

# Food Safety Update

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# Why is the law needed?

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- Globalization
  - 15% 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%) of individuals are especially “at risk” for foodborne illness

# FSMA Big Picture

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- Bill passed in Lame Duck session in December 2010
- In the 111th Congress, food safety was broadly bipartisan
- What politician is against safe food?

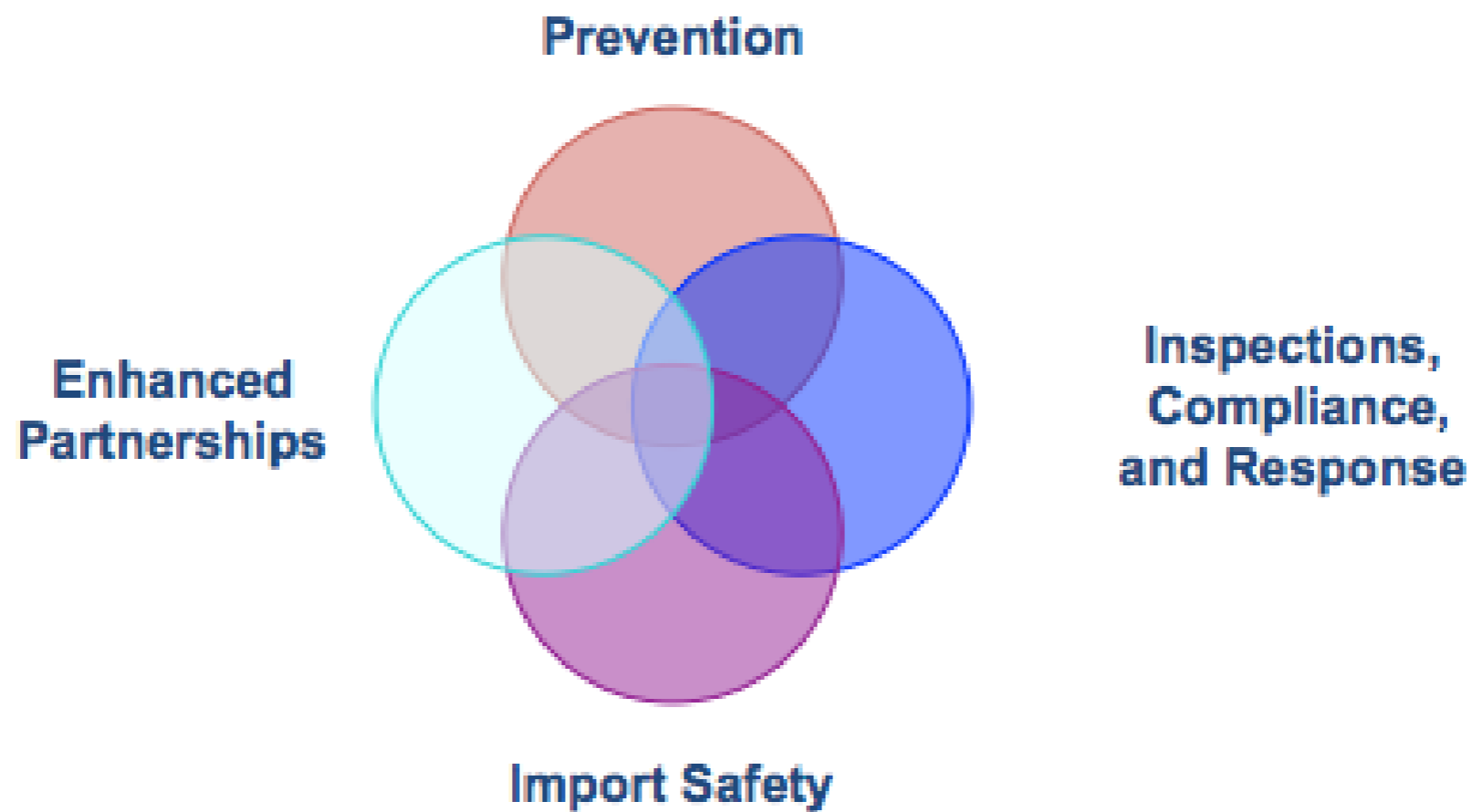
# Historic Law

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- Involves creation of a new food safety system
- Broad prevention mandate and accountability
- New system of import oversight
- Emphasizes partnership (i.e. State Ag)

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# Main Themes of the Legislation



# Inspection, Compliance, and response

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- Mandated inspection frequency
  - Food facilities every 2 years
- New tools
  - Mandatory recall
  - Expanded records access
  - Enhanced product tracing
  - Third party lab testing

# FDA Regulated Foods

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- These rules apply to everything not meat and poultry
- And not
  - Seafood (already a seafood HACCP rule)
  - Juices (already a juice HACCP)

# Proposed “Produce Safety Rule”

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- Standards for the growing, harvesting, packing, and holding of produce for human consumption
  - 547 pages, last 66 are the actual rule
- Applies to raw agricultural commodities
  - Includes fruits, vegetables, mushrooms (yes, different than vegetables), tree nuts, and sprouts
- Five areas covered: Workers, Ag. water, Animal-derived soil amendments, facilities and food contact surfaces



# Farm Defined...

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- to mean a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood) or both.
- This includes:
  - (i) facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and
  - (ii) facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

# Produce Safety Rule

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- 2 years after the acceptance date for large farms, 3 years for small farms (<\$500,000 in sales) and 4 years for very small (<\$250,000 in sales) farms.
- Rules will not address a farm selling less than \$25,000 annually
- Rule allows for variances and alternatives to the soil and water amendments
- Records/documentation for 2 yrs.

# Five Defined Hazards

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- Personnel qualifications/Worker health and hygiene training  
SUBPART C & D
- Agricultural water (that contacts the produce or food contact surfaces) SUBPART E
- Animal-derived soil amendments (reasonably likely to contact the produce or food contact surfaces) SUBPART F
- Animals (wildlife and domestic) SUBPART I
- Facilities and food contact surfaces (equipment, tools, instruments and controls, transport) SUBPART L
- Specific requirements for sprouts SUBPART M

# Subpart C: Standards Directed to Personnel Qualifications and Training

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- All personnel (temporary, part-time, seasonal and contracted) who supervise or handle covered produce or food-contact surfaces must receive adequate training
  - Beginning of each growing season, periodically afterwards or as needed
- Minimum training required for personnel that handle produce includes:
  - Principles of food hygiene and food safety, recognition of product related issues that may affect food safety, techniques on how to inspect harvest containers and equipment for proper functionality, cleanliness and maintenance so as not to become a source of contamination
- Management training responsibilities
  - Supervisor/responsible party must have successfully completed approved food safety training
- Records of trainings

# Subpart D: Standards Directed to Health and Hygiene

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- Management is required to take steps to prevent ill/infected persons contaminating product or food contact surfaces
  - Exclude ill personnel from work
  - Instruct personnel to report to management any possibility of applicable health conditions
- Personnel Hygienic Practices
  - Personal cleanliness
  - Avoid contact with animals other than working animals; Minimize potential for contamination from working animals
  - Washing hands; If using gloves: maintain gloves in an intact and sanitary condition
- Visitor control:
  - Make visitors aware of policies and procedures
  - Make toilet and hand-washing facilities accessible to visitors

# Subpart E: Agricultural Water

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- Agricultural water is defined as: water used in growing activities or on produce and include:
  - Water that may contact food-contact surfaces; growing activities: irrigation water w/ direct application, crop sprays, packing, and holding actives (including washing, cooling, etc.)
  - Agricultural water does not include indirect water application methods utilized during growing activities
  - Requires that all agricultural water must be of safe and sanitary quality for its intended use

# Subpart E: Agricultural Water (continued)

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- Water-change schedules for re-circulated water:
  - The quality of water visually monitored (dump tanks, flumes, or wash tanks, and water used in hydrocoolers) for build-up of organic materials (such as soil and plant debris)
- Temperature of water must be maintained and monitored appropriately for the commodity and operation (time and depth of submersion)
- Must establish and keep the following records:
  - The findings of the inspection; Documentation of the results of any analytical tests; Scientific data or information to support the adequacy of a method; Documentation of the results of water treatment monitoring; Documentation of the results of water testing that is performed, Scientific data or information you rely on to support any alternative to the requirements established in § 112.44(c) for agricultural water used during growing activities using a direct water application method in accordance with the requirements of § 112.44(d). Annual documentation of results or certificates of compliance from a public water system.

# Subpart E: Agricultural Water (continued)

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- Inspect entire water system “under your control”(ie water source, distribution system, facilities, and equipment)
- Testing: (exception: public water, treated water)
  - For everyone: Beginning of growing season and every 3 months (minimum)
- Testing-Untreated Surface Water
  - Subject to runoff (river/lake)-every 7 days
  - NOT subject to runoff (aquifer)-monthly



# Subpart E: Agricultural Water (continued)

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- Testing
  - No generic E. coli (0 MPN/100mL)
    - Directly contacts produce during/after harvest (postharvest)
    - Used to make treated “agricultural tea” (vermicompost)
    - Food contact surfaces
    - Washing hands
  - Direct water application during growing (field)
    - Generic E. coli <235 MPN/100 mL (single sample) and <126 MPN/100 mL (5 samples rolling geometric mean)
- No standard for non-direct water application (drip)
- Records of test results required

# Subpart F Animal-derived soil amendments

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- Human waste prohibited, unless in compliance with 40 CFR part 503 (biosolids)
- 9 month interval for use of untreated amendments that contact produce
- Standards for testing:
  - *Listeria Monocytogenes*, *Salmonella*, *E coli* O157:H7 and fecal coliform
    - No interval if meets all standards
    - 45 interval if meets *Salmonella*/fecal coliform standard and may contact produce
    - No interval if does not contact produce

# Subpart I: Animals (wildlife and domestic)

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- Domestic/working animals
  - “Adequate waiting period” after allowing animal to graze
  - “Measures to prevent” if animals allowed where crop has been planted
- Animal intrusion
  - “Must monitor” during growing season and immediately prior to harvest
  - If intrusion occurs, evaluate whether to harvest

# Subpart K: Standards Directed to Growing, Harvesting, Packing and Holding Activities

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- All food containers (re-used or single use) must be adequately cleaned to prevent Clostridium Botulinum
- Facilities handling both covered and excluded produce must protect covered produce from cross contamination by:
  - Keeping covered produce separate & adequately clean and sanitize any food contact surfaces
- Produce visibly contaminated with animal excreta shall not be harvested
- Cut produce should not contact soil after harvesting
- Dropped produce is prohibited

# Subpart L: Standards Directed to Equipment, Tools, Buildings and Sanitation

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- Hand washing facilities must be adequately provided at each step of the process and include running water and drying devices
- Appropriate controls must be established to dispose of waste and prevent contamination of covered produce, food contact surfaces, and areas of activity
- Hand sanitizers and antiseptics may not be substituted for soap and water
- Plumbing
  - Animal excreta and litter from domesticated animals must be controlled to prevent contamination of produce, food contact surfaces, water sources and water distribution systems

# Preventive Controls Rule

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- Applies to facilities that manufacture, process, pack or hold human food. In general, with some exceptions, the new preventive control provisions would apply to facilities that are required to register with FDA under FDA's current food facility registration regulations.
- NC has several large CSA operations, and under the new rule, these would be considered food facilities, and subject to these rules

# Hazard Analysis and Risk-based Preventive Controls

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- The preventive controls are science and risk-based in that the rule would require controls only where necessary to prevent hazards to public health and exempt certain facilities from requirements or modify requirements for certain low-risk activities.
- FDA would evaluate the plans and continue to inspect facilities to make sure the plans are being implemented properly.

# Hazard Analysis and Risk-based Preventive Controls

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- Written food safety plan prepared by a qualified individual
  - Hazard analysis
  - Preventive controls
  - Monitoring
  - Corrective actions
  - Verification
  - Recordkeeping
- Looks like HACCP!



# Comments submitted by North Carolina

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- Buyers have mandated that many of our state's farms register as food facilities, even though by law they are exempted from the registration requirement in 21 CFR 1.226 (Bioterrorism act of 2002)
- North Carolina farmers believe that FDA should develop and publish a procedure for farms that are exempted from facilities registration requirements to "unregister" as food facilities
- FDA should use its discretion to prohibit companies or certifiers from mandating that farms register as food facilities when they have been specifically exempted (Jensen Farms)

# Comments submitted by North Carolina

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- Major buyers require audits (sometimes multiple). Compliance with 3rd party audits and/or USDA GAPs audit should be verification of compliance and
- Farmers who comply should receive consideration
  - Compliance should be mitigating factor in an investigation; violations immediate risk to public health should be handled differently than paperwork violations. Not all violations are equal.

# Implementation

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- Comments due: November 2013
- Final rule: ~Summer 2015
  - Farms with more than \$500,000 food sales
    - Summer 2017
  - Small businesses  $\geq$ \$500,000
    - Summer 2018
  - Very small businesses  $\geq$  \$250,000
    - Summer 2019

# FSMA: In a Nutshell

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- FDA has the authority to order a recall of food
- FDA has the authority to administratively detain food based only on a “reason to believe” the food is adulterated or misbranded
- FDA has the power to suspend the registration, thereby suspend the operations of any food facility if FDA determines that food manufactured, processed, packed, or held by the facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals
- Expands FDA authority over imported food
- FDA must review health data every 2 years and issue guidance documents or regulations setting contaminant-specific performance standards
- FDA is required to establish a product tracing system within FDA to effectively and rapidly track and trace food

# Questions/Comments

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