,000.

• **Public Comments** - various concerns, incl.
  – Concern about costs to very small facilities
  – Concerns about including all food, including animal feed
  – Concern that Options 2 & 3 would nullify the intent of § 418(l) to create two types of qualified facilities
Very Small Business

- **FDA Action in Supplemental Proposed Rule**
  - Defined very small business to mean a business that has less than $1,000,000 in total annual sales of human food adjusted for inflation.
  - Would be qualified facilities subject to modified requirements.
    - Subject to FD&C Act
    - Subject to mandatory inspection frequency
    - Produce only a small percentage of food supply
Framework for Hazard Analysis / Preventive Controls

• **Proposed**
  – Conduct a hazard analysis of known or reasonably foreseeable hazards to determine which are reasonably likely to occur
  – Implement preventive controls (PCs) for these hazards

• **Public Comments** - various concerns, incl.
  – Framework would require all PCs to have critical control points (CCPs)
  – Lack of flexibility to manage PCs as appropriate based on risk
Framework for Hazard Analysis / Preventive Controls

• FDA Action in Supplemental Proposed Rule
  – Revised the framework to refer to “significant hazards” instead of “reasonably likely to occur”
  – Clarified that not all preventive controls require CCPs
  – Provided more flexibility with respect to how preventive controls are implemented based on the food, the facility and the nature of the control
Product Testing/Environmental Monitoring

• **Proposed**
  – Requirements not included; requested comment on when and how finished product testing and environmental monitoring would be appropriate

• **Public Comments** - various issues, incl.
  – General support for their inclusion
  – Many suggestions for what should be required
  – Requirements should be risk-based
  – Concerns about being too prescriptive
Product Testing/Environmental Monitoring

• FDA Action in Supplemental Proposed Rule
  – Included flexible requirements for product testing and for environmental monitoring as verification activities
  – Such verification activities would be conducted as appropriate to the facility, the food and the nature of the preventive control
Supplier Program

- **Proposed**
  - Requirements not included; requested comment on when and how supplier verification would be appropriate

- **Public Comments** - various issues, incl.
  - General support for its inclusion
  - Many suggestions for what should be required
  - Requirements should be flexible and risk-based (Include consideration for ingredient inherent risk and supplier performance history)
Supplier Program

- FDA Action in Supplemental Proposed Rule
  - Would establish a risk-based requirement (for manufacturers/processors) for a written supplier program for hazards controlled before receipt of raw material or ingredient
  - Would require use of suppliers approved for control of the hazard(s)
  - Would provide flexibility for facility to determine appropriate verification activities
  - Would require annual audit for SAHCODH hazards unless facility can document that an alternative approach provides adequate assurance hazards are controlled

Cont. on next slide
Supplier Program (cont.)

- FDA Action in Supplemental Proposed Rule
  - Would allow alternative verification procedure for supplier that is a qualified facility or not subject to produce safety rule
  - Would establish requirements applicable to an onsite audit
  - Would provide for inspections in lieu of audit
  - Would require facilities to address supplier non-conformance
Economically Motivated Adulteration

- **Proposed**
  - No requirement; we requested comment on whether to include potential hazards that may be intentionally introduced for economic reasons.
  - Intentional adulteration rule indicated best addressed in the PC rule

- **Public Comments**
  - Most comments opposed inclusion of EMA requirements – difficult to determine if such adulteration is reasonably foreseeable
  - Others supported inclusion of “expected intentional adulterants”
Economically Motivated Adulteration

• FDA Action in Supplemental Proposed Rule
  – Would require facilities to consider hazards that may be intentionally introduced for purposes of economic gain
  – Limited circumstances - where there has been a pattern of such adulteration in the past, with adverse public health consequences
Withdrawal of Exemption

• **Proposed**
  – Certain procedures for withdrawal of exemption for qualified facility

• **Public Comments**
  – Clarify circumstances under which FDA would withdraw the exemption
  – Provide for intermediate steps prior to withdrawal
  – Provide for reinstatement of exemption that is withdrawn
Withdrawal of Exemption

- FDA Action in Supplemental Proposed Rule
  - Clarified that before withdrawing an exemption we would first consider other steps (e.g., warning letter, injunction) and the actions taken by the facility to correct the problem
  - Would explicitly provide for notification and opportunity for response before determining to withdraw an exemption
  - Would provide process for reinstatement of exemption that has been withdrawn
Questions and Discussion