

FSMA (Food Safety Modernization Act)

What you need to know

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FSMA (Food Safety Modernization Act)

- Federal food safety law -- applies to farms growing fruits and vegetables normally eaten raw (covered produce) and to food facilities
- Law was passed January 4, 2011
- Regulations are in proposed form and establish mandatory practices to prevent microbial contamination of fresh produce and processed foods
- FDA is the Regulatory Authority!!!

FSMA...

- Disclaimers
 - Proposed rules are hundreds of pages long
 - Our understanding is evolving (and the only interpretation of it that really counts is the interpretation of the FDA inspectors)
 - Rules are currently in proposed form, comment period open till November 15th
 - This presentation is merely a summary, for more details of the proposed rules refer to the full text FDA documents

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>
<http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0920-0001>

FSMA...

- Most important things you can do...
 - Educate yourself
 - Decide if you want to comment
 - As an individual
 - As part of any of the organizations you are a member of

FSMA...

- FSMA has 5 parts but 2 that most apply to us
 - Produce Safety (applies to farms)
 - Rule for Hazard Analysis and Risk-Based Preventive Controls for Human Food (applies to those who manufacture, process, pack or hold human food... "facilities")
 - ...and the exemptions and time frames for coming into compliance are different for each part
 - ...qualifying for an exemption under one part does not automatically mean you will qualify for an exemption under the other

Produce Safety

- "Small farms" may qualify for either a complete or qualified exemption
- Not all farms will qualify
- Exemptions based on **total food sales**

"Food" is defined according to the Federal Food, Drug and Cosmetic Act section 201(f), which says:
 The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

Produce Safety Exemptions...

- Sales below \$25K/yr averaged over 3 yrs = Exempt
- Sales between \$25K and \$500K/yr averaged over 3 yrs **AND** more than half your sales to "qualified end users" = Qualified Exemption
 - Keep records to prove exemption
 - Covered produce must be labeled with your business name and address or with a sign featuring this information at point of sale
- Everyone else is not exempt

BUT...if implicated in an outbreak of foodborne illness, exemption can be revoked and those you sell to may require more of you

Produce Safety Exemptions...

- Qualified End Users
 - Consumers
 - Restaurants
 - Retail Food Establishments (primary function is to sell food to consumers, ex grocery stores, and convenience stores)
- Must be in-state **or** within 275 mi of the farm

Produce Safety...

- For Non-exempt farms Produce Safety rules only apply to covered produce
- Covered produce includes crops commonly consumed raw— almonds, apples, apricots, asian pear, aprrium, avocados, babco, bamboo shoots, bananas, Belgian endive, blackberries, blueberries, broccoli, cabbage, cantaloupe, carambola, carrots, cauliflower, celery, cherries, citrus, cucumbers, curly endive, garlic, grapes, green beans, guava, herbs (such as basil, chives, cilantro, mint, oregano, and parsley), honeydew, kiwifruit, lettuce, mangos, other melons, 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, 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).

THIS IS NOT AN EXHAUSTIVE LIST

FSMA...

- Non-covered produce or produce rarely eaten raw, are identified by the FDA using the following **exhaustive list**— 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

THE ABOVE CROPS ARE EXEMPT FROM THE PROPOSED PRODUCE SAFETY RULES: A "kill step" is used in food preparation.

Produce Safety Proposed Rules...

- Non-Exempt Farms Must comply with regulations related to
 - Worker Health and Hygiene
 - Agricultural Water
 - Equipment, Tool, and Building Sanitation
 - Biological Soil Amendments (compost & manure)
 - Domestic and Wild Animals
 - Records must be kept to prove that you are in compliance with all regulations

Worker Health and Hygiene

- Workers must be trained in handwashing and food hygiene
- Trainer can be a member of your staff, but they have to take an accredited course
- Toilets and hand washing stations with running water, soap and single use towels must be readily accessible. Sanitizer is not adequate.
- Workers must take steps to prevent carrying contaminants from livestock to covered produce
- Training records must be kept

Agricultural Water..

- Ag water is defined as water that is used in such a way that it **contacts or is likely to contact covered produce**, this includes
 - Irrigation water
 - Water used to make ag teas and pesticide sprays
 - Water used to wash or cool produce
 - Water used to prevent dehydration produce
 - Water used in cleaning and handwashing
- Portions of the agricultural water system under your control must be inspected at the beginning of the season and must be maintained.

Agricultural Water..

- Ag water must be tested. The frequency depends on the source and use
 - If at any point ag water fails a test, you need to cease using it and take corrective action
 - The water system must be re-inspected and the water re-tested after corrective action has been taken.

Agricultural Water..

- Testing Requirements
 - Farms using municipal water can replace testing with documentation from the water facility proving that the water meets the standards
 - Well water must be tested at the beginning of the season and every 3 months thereafter
 - Well water that has been stored in an above ground holding tank or pond must be tested every month
 - Surface water must be tested every 7 days unless it is from a source that you control, then every month

Agricultural Water..

- Testing Standards...
 - If it contacts covered produce during growing it must contain no more than 235 CFU generic E. coli per 100 mL sample, and no more than an average of 126 CFU per 5 samples (recreational water)
 - If it contacts covered produce during or after harvest must have no E. coli (less than detectable levels) per 100 mL sample (potable)
 - Again, if it does not meet the standards it cannot be used until corrective actions have been taken and subsequent testing shows the actions were effective

Agricultural Water..

- Ag water can be treated with antimicrobials in place of testing, but
 - at the current time no such antimicrobials are EPA approved for use in irrigation systems.
 - If wash water is treated with more than 200 ppm chlorine the farm is processing and must comply with the requirements of Preventive Controls.
- Wash water must be changed frequently enough that it has no detectable levels of E. coli or treated with sanitizer
- Records must be kept of inspections, testing, and corrective actions

Sanitation: Equipment, Tools, and Buildings

- This section includes equipment or tools likely to contact covered produce. Some examples are knives, harvest buckets, thermometers, tables, tractors, wagons, and trucks. There must also be a focus on anything that moves from manure areas to fields or packing houses.
- The above items must be of proper design so that they can be kept clean, and they must be inspected, maintained, cleaned, sanitized and stored properly in order to prevent contamination of covered produce.

Sanitation: Equipment, Tools, and Buildings

- "Buildings" includes fully or partially enclosed buildings used for growing, washing or holding covered produce, or storing food contact surfaces such as harvest buckets.
- Greenhouses and high tunnels are classified as buildings which cannot have for example
 - condensation dripping from the ceiling
 - water pooling on the floor
 - and they must be laid out so workers can move freely without clothing touching covered produce

Biological Soil Amendments

- Biological soil amendments are defined as amendments of animal origin (fecal or non-fecal byproducts including table waste); it does not include any form of human waste
- Green manures and vegetative matter and the agricultural teas made from them do not fall under this category and may be applied at any time as long as the water used to make the teas are in compliance with the standards for ag water.
 - Unless composted according to specific standards designed to adequately reduce microorganisms of public health significance, biological soil amendments of animal origin are considered untreated.

Biological Soil Amendments...

- If the untreated amendments are applied in a way that they are likely to touch **covered produce**
 - They must be applied 9 months before harvest.
 - Agricultural teas made from untreated biological soil amendments must also meet this standard.

Biological Soil Amendments...

- Treated soil amendments of animal origins may be applied 45 days before harvest
 - Acceptable Treatments
 - Static composting -- aerobic conditions at a min of 131 F for 3 days, followed by adequate curing including proper insulation.
 - Turned compost -- aerobic conditions at a min of 131 F for 15 days with a min of 5 turnings, followed by adequate curing including proper insulation.
 - Chemical methods of treatment will also be acceptable, but they have not been defined yet.
 - Records must be kept to prove these conditions were achieved.

Biological Soil Amendments...

- If you purchase treated soil amendments of animal origins, you must keep documentation provided by the seller that shows it was composted according to the standards, ex. "Certificate of Conformance".
- The use of human waste is prohibited except for biosolids used in accordance with federal or local regulations.

Domestic and Wild Animals

- Must take steps to keep animals out of fields or buildings where covered produce is grown, washed, packed or held – some exceptions made for traction and service animals.
- Must monitor for animals that cannot be kept out.
- Must not harvest produce with obvious signs of excrement on them.

Record Keeping Requirements

- Yes!... and that includes everything we have talk about so far

Compliance Timelines

Non-Exempt Farms...

- Avg <\$250K/yr – 4 yrs, 6 for some water reqs
- Avg <\$500K/yr – 3 yrs, 5 for some water reqs
- Everyone else – 2 yrs, 4 for some water reqs

To Comment by Mail Produce Rule

- By Mail To (make sure they arrive before November 15th):

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

- Comment must include

Agency name and Docket No. FDA-2011-N-0921
Regulatory Information Number RIN 0910-AG35

- You comments may be posted to www.regulations.gov without change including your contact information

To Comment Online Produce Rule

- Go to:

<http://www.regulations.gov/?source=govdelivery#!submitComment;D=FDA-2011-N-0921-0199>

Rule for Hazard Analysis and Risk-Based Preventive Controls for Human Food (aka Preventive Controls)

- Applies to farms or other facilities that manufacture, process, pack or hold human food
- These operations are considered food facilities and must register with the federal government
- If you only grow, wash, and trim off outer leaves, and if you only pack at your own farm, and if you only sell products you grow, you are a farm; **Preventive Controls does not apply to you**

Preventive Controls...

- If you peel, chop, combine ingredients or buy and resell products from another farm you may be subject to some or all requirements under this section
- Exemptions do apply based on type and size of the operation, see table on pg 2 of UVM factsheet "FSMA Proposed Rule for Hazard Analysis and Risk-Based Preventive Controls for Human Food"
www.uvm.edu/.../Documents/PSFSMAPrevControlsFactSheet.pdf

Preventive Controls... Summary

- Hazard Analysis and Risk-Based Preventive Controls

HACCP Approach: } **Food Safety Plan**

- Risk Assessment
- Risk Management

- Updated Good Manufacturing Practices

Preventive Controls...

Risk Assessment – Hazard Analysis

Determining Hazards:

- Biological – Bacteria, Viruses, Parasites
- Chemical
- Physical
- Radiological

Determining Critical Control Points

Preventive Controls...

Risk Management

- **Process Controls** (HACCP) – Food Safety Plan includes:
 - Critical limits
 - Monitoring
 - Records
 - Corrective Actions
 - Verification/Validation

Preventive Controls...

Other Preventive Controls Required:

- Sanitation Controls
- Recall Program (Traceability)
- Allergen Controls (Cross Contact)
- Supplier Controls (proposed, looking for comment)

Preventive Controls...

There will be a training requirement for this rule but the details have not yet been worked out; however, evidence of knowledge from "life" may substitute for the person who will oversee this program.

To Comment by Mail Preventative Control Rule

- By Mail To (make sure they arrive before November 15th):

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

- Comment must include

Agency name and Docket No. FDA-2011-N-0920
Regulatory Information Number RIN 0910-AG36

- You comments may be posted to www.regulations.gov without change including your contact information

To Comment Online Preventative Control Rule

Go to:

<http://www.regulations.gov/#!submitComment;D=FDA-2011-N-0920-0188>

The screenshot shows the 'Submit a Comment' form on the regulations.gov website. The form is titled 'Submit a Comment' and is for a proposed rule: 'Current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Document ID FDA-2011-N-0920-0012)'. The form is divided into four sections: 1. ENTER INFORMATION (with fields for First Name, Middle Name, Last Name, and Organization Name), 2. TYPE COMMENT (with a large text area and a '2000 character remaining' indicator), 3. UPLOAD FILE(S) (Optional), and 4. SUBMIT COMMENT (with 'Previous Comment' and 'Submit' buttons). A blue arrow points to the 'Submit' button, and another blue arrow points to the '2000 character remaining' indicator.