

What's New with the FSMA Rules?

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**United Fresh 2014**
Produce Innovation Starts Here



What's New with the FSMA Rules

David Gombas, Ph.D.
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Food Safety Modernization Act

- Fundamental changes in how FDA regulates food
- Generally supported by food industry
 - Produce wants comprehensive food safety platform across all production and distribution
- Signed by President Obama Jan 4, 2011
 - Requires at least 12 new regulations from FDA

Food Safety Modernization Act

New authorities, responsibilities for FDA

- Mandatory recall authority
- Expanded records access
- New facility registration requirements
- New detention authority
- New authority to withdraw registration
- New requirements for Reportable Foods

Seven FSMA Proposed Rules

- Produce Safety Standards
- Preventive Controls for Human Food
- Foreign Supplier Verification Program
- Accredited Third Party Certification
- Preventive Controls for Animal Feed
- Intentional Adulteration
- Sanitary Transportation
- and more to come...

United Fresh process

Open dialogue with United Fresh members

- All member companies invited to participate in working groups
- Some face-to-face meetings, most by web
- Reviewed rules line-by-line
 - What do we like and support
 - Alternative approach/requirement
- Draft comments reviewed/revised by working group participants before submission to FDA
- Working group participants encouraged to submit their own comments

Produce Safety

- Published January 16, 2013; Comments closed November 22
- Limited to microbiological hazards
- Applies to domestic and imported raw agricultural commodities, including fruits and vegetables, mushrooms, tree nuts and mixes of intact fruits and vegetables
- Covers the edible portion (including peel or shell) but not the rest of the plant
- Exemptions for produce commercially processed or rarely consumed raw
- Separate subpart for sprouts

What did we hear?

FDA did pretty well:

- 5 most likely risks
- Animal monitoring, Worker health and hygiene
- No standards for water, compost not likely to contact harvestable portion
- No product testing
- Limited mandatory records

but...

- Water (and all the other metrics)
- Exemptions
- Alternatives/Variations
- And several details...

What did we hear?

Water is the biggest issue

- Recreational water standards for *E. coli* in direct contact water used pre-harvest (irrigation, plant protection sprays)
- Testing
 - Wells: Every 3 months throughout growing season
 - Protected Surface Water: Monthly
 - Surface Water subject to runoff: Weekly

What else did we hear?

- Blanket exclusions, carved in stone
 - Rarely Consumed Raw
 - Commercially Processed
 - Very small (<\$25,000) and “Tester” Operations
- Practices, Dietary Preferences and Risks change
- Many foreign suppliers will meet the <\$25,000 exemption
- Will growers be held responsible if produce grown for processing is diverted to fresh?

What else did we hear?

- For those not excluded, it's one size fits all
 - We like no mention of “high risk” commodities
 - We agree that some practices are a greater risk than others (raw manure vs. compost vs. non-animal)
 - But there is no consideration, or allowance, for commodity-specific risks (commodities that have never been linked to foodborne illness)
- Variances could allow for future science
 - But only state/foreign governments are allowed to submit variances

So what did we say?

- Don't put testing requirements in the rule
 - They belong in Guidance, where they can be updated
- A "safe harbor" standard is fine, but
 - Allow for science-supported alternatives to all aspects of the requirement (what is tested for, frequency of testing, and action limits)
 - Allow for science-supported variances for commodities when waterborne/soilborne contaminants are not likely to pose a public health risk

So what did we say?

- No “all exempted” lists in the rule
 - Modified requirements, or guidance for how to account for lower risks due to consumer, commercial handling
 - Size appropriate requirements for operations <\$25,000
- Allow variances to be submitted by any entity
- Create a process by which growers can “vet” alternatives

Meanwhile, what about facilities?

Part 117 — *Current Good Manufacturing Practice And Hazard Analysis And Risk-based Preventive Controls For Human Food*

- Published January 16, 2013; Comments closed November 22, 2013
- Applies to operations that manufacture/ process, pack or hold food for sale in the U.S. (operations required to register with FDA, as defined in 21 CFR part 1, subpart H
- Including “farm mixed-type facilities”

When is a farm not a farm?

- When it:
 - Is registered with FDA
 - Does any processing (e.g., cutting, cooking)
 - Packs produce other than that grown on the farm
 - Is not in the same general location as where the produce is grown
 - Does activities not specifically identified as “farming”, like waxing, fumigation, sprouting control, ripening control
- But Produce Safety already covers transport, buildings, tools, equipment, other food contact surfaces, sanitation, plumbing, toilet/handwashing facilities, trash, pests

So what did we say?

Any operation that handles and ships only raw, intact produce should be covered by Produce Safety rule

- Separation of farms and facilities based on registration requirement is artificial
- No new hazards reasonably likely to occur because produce came from another farm
- Handling activities that are low risk on very small farms are low risk on large farms
- This includes in-field trimming, packaging

Key Features of the Rule

- Replaces current GMPs, with added emphasis on training, allergen control and radiological hazards
- Written Hazard Analysis required
- “Preventive Controls” for identified hazards, including Process Controls (e.g., CCPs), Sanitation Controls, Allergen Controls, as needed
- Written food safety plan, including monitoring, corrective actions, verification of Preventive Controls (validation of process controls)
- Preliminary steps (expected use, flow diagram) not mentioned
- Recall plan required

It could have been worse...

- Mandatory microbiological testing of raw materials, finished product
- Mandatory environmental monitoring for pathogens
- Mandatory supplier approval and verification program

Short shelf-life of fresh-cut products and many fresh fruits and vegetables would be significant obstacle to routine implementation of these requirements

Accredited Third-party Certification & Foreign Supplier Verification Programs

- Published July 29, 2013; Comments closed January 27
- Not much identified as warranting comment in proposed third-party rule
 - Intended to support Certification of High Risk Foods and Voluntary Qualified Importer Program

Foreign Supplier Verification Programs

- Holds U.S. importer responsible for verifying that foreign suppliers are in compliance with Produce Safety, Preventive Controls, and not providing adulterated or misbranded food
- Importer must perform or obtain a written hazard analysis for every imported food, every supplier
- Must be performed by a “qualified individual”
- No exemptions for rarely consumed raw
- Hazard analysis goes beyond microbiological

§ 1.505(c) Hazard evaluation

“...you must consider the effect of the following...”

- (1) The ingredients of the food;
- (2) The condition, function, and design of the foreign supplier’s establishment and equipment;
- (3) Transportation practices;
- (4) Harvesting, raising, manufacturing, processing, and packing procedures;
- (5) Packaging and labeling activities;
- (6) Storage and distribution;
- (7) Intended or reasonably foreseeable use;
- (8) Sanitation, including employee hygiene; and
- (9) Any other relevant factors.

So what do we think?

- First, who is the foreign supplier and whose programs do we have to audit?
 - The aggregator/packinghouse?
 - The growers who supply to the aggregator?
 - Which growers/how many?
 - If they are <\$25,000, are they exempt?
- Modified requirements for very small importers or very small suppliers
 - If it's low risk for very small, it's low risk for all
 - Same requirements regardless of size

So what did we say?

- Importers should be responsible only for verifying compliance by immediate supplier, not the supplier's suppliers
- Verification should be limited to foreign supplier's compliance with the relevant rule (no hazard analysis or control beyond microbiological for produce suppliers)
- Flexibility in how to verify (no mandatory audits)

Preventive Controls for Animal Feed

- Published October 29, 2013; Comments closed March 31
- Applies to “animal facilities” required to register with FDA, including waste from human food facilities intended for use in/as animal feed
- Exempt from the rule:
 - Farms not required to register with FDA
 - very small businesses (<\$500K/\$1M/\$2.5M in total annual sales of animal food)
- List of mixed-type farm activities exempted from subpart C (Preventive Controls)

Preventive Controls for Animal Feed

- If a facility is required to comply with this rule and proposed 21 CFR part 117 (Preventive Controls for Human Food) subparts B (GMPs) and/or C (Preventive Controls), then they can EITHER
 - Comply with subparts B and/or C of this rule, as applicable, or
 - Comply with subparts B and/or C of part 117 “so long as the food safety plan also addresses all hazards that are reasonably likely to occur in the animal food, including nutrient imbalances”

So what did we say?

Culls and waste should not be covered by the rule, regardless of the source

- If farms and “subject to Produce Safety” are exempted, culls and waste from all produce operations should be exempted
- Not manufactured as animal feed
- No way to control nutrient content
- Will always be “adulterated”, so doomed before we start
- Covering these under the rule will end a low-cost source of animal nutrients for farms

Two New Proposed Rules

- **Intentional Adulteration**
Published Dec. 24; Comments due June 30
- **Sanitary Transportation**
Published Feb. 5; Comments due July 30

And maybe something worse...

- **Designation of Foods as High Risk**

Intentional Adulteration

- 21 CFR Part 121, *Focused Mitigation Strategies To Protect Food Against Intentional Adulteration*
- Applies to facilities required to register with FDA, including farm mixed-type facilities
 - Exempt: farms, food storage facilities (except bulk liquid), packers/labelers where the direct contact container remains intact, and qualified facilities (<\$10,000,000 total annual sales of food)

Intentional Adulteration

You must have written focused mitigation strategies and monitoring, corrective action and verification procedures if you do/have any of the following:

- Bulk liquid receiving and loading
- Liquid storage and handling
- Secondary ingredient handling
- Mixing and similar activities

Or have performed your own vulnerability assessment

So what do we think?

- “Bulk liquid” only applies to foods
- Doesn’t apply to farms; doesn’t appear to apply to packinghouses, warehouses or distributors
- May apply to fresh-cut operations
 - Those on the calls had “no objection”

Sanitary Transportation of Human and Animal Food

- In the works since 2005
- Applies to shippers, receivers, and carriers engaged in transportation operations of food intended for consumption in the U.S.
- Vehicle design and sanitary condition
- Temperature control, when needed for safety or spoilage
- Written procedures and records of sanitary control

Designation of High-Risk Foods for Tracing

- Published Feb 4, Comments closed May 22
- “the designation of high-risk foods must be based on the: (1) Known safety risks...including the history and severity of foodborne illness outbreaks...(2) likelihood that a particular food has a high potential risk for microbiological or chemical contamination...(3) point ...where contamination is most likely to occur; (4) likelihood of contamination and steps taken...to reduce the possibility of contamination; (5) likelihood that consuming a particular food will result in a foodborne illness...and (6) likely or known severity...”

Designation of High-Risk Foods

“The draft approach would utilize the food categorization scheme used for the Reportable Food Registry... What other practical alternatives to this food categorization scheme should we consider in light of the practical constraints of evaluating individual commodities?”

- Fruit and Vegetable Products
- Nuts, Nut Products, and Seed Products
- Produce- Fresh Cut
- Produce- Raw Agricultural Commodities

So what did we say?

Congress got it wrong

- “High risk” and the need for traceability are not connected
- No food is inherently “high risk”
 - FDA emphasis on practices is better approach to identifying “high risk” (recognizing that some commodities may be inherently low risk)
 - No way to ever come off the “high risk” list
 - Consequence of a “high risk” designation to public perception and confidence in the safety of the food
- May require a legislative fix

Rulemaking Process

- FDA publishes proposed rule
- Public comment period
- FDA publishes final rule
 - August, October 2015 (first 5)
 - March, May 2016 (ST, IA)
- 1-2 year implementation
- Dates to be staggered for small and very small operations

Rulemaking Process

- FDA publishes proposed rule
- Public comment period
- FDA publishes re-proposed sections
- Public comment period
- FDA publishes final rule
- 1-2 year implementation
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And when it's all final...

Training, outreach begins in earnest

- Training for Qualified Individual



- State agencies, Extension, Universities
- Trade associations, Commodity groups
- Private sector consultants

United Fresh News

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Implementation of the Food Safety Modernization Act



The FDA Food Safety Modernization Act (FSMA) was signed into law by President Obama on January 4th, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it. Use these pages to

learn more about the law, the proposed rules under the law, and ways you can get involved with United Fresh to help provide comments to FDA and prepare for implementation.

United Fresh has submitted its comments to FDA on the following proposed rules under FSMA. Click on the links below to read United's comment documents.

United Fresh Comments on Proposed Rules

- [United Fresh Comments on FDA's Proposed Designation of High Risk Foods](#) (May 22, 2014)
- [United Fresh Comments on Proposed Preventive Controls for Animal Feed Rule](#) (March 31, 2014)
- [United Fresh Comments on Proposed Foreign Supplier Verification Rule](#) (January 27, 2014)
- [United Fresh Comments on Proposed Produce Safety Rule](#) (Nov. 15, 2013)
- [United Fresh Comments on Proposed Preventive Controls Rule](#) (Nov. 15, 2013)



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Questions?

dgombas@unitedfresh.org

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