

U.S. Food and Drug Administration  
Office of International Programs



FDA's China Office:  
Focus on Food Safety  
and the Food Safety  
Modernization Act

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# U.S. Food and Drug Administration Office of International Programs



## The FDA China Office and Food Safety



# FDA's Role in Food Safety

- FDA is the U.S. regulatory agency charged with ensuring the safety and proper labeling of:
  - Human food (besides meat, poultry, processed egg products)
    - Includes dietary supplements, food and color additives, bottle water, infant formula...
  - Animal feed/pet food
- Central focus: protecting U.S. consumers
- FDA does not:
  - Regulate meat, poultry, or processed egg products (U.S. Department of Agriculture Food Safety Inspection Service responsible)
  - Directly regulate U.S. exports
  - Promote U.S. exports
  - Regulate safety of Chinese domestic products
  - Certify food firms or products



# FDA China Office

## Posts Officially Opened in 2008

- Beijing
  - Country Director, Deputy Director
  - Three Senior Technical Experts (Foods, Medicines, and Medical Devices)
- Shanghai
  - Inspectors
- Guangzhou
  - Senior Technical Expert for Foods
  - Inspectors (Foods Expertise)
- Local Hires in All Three Posts in China (Five in Total)



# Key Activities

- Further relationships with counterpart agencies
  - For foods, primarily AQSIQ and CNCA
  - Includes capacity building, training (aquaculture, labs, low-acid canned foods, nutrition and labelling, food defense/food protection)
- Engage with regulated industry to support production of safe and high quality foods
- Conduct inspections
- Monitor and report on conditions and events that might affect the safety and quality of FDA-regulated products
- Collaborate with other U.S. government agencies, academia, multilateral organizations



# Key Food Safety Initiatives

## Aquaculture (Farm-Raised Seafood)

- Based on findings of unapproved drugs in Chinese aquaculture, FDA put 5 species of Chinese aquaculture on import alert.
- FDA has worked with AQSIQ to put on workshops for industry to better understand good aquaculture practices.
- FDA is working closely with AQSIQ to better understand the Chinese control system with respect to aquaculture to address concerns related to the import alert.



# Key Food Safety Initiatives

## Low-Acid Canned Foods (LACF)

- Initial inspectional findings indicated a lack of understanding of FDA requirements.
- FDA worked closely with AQSIQ to conduct training for industry.
- AQSIQ/CNCA developed an oversight program based on FDA requirements.
- FDA China Office worked to establish the first Better Process Control Schools (BPCS) training program in China.
- Currently, working with AQSIQ/CNCA on pilot project to determine whether FDA can use CNCA registration information to determine FDA risk scores for LACF shipments from China.





# Key Food Safety Initiatives

## Increased Food Facility Inspections

- Allows FDA to have insight on local manufacturing practices and give feedback to firms.
- Focused on areas of higher risk:
  - LACF production
  - Seafood
  - Dietary supplements
  - Produce, Seeds, Low-moisture foods





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The Food Safety  
Modernization Act  
(FSMA)

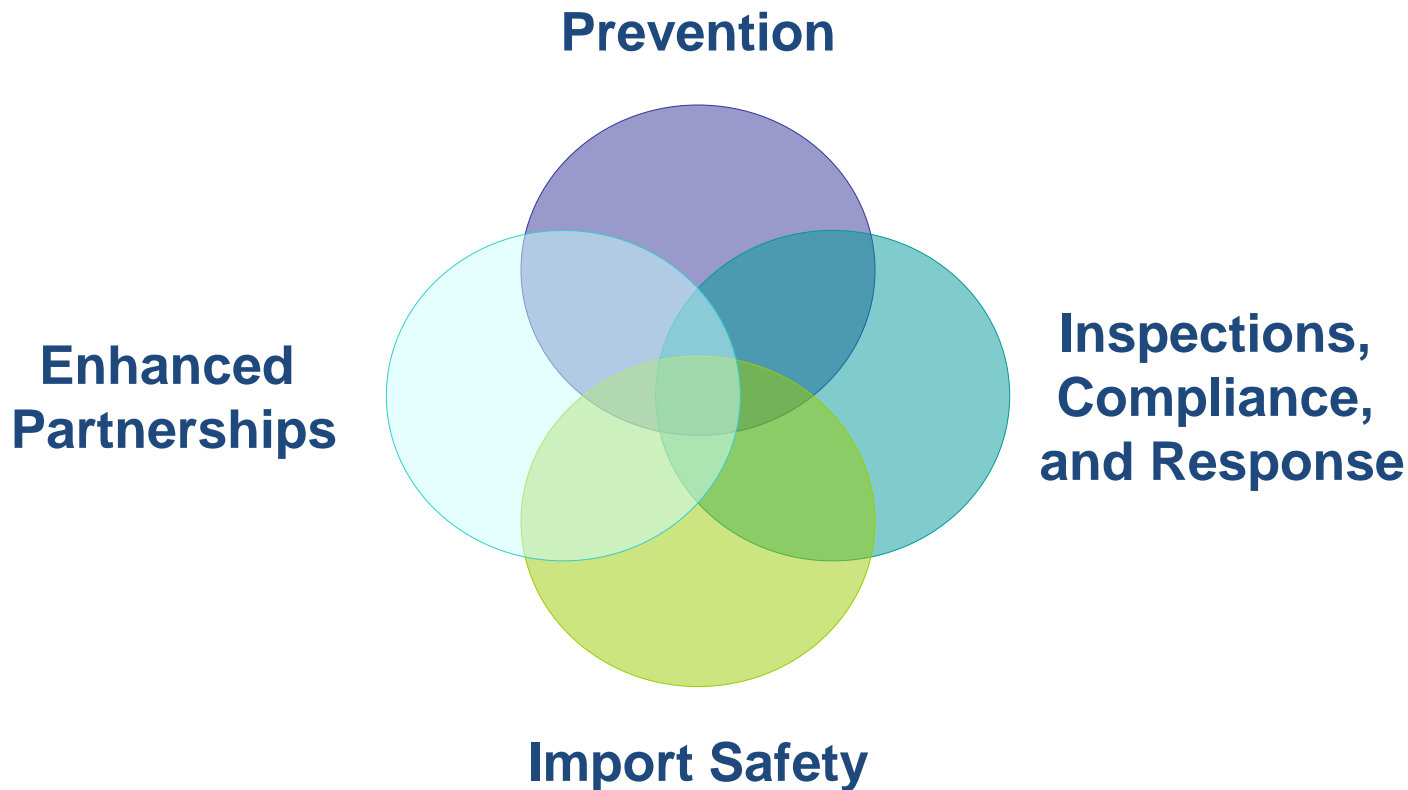


# Why is the Law Needed?

- Globalization
  - 15 percent of U.S. food supply is imported
- Food supply more high-tech and complex
  - More foods in the marketplace
  - New hazards in foods not previously seen
- Shifting demographics
  - Growing population (about 30 percent) of individuals are especially “at risk” for foodborne illness



# Main Themes of the Legislation





# Implementation Approach

- Focus on public health protection
- Engage with stakeholders to help determine reasonable and practical ways to implement provisions
- Transparency a priority
  - At each stage of the implementation process, we will make every effort to ensure that our proposed activities, policies, and measures are consistent with WTO requirements



# International Capacity Building

- FDA has mandate to work with foreign governments to build their food safety capacity
- Allows FDA to rely more heavily on foreign government oversight
- Capacity building helps to prevent problems before products reach the U.S. port of entry
- In February 2013, FDA issued its new International Food Safety Capacity-Building Plan
  - Available at:  
<http://www.fda.gov/Food/FoodSafety/FSMA/ucm301708.htm>



# Five Proposed Rules Establish Food Safety Framework

- Standards for Produce Safety - Published January 2013
- Preventive Controls for Human Food - Published January 2013
- Foreign-Supplier Verification Program
- Preventive Controls for Animal Food
- Certification by Accredited Third Parties



# Key Aspects of Proposals

- Confirm industry's primary role on food safety
- Risk-based and flexible
- Address small business issues
- Extensive government, stakeholder Input





# Proposed Standards for Produce Safety

## Focus on identified routes of microbial contamination

- Domesticated and wild animals
- Equipment, tools, buildings and sanitation
- Worker health and hygiene
- Agricultural water
- Growing, harvesting, packing and holding activities
- Biological soil amendments of animal origin
- Specific requirements for sprouts



# 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



# 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 \$25,000 or less per year
- Qualified exemption and modified requirements



# Preventive Controls for Human Food Proposed Rule

- 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 is Covered?

- Facilities that manufacture, process, pack or hold human food
- In general, facilities required to register with FDA under Section 415 of the U.S. Food, Drug and Cosmetic Act
- Applies to domestic and imported food
- Some exemptions and modified requirements are being proposed



# Hazard Analysis and Risk-Based Preventive Controls

Human PC







# Rulemaking Process

- Rulemaking is open and public
- Draft rules are published on <http://www.regulations.gov>
- Time is allowed for public comment, and FDA is required to consider significant comments during the rulemaking process
- Check <http://www.fda.gov/fsma> for most current information.