China Stakeholder Session

China

September 24-27, 2013

FDA FOOD SAFETY
MODERNIZATION ACT

FDA

Global Food Safety Modernization Through Partnerships

- The US, the China, and other competent authorities are modernizing their food safety frameworks
- Consumer confidence in government depends on teamwork to respond quickly to outbreaks
- Governments share information to set standards (e.g., Codex)
- Leveraging and strengthening capacity of competent authority partners is vital for food safety

Why Are These Proposed Rules Important?

- Consumers depend on both domestically produced and imported foods
- About 15 percent of the U.S. food supply is imported (incl. nearly 50 percent of fresh fruit and 20 percent of fresh vegetables)
- Consumers expect that their foods be safe whatever the source

Proposed Rules Implement Preventive Framework

- Safety standards established by FDA
  - Standards for produce safety
  - Preventive controls for human food
- Industry must verify standards are met
  - Foreign supplier verification program
  - Accreditation of third-party auditors
- Additional rules and guidance coming

Produce

FDA Proposed Rule on Produce Safety

Key Principles

Produce

- 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

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Produce

21 CFR Part 112

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption

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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

Produce

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

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”
- Qualified exemption
  - Size < $500,000 sales AND
  - Market channels > 50% to qualified end users

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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

- Growing, harvesting, packing and holding
- Sprouts

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Agricultural Water

- **"Agricultural water":** Water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food-contact surfaces
- Agricultural water must be safe and of adequate sanitary quality for its intended use
- Inspection of agricultural water system
- Specific criteria for quality of water used for certain purposes, and analytical testing

Biological Soil Amendments of Animal Origin

Produce

- Proposed rule covers “biological soil amendments of animal origin” (BSAoAO)
  - Which consist, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts, or table waste, alone or in combination
  - This term does not include any form of human waste
  - May contaminate produce with pathogens
- Physical and chemical soil amendments not covered by proposed rule

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Simplified Application Interval Table

Treatment	Crop Contact	Application Interval
Untreated	None at application/ Minimized after	9 months
Untreated	None	0 days
Composting	Minimized	45 days
Composting	None	0 days
Chemical/Physical (such as heating)	Minimized	0 days
“Mushroom substrate” or equivalent	No restrictions	0 days

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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

Produce

- 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

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Domesticated/Wild Animals

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- 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)

FDA

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

Produce

Variances 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.

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Compliance Dates

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- **Very small farms**
  - Average annual value of food sold >$25,000 and ≤$250,000 - 4 years after the effective date to comply
- **Small farms**
  - > $250,000 and ≤ $500,000 - 3 years
- **Other covered farms (not small or very small)**
  - Would have 2 years after the effective date to comply

All would have an additional 2 years for some water requirements

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National Environmental Policy Act review of the Proposed Rule

- The National Environmental Policy Act requires that the environmental impacts of final actions be assessed.
- FDA has determined that the proposed action may significantly affect the quality of the human environment and, therefore, an Environmental Impact Statement (EIS) is necessary for the final rule.

Human PC

Preventive Controls for Human Food Facilities

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Human PC

21 CFR Part 117

- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food
  - Hazard Analysis and Risk-Based Preventive Controls
  - Updated Good Manufacturing Practices

Human PC

Who is 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

Hazard Analysis and Risk-Based Preventive Controls

Human PC

FDA

Exemptions and Modified Requirements -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 - 2

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

Exemptions and Modified Requirements - 3

- Facilities, such as warehouses, that only store packaged foods that are not exposed to the environment are exempt from the requirements for hazard analysis and risk-based preventive controls
  - If refrigeration is required for safety, the facility must have temperature controls, monitoring, verification and records

Exemptions and Modified Requirements - 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.

Human PC

Human PC

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

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Human PC

Specific Provisions

Proposed Requirement for a Food Safety Plan

- Facility must prepare and implement a written food safety plan
  - Identify and evaluate hazards
  - Implement preventive controls for the hazards
    - Process controls, food allergen controls, sanitation controls, recall plan
  - Monitor and verify preventive controls and take corrective actions if not properly implemented
  - Keep records of these activities

Additional Provisions Being Considered

- Supplier approval and verification program
- Review of complaints,
- Finished product testing and
- Environmental monitoring

As appropriate to the food and facility

Human PC

Compliance Dates

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

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Compliance Dates (cont.)

- **Other Businesses**—a business that does not qualify for exemptions would have one year after publication of the final rule to comply.

FSVP

Proposed Regulations for Foreign Supplier Verification Programs (FSVPs)

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FSVP

Key Principles

- Importers would be responsible for ensuring that the food they bring into the U.S. meets FDA safety standards
- The requirements provide flexibility based on the risk of the food
- Under sec. 404 of FSMA, the requirements must be consistent with the WTO agreement and any other treaty or international agreement to which the U.S. is a party

FDA

Overview of FSVP

- Importers would be required to develop, maintain, and follow an FSVP for each food imported, unless an exemption applies.
- The requirements vary based on:
  - Type of food product
  - Category of importer, such as very small
  - Nature of the hazard identified in the food
  - Who is to control the hazard

FSVP

Who Is Covered?

- An importer is a person in the U.S. who has purchased the food being offered for import
  - If there is no U.S. owner at the time of entry, the importer is the U.S. consignee
  - If no U.S. owner or consignee at time of entry, the importer is the U.S. agent or representative of the foreign owner or consignee

FDA

What Is Exempt?

- Importation of juice and seafood whose suppliers are in compliance with HACCP regulations
- Food imported for research and evaluation purposes
- Food imported for personal consumption
- Alcoholic beverages

What Is Exempt? (cont.)

- Food that is transshipped or that is imported for future export and not consumed or distributed in the U.S.
- Products from facilities subject to FDA's low acid canned food requirements (for microbiological hazards only, not subject to standard FSVP requirements)

FSVP Requirements

- In general, importers would need to conduct the following activities as part of their FSVPs:
  - Compliance status review of foods, suppliers
  - Hazard analysis
  - Supplier verification activities
  - Complaints, investigations, and corrective actions (if necessary)
  - Periodic reassessment of the FSVP
  - Importer identification at entry
  - Recordkeeping

FSVP

Control of Hazards

- The proposed requirements for supplier verification are primarily based on who is to control the hazards that are reasonably likely to occur.

Importer or Customer Controls Hazard

FSVP

- If the importer will be responsible for controlling a hazard identified as reasonably likely to occur, the importer would be required to document, at least annually, that it has established and is following procedures that adequately control the hazard.

Importer or Customer Controls Hazard (cont.)

- If the importer's customer will be controlling a hazard, the importer would need to obtain written assurance, at least annually, that its customer has established and is following procedures that adequately control the hazard.

Hazard Controlled by Foreign Supplier or Its Supplier

FSVP

- FDA is proposing two options for supplier verification activities when:
  - The foreign supplier is to control a hazard or
  - The foreign supplier verifies that its raw material or ingredient supplier is controlling a hazard
- The options differ based on approach to hazards that can cause serious adverse health consequences or death to humans or animals (SAHCODHA)

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Option 1

- If the foreign supplier controls the hazard at its establishment and it is a SAHCODHA hazard, the importer would be required to conduct or obtain documentation of onsite auditing of the foreign supplier.
- Onsite auditing would also be required for microbiological hazards in certain raw agricultural commodities.

Option 1 (cont'd)

- For non-SAHCODHA hazards and all hazards for which the foreign supplier verifies control by its raw material or ingredient supplier, importer would be required to choose a verification activity:
  - Onsite auditing
  - Sampling and testing
  - Review of supplier food safety records
  - Some other appropriate procedure

FSVP

Option 2

- For all hazards that the foreign supplier will either control or verify that its supplier is controlling, importers would need to choose a verification procedure from among:
  - Onsite auditing
  - Sampling and testing
  - Review of supplier food safety records
  - Some other appropriate procedure.

FSVP

Option 2 (cont.)

- In determining which verification activities are needed and how often they should be conducted, the importer would need to consider:
  - The risk presented by the hazard
  - The probability that exposure to the hazard would result in serious harm
  - The food and foreign supplier's compliance status.

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Modified FSVP Requirements

- Dietary supplements and dietary supplement components
- Food imported by a very small importer or from a very small foreign supplier
- Food from a foreign supplier in good compliance standing with a food safety system that FDA has officially recognized as comparable or equivalent

FSVP

Effective and Compliance Dates

- Effective date expected to be 60 days after publication of the final rule
- Compliance dates
  - Generally 18 months after publication; or
  - Six months after the importer's foreign supplier is required to comply with the new preventive controls or produce safety regulations.

3rd Party

Proposed Rule Accreditation of Third-Party Auditors

FDA

Key Principles

- A credible third-party program will allow the agency to leverage industry audits
- A credible third-party program will help to facilitate entry of certain imported food
- A comprehensive third-party program will create a new path for working with foreign governments

Overview

- FDA must establish voluntary program for accrediting third-party auditors to conduct food safety audits of foreign facilities and their foods
- FDA will recognize accreditation bodies, which will in turn accredit third-party auditors under the program
  - FDA can directly accredit third-party auditors in limited circumstances

Are Third-Party Audits Required?

- Importers will not generally be required to obtain certifications
- In certain circumstances FDA would use certifications in determining:
  - Whether to admit certain imported food into the U.S. that FDA has determined, based on FSMA criteria, poses a food safety risk, or
  - Whether an importer is eligible to participate in VQIP

How it Would Work

3rd Party

FDA

FDA would recognize accreditation bodies based on certain criteria such as competency and impartiality.

Accreditation Bodies

Accreditation bodies would in turn accredit qualified third-party auditors.

Third-Party Auditors or Certification Bodies

Third-party auditor s/certification bodies would audit and issue certifications for foreign facilities and foods.

Foreign Facility

Foreign facilities may choose to be audited by an accredited auditor /certification body.

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Eligibility for Recognition of Accreditation Bodies (ABs)

- Foreign government agencies or private organizations
- Must meet requirements on authority, competency, capacity, impartiality, quality assurance, and records

Eligibility for Accreditation- Third Party Auditors/ Certification Bodies

3rd Party

- Foreign government or government agency; a foreign cooperative or other private third party
- Must meet requirements regarding authority, competency, capacity, conflict of interest, quality assurance and records

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Requirements for Accredited Auditors

- Audit agent competency
- Audit protocols
- Notifications
- Audit reports
  - Consultative audit
  - Regulatory audits (these are not FDA inspections)

Use of Certifications Issued by Accredited Third-Party Auditors

- In meeting eligibility requirements for VQIP for expedited review and entry of food
- In providing certification or other assurances of compliance as a condition of entry for food determined by FDA to pose a safety risk under FSMA criteria

Next Steps

- FDA to hold three public meetings on FSVP and third party accreditation rules during the comment period
  - First meeting Sept. 19-20, Washington, DC
- FDA to continue outreach to stakeholders through webinars, listening sessions, other meetings

Web Page: http://www.fda.gov/fsma

Food

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Guidance & Regulation

- Food Safety Modernization Act (FSMA)
- The Law, Rules & Guidance
- How to Comment on FSMA
- Fact Sheets
- Frequently Asked Questions
- Speeches, Videos, & Webinars
- FDA Actions to Date

Resources for You

- FSMA Blog
- The Rulemaking Process (a video tutorial)
- FSMA 101 (a video tutorial)
- Translations of Key FSMA Resources
- Foodborne Illness Outbreaks

FDA Food Safety Modernization Act (FSMA)

The FDA Food Safety Modernization Act (FSMA), the most sweeping reform of our food safety laws in more than 70 years, was signed into law by President Obama on January 4, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it.

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Spotlight

FDA Answers Farmers' Questions on the Proposed Rule for Produce Safety
Q&A with Mike Taylor, Deputy Commissioner for Foods and Veterinary Medicine

What's New

Strengthening the Oversight of Imported Foods
FDA issues two proposed rules under the Food Safety Modernization Act (FSMA) aimed at strengthening assurances that imported food meets the same safety standards as food produced domestically.

- Proposed Rule on Foreign Supplier Verification Programs for Importers of Food for Humans and Animals
- Proposed Rule on Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications

Most Popular

- FSMA Information by Topic
- Full Text of the Law
- Food Facility Registration
- FSMA Rules & Guidance for Industry
- Public Meetings

For Consumers

- What Does the New Food Safety Law Mean for You?
- FDA Strengthening Our Food Safety Foundation
- Foreign Exporters Study Food Safety Law
- Fact Sheets

Input from FSMA Partners is Vital

- Proposals are opportunity for government, industry, and the public to partner with FDA in putting FSMA regulations in place
- Your comments and feedback are important to us!
- Please voice your questions and concerns which will help FDA during finalization

Commenting on Proposed Rules

- Where to find proposed rules
  - www.regulations.gov
  - Link to rules on www.fda.gov/fsma
- Comments due:
  - Produce and preventive: Nov. 15
  - FSVP and third party accreditation: Nov. 26
- Comment periods coordinated to enable comment on how the rules can best work together.