

Food Safety Modernization Act (FSMA)



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Rulemaking Process

- FSMA passed in 2011
- FDA publishes proposed rule in Federal Register (January 4, 2013)
- Public comment period: 120 days (May 16; subject to extension)
- FDA publishes final rule maybe 1 year after comments close (2013-'14)

FDA regulated foods

- All foods except most meat and poultry products
- These rules apply to everything not meat and poultry
- And not
 - Seafood (because there already is a Seafood HACCP rule)
 - Juices (and similar products, already a Juice HACCP rule)
 - LACF (because there is an LACF regulation)



Proposed “Produce Safety Rule”

- *Standards For The Growing, Harvesting, Packing, And Holding Of Produce For Human Consumption*
- *547 pages, last 66 pages are actual rule, preamble*
- **Applies to raw agricultural commodities**, including fruits and vegetables, mushrooms, tree nuts, sprouts and mixes of intact fruits and vegetables
- **Applies to farms**, not to operations <\$25,000 total sales (3 yr. avg.)
- **5 areas covered:** Workers, Ag. Water, Animals, Animal-derived soil amendments, facilities and food contact surfaces. (record keeping)

Covers fruits and vegetables such as:

- almonds, apples, apricots, aprium, asian pear, avocados, babaco, bamboo shoots, bananas, Belgian endive, blackberries, blueberries, broccoli, cabbage, cantaloupe, carambola, carrots, cauliflower, celery, cherries, citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cucumbers, curly endive, garlic, grapes, green beans, guava, herbs (such as basil, chives, cilantro, mint, oregano, and parsley), honeydew, kiwifruit, lettuce, mangos, other melons (such as canary, crenshaw and persian), mushrooms, nectarine, onions, papaya, passion fruit, peaches, pears, peas, peppers (such as bell and hot), pineapple, plums, plumcot, radish, raspberries, red currant, scallions, snow peas, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), tomatoes, walnuts, watercress, and watermelon
- And mixes of intact fruits and vegetables (such as fruit baskets).
- **Not produce rarely consumed raw , produce for personal consumption, produce that is not a raw agricultural product**

Exempt Produce

- arrowhead, arrowroot, artichokes, asparagus, beets, black-eyed peas, bok choy, Brussels sprouts, chick-peas, collard greens, crabapples, cranberries, eggplant, figs, ginger root, kale, kidney beans, lentils, lima beans, okra, parsnips, peanuts, pinto beans, plantains, potatoes, pumpkin, rhubarb, rutabaga, sugar beet, sweet corn, sweet potatoes, taro, turnips, water chestnuts, winter squash (acorn and butternut squash), and yams.

Farm Defined....

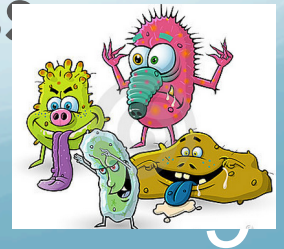
- to mean a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood) or both.
- Includes
 - (i) facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another 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

- 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.
- Tester/Hagan ammendment (although that text doesn't exist in the rule)
- 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.

Qualified Exemption

- < \$500,000 annual av. for 3 years
- Sell more than half of produce to direct markets (consumers, retailers, restaurants)
 - Within the same state or 275 miles radius of their farm
- **Required to label the product with a complete business name and address**



Withdrawal Of Qualified Exemptions

- In the event of an active investigation of a foodborne illness outbreak that is directly linked to farm
- If FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the farm

Five defined hazards

- 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

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

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

* USDA's National Organic Program/Natural Resources Conservation Service/US Fish and Wildlife Service/EPA: taken into consideration in developing these provisions.

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, growing sprouts;
Water that is used in harvesting, packing, and holding activities
(including washing cooling, & preventing dehydration

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)

- **Water-change schedules for re-circulated water** established and followed
- The quality of water **visually monitored** (dump tanks, flumes, or wash tanks, and water used in hydrocoolers) for build-up of organic material (such as soil and plant debris).
- **Temperature of water** must be maintained & monitored appropriate for the commodity and operation (time and depth of submersion)
- You 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)

- Inspect entire water system “under your control”: water source, distribution system, facilities and equipment
 - At beginning of growing season and “maintain”
 - “Immediately discontinue use” until...
- **Testing:** (exception: public water, treated water)
 - 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)

- Testing **Quantitative or Presence/Absence** with :
 - **NO generic *E. coli* (0 MPN/100 mL)**, for
 - Directly contacts produce during/after harvest (**postharvest**)
 - Used to make treated “agricultural tea”
 - 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; Option for alternative standards

Subpart F: Animal-derived soil amendments

- **Human waste prohibited**, unless in compliance with 40 CFR part 503 (biosolids)
- **9 month “interval” for use of untreated** amendment that contacts produce
- **Standards for testing:** *L. monocytogenes*, *Salmonella*, *E. coli* O157:H7 and fecal coliform
 - No interval if meets all standards
 - 45 day if meets *Salmonella*/fecal coliform standard and may contact produce
 - No interval if does not contact produce
- Option for **alternative standards**

Subpart I: Animals (wildlife and domestic)

Domestic/working animals

- “Adequate waiting period” after allowing animals 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

All food containers (re-usable or single use) must be adequate be clean,: packed to prevent C. botulinum, packing material

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 would be prohibited

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

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 wasted 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

Controls must be applied for **disposal of sewage**

Controls must be applied for conveying, storing or disposing of trash, litter and waste to minimize the potential for pest harborage/attraction and protect produce, food contact surfaces, covered activities, water sources and agricultural water systems from becoming contaminated

Plumbing

Animal excreta and litter from domesticated animals must be controlled to prevent contamination of produce, food contact surfaces, areas of activities, water sources and water distribution systems

Preventive Controls rule

- Applies 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.

Hazard analysis and risk-based preventive controls

- 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

- Written food safety plan prepared by a qualified individual
 - Hazard analysis
 - Preventive controls
 - Monitoring
 - Corrective actions
 - Verification (**with a validation**)
 - Recordkeeping

This looks a lot like HACCP. Without saying HACCP. This is good. The same principles apply.

Hazard analysis

- A written document that identifies known or reasonably foreseeable hazards
- **Each** type of food at the facility
- **Microbiological**, physical, chemical and radiological

Preventive Controls

- How do you minimize or prevent hazards identified in the analysis
- 1) process controls
- (2) food allergen controls,
- (3) sanitation controls, and
- (4) a recall plan
- Also written document – this is beginning to look like a food safety plan

Monitoring

- Procedures that provide assurances that the above controls are consistently performed.
 - Sanitation process logs
 - Sanitizer level in a wash water system

Corrective actions

- Facilities would be required to correct problems and minimize the likelihood of reoccurrence, evaluate the food for safety and prevent affected food from entering commerce when necessary
- Answers the question of “so the monitoring showed that the preventive control was not being carried out consistently, what do I do.”

Verification

- It's not enough to pick a random preventive control
- The most science-based part of the proposed rules are that a chosen preventive step needs to be verified as appropriate for the specific hazard/situation
- Validation studies
- And the proposed rule suggests that a facility needs to reassess all verification every three years to ensure it is still up to date.

Recordkeeping

- All things above are recorded in a food safety plan.

Other things

- A qualified individual must manage the above items
 - To be qualified, an individual would be required to successfully complete training in accordance with a standardized curriculum or be otherwise qualified through job experience to develop and apply a food safety system.
- Revisions to current CGMP are proposed
 - Allergens
 - Mandating training for employees

Compliance

- 60 days after the final rule is published
 - one year for a business that is not small or very small and does not qualify for an exemption
 - two years for small businesses
 - three years for very small

Proposed Exemptions

- Risk-based
- Size-based
- Whether or not it occurs on the FDA's definition of a farm (and not a food facility)
- Other regulations

FSMA homepage

<http://www.fda.gov/fsma>

The New 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.

✉ Get FSMA Updates by E-mail.

What's New

FDA Issues Two Major Proposed FSMA Rules on January 4, 2013

Preventive Controls for Human Food: Fact Sheet on the Proposed Rule



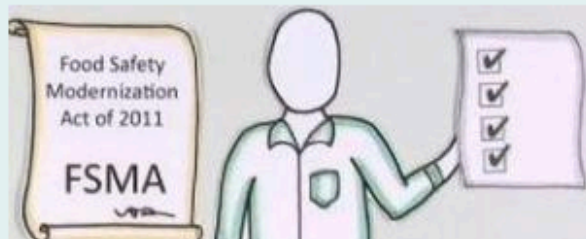
Standards for Produce Safety: Fact Sheet on the Proposed Rule



See [Overview of Proposed Rules](#).

The Rulemaking Process

A video tutorial on the rulemaking process.



FDA FSMA: A Primer by FDA

A video tutorial on the law.



Public
Comments
are
needed!

http://ncfreshproducesafety.ncsu.edu

N.C. Cooperative Extension | Plants for Human Health Institute | Agent Resources

N.C. FRESH PRODUCE SAFETY



FSMA Rules Released – Comments Due by May 16, 2013!

[Read about the new rules here.](#)

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FDA Releases Two FSMA Rules

FDA has released two proposed rules under FSMA for public comment. The proposed **Produce Safety Rule** concentrates on standards for the safe production and harvesting of produce. The **Preventative Controls Rule** applies to many domestic and foreign firms that manufacture, process, pack or hold human food.

[Learn more...](#)

FSMA Framework for Food Safety



Human Food



Produce Safety



Imports

- Foreign Supplier Verification
- Accredited Third Party Certification



Animal Food

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N.C. FRESH PRODUCE SAFETY



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FDA'S FOOD SAFETY MODERNIZATION ACT (FSMA) UPDATES

FDA's Teleconference on FSMA's Two Rules Posted

On January 4, 2013, FDA held a stakeholder teleconference for industry regarding the proposal of two rules under the **Food Safety Modernization Act (FSMA)** that set science-based standards for the prevention of foodborne illnesses. The stakeholder teleconference was held on Friday, January 4, 2013.

A replay of the briefing can be accessed by calling 888-566-0497.

FDA announced at the January 4th teleconference that they **released two proposed rules for public comment:**

- 1. Standards for Produce Safety**
 - 2. Preventive Controls for Human Food**
- [View Summary and Complete Proposed Rules](#)**

Public Comments are due by May 16, 2013 (120 days from posting).
[Learn how to submit comments.](#)

