



FSMA: Understanding FDA's New Food Safety Rules

Sophia Kruszewski, *National Sustainable Agriculture Coalition*

NSAC is an alliance of grassroots organizations that advocates for federal policy reform to advance the sustainability of agriculture, food systems, natural resources, and rural communities.

- Started in 1988; currently have over 110 member organizations around the country – including Wallace Center!
- We bring farmers and grassroots advocates across the country to the policy table in DC

www.sustainableagriculture.net



- **FSMA 101**– where did these rules come from, where are we in the process, and why does it matter for farmers and food systems?
- **Who's in? Who's out?** – what types of farms and businesses may be affected by the final rules?
- **Some Specifics** – what do the rules cover, what did we win, and what is still a concern?
- **What Happens Next?** – compliance timelines, training, guidance documents, inspections/compliance...
- **Q&A**

Big Picture Overview: FSMA 101

- First major overhaul to food safety laws since the 1930s
- Debated in Congress 2009-2010; became law Jan 4, 2011
- Gives the Food and Drug Administration (FDA) new powers to prevent food safety problems, detect and respond to food safety issues, and improve safety of imported foods.
- Seven main rules; big two are **Produce Rule** and **Preventive Controls Rule** (“food facility rule”)
- Advocates made sure Congress: included protections for local food and conservation; specified that the rules must be scale-appropriate and not conflict w/ organic standards

Produce Safety Standards

- Proposed rule: Jan – Nov 2013
- Supplemental proposal: Sep – Dec 2014
- **Final Rule: November 26, 2015**
 - ***Effective date: January 26, 2016*

Preventive Controls for Human Food Facilities

- Proposed rule: Jan – Nov 2013
- Supplemental proposal: Sept – Dec 2014
- **Final Rule: **September 17, 2015**
 - *Effective date: November 16, 2015*



Produce Rule:

- Applies to farms that grow, harvest, pack, or hold produce for human consumption.

Preventive Controls Rule:

- Applies to food facilities that must register with FDA: manufacture, process, pack, or hold food for human consumption.

So... how do these rules impact food hubs? (& farms & value-added agricultural operations & produce packing & CSAs &...)



Produce Rule: Who is covered?

- **Exemptions (Not Covered)**
 - Produce rarely consumed raw
 - Produce for personal or on-farm consumption
 - Farms with \leq \$25,000 in annual produce sales (3 yr avg)
- **Modified Requirements**
 - Produce that will receive commercial processing
 - Qualified exempt farms: less than \$500K food sales & >50% sales direct to a “qualified end user”
- **Covered, but with extended compliance time**
 - Very small business: no more than \$250,000 in produce sales
 - Small business: no more than \$500,000 in produce sales
- **Covered**
 - Over \$500,000 in produce sales

□ Qualified Exemption

- <\$500K food sales and >50% direct to “qualified end user”
 - Individual consumer OR
 - Restaurant or retail food establishment in same state or 275 miles

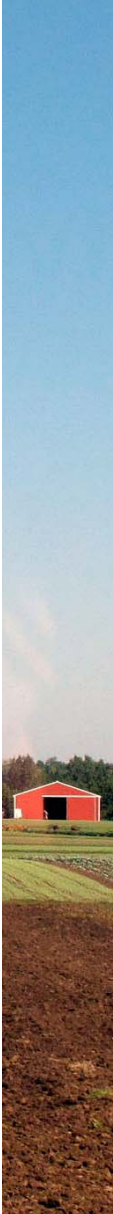
□ Sales Records

- 3 years worth; start NOW (Jan 1, 2016)
- Annual verification after general compliance date

□ Labeling

- Business name and address “prominent and conspicuous” at point of sale (poster, sign) or contemporaneous with sale (email, invoice)
- By general compliance dates

□ Withdrawal/Reinstatement



- Personnel Qualifications and Training
- Health and Hygiene
- Agricultural Water
- Biological Soil Amendments of Animal Origin
- Domesticated and Wild Animals
- Growing, Harvesting, Packing, and Holding Activities
- Equipment, Tools, and Buildings
- Recordkeeping

- **Personnel Qualifications and Training**
- Health and Hygiene
- **Agricultural Water**
- **Biological Soil Amendments of Animal Origin**
- **Domesticated and Wild Animals**
- Growing, Harvesting, Packing, and Holding Activities
- Equipment, Tools, and Buildings
- Recordkeeping

- Training required for both supervisors and personnel “as appropriate to their duties”
- Combination of education, training, and experience necessary to perform assigned duties;
- At least one “supervisor or responsible party” for the farm must take a food safety training that is “at least equivalent” to that received under “standardized curriculum recognized as adequate by FDA”
 - Produce Safety Alliance
 - Local Food Cooperative Agreement
 - Tribal Producer Cooperative Agreement
 - Others?

Agricultural Water Standard

- Applies to “agricultural water”
 - Intended or likely to contact covered produce or food contact surfaces, during growing (direct application) and in harvesting packing, and holding
- Inspection and maintenance requirements
- Microbial water quality criteria based on use
 - Harvest/post-harvest handling; food contact surfaces; handwashing during harvest/post-harvest; sprouts
 - During growing activities
- If you don’t satisfy the criteria you must either: stop, re-inspect, rectify, verify; treat; or apply a die off interval (in days)
- Testing
 - Surface water: 20 sample baseline; 5 annual samples; rolling reassessment
 - Groundwater: 4 sample baseline; 1 annual sample; rolling reassessment
- Alternatives?
- Expect *a lot* of guidance/tools/resources on this topic in the coming years

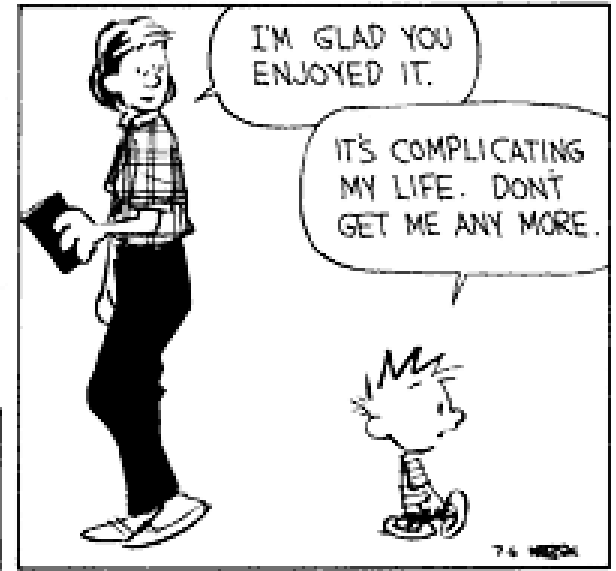
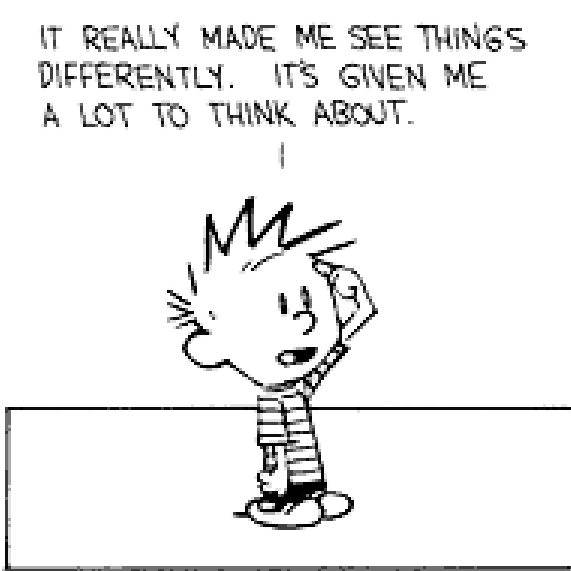
Biological Soil Amendments

- Standards for handling, transporting, storing, treating, and applying BSAs of animal origin
 - Raw and composted manure; also agricultural teas when they contain animal manure or other by-products
 - Requirements break out by “treated” vs “untreated”
 - Treatment includes composting; requires records that document the validity of the process (e.g. time and temperature controls, turning)

- Application intervals
 - Treated (including compost): zero days
 - Untreated: zero days (if no contact during or after application)
 - If possibility of contact, then [DEFERRED]
 - Risk assessment process underway; FDA currently soliciting comments on research and on-farm usage to inform risk assessment model; new proposed standard in 5-10 yrs...

- If there is a reasonable probability that grazing animals, working animals, or wild or domesticated animal intrusion will contaminate produce, then you must:
 - Monitor, assess, evaluate, and take measures to avoid harvesting contaminated produce

- “Nothing in the rule requires covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.”





Preventive Controls Rule: Who is covered?

- **Exempt from Registration** - Do not register, PC Rule doesn't apply
 - Farms (unless...)
 - Retail Food Establishments
- **Exempt from HARPC** - Must register, follow cGMPs
 - Small and very small farms doing low risk processing
 - Food covered by other regulations
 - Facilities that only store packaged foods OR only store raw agricultural commodities (non-produce) for further processing
- **Qualified Facilities** - Must register, follow modified requirements
 - Very small businesses: less than \$1 million in sales of human food
- **Covered, but extended compliance timelines**
 - Register, follow HARPC, but extra time to come into compliance
 - Small (<500 employees) and Very Small (<\$1M sales)

Farm Definition

A “farm” can be either:

(1) A **primary production farm**: an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals, or some combination

(2) A **secondary activities farm**: an operation *not located on a primary production farm*, devoted to harvesting, packing, and/or holding raw agricultural commodities.

□ However, must be majority owned by farmers that supply a majority of the commodities harvested, packed, or held.



Retail Food Establishments

- Exempt from registration req (and t/f PC Rule)
- Sells food products directly to consumers “as its primary function”
 - Annual food sales direct to consumer (\neq businesses) exceed annual food sales to all other buyers
- Includes grocery stores, convenience stores, vending machines
- Should also include: farms stands, CSAs, farmers markets, and other direct-market venues
 - Final Rule expected in June
 - State law (food code) may apply

Low-risk On-farm Processing

- Must register, but exempt from HARPC if:
 1. On-farm
 2. Low-risk food/activity combinations ONLY, and
 3. Small or very small business

Then, must register and follow cGMPs, but exempt from HARPC and supply chain program. Recordkeeping and training requirements still apply

Examples (from exhaustive list): milling grain; making baked goods; boiling sap to make maple syrup



PC Rule: Qualified Facility

- Modified Requirements (<\$1M food sales)
 - Registration
 - Two attestations required:
 - (1) Qualified status
 - (2) You either:
 - (A) have identified potential hazards and are implementing and monitoring effectiveness of preventive controls
 - OR
 - (B) are in compliance with applicable non-Federal food safety law
 - *If 2(B), then labeling requirements apply*
 - Attestations first required by Dec 17, 2018 (existing biz)
 - Then every two yrs between Oct 1-Dec 31 starting in 2020
- Withdrawal/Reinstatement

Non “farm” produce packing

- If you don't satisfy the farm definition, and you aren't a qualified facility, and you aren't a retail food establishment... then the full requirements apply, even if you're just packing and holding produce.
- However, according to FDA, your food safety plan would likely focus on a few key preventive controls: water used during packing; food contact surfaces; prevention of cross-contamination from personnel to food, food-packaging, material, and other food contact surfaces
- Expect additional guidance on this subject



General Compliance Timelines

	Produce Rule		Preventive Controls	
	Gross annual produce sales (3 yr avg)	Years (from 1/26/16)	Gross annual food sales (3 yr avg)	Years (from 9/27/15)
Very Small Business	≤ \$250,000	4 + 2 for water	< \$1M	3
Small Business	≤ \$500,000	3 + 2 for water	< 500 employees	2
All Other (Large) Businesses	> \$500,000	2 + 2 for water	≥ \$1M ≥ 500 employees	1

Preventive Controls Requirements

- Hazard analysis;
 - Preventive controls;
 - Supply chain program;
 - Recall plan;
 - Procedures for monitoring the implementation of the preventive controls;
 - Procedures for taking corrective actions; and
 - Verification procedures
- Written food safety plan must be prepared by a PC Qualified Individual



Preventive Controls Requirements

- Hazard analysis;
 - Preventive controls;
 - **Supply chain program;**
 - Recall plan;
 - Procedures for monitoring the implementation of the preventive controls;
 - Procedures for taking corrective actions; and
 - Verification procedures
- Food safety plan prepared by a **PC Qualified Individual**

- Implications for both Produce Rule and PC Rule
- Required of processors that supply raw materials/ingredients where the hazard is controlled by the supplier
 - Must verify their suppliers are applying preventive controls
 - If buying produce from a distributor, must verify either:
 - that the distributor verified the farm's practices or
 - the farm's documentation itself
- This means food hubs could be:
 - Suppliers or distributors within a processor's supply chain program, or
 - Facilities themselves with their own supply chain program

Questions and concerns abound...

- Can verify suppliers based on a range of activities:
 - onsite audit (conducted by the receiving facility or documentation of a recently-passed audit)
 - sampling and testing of raw material/ingredient;
 - review of supplier's relevant food safety records;
 - and other activities based on supplier performance and the risk associated with the raw material.

- NOT required for qualified exempt/exempt farms or for qualified facilities
 - Can accept written assurances instead

- Compliance timelines for SVP vary based on who the supplier is: receiving facilities don't have to be in compliance with SVP until their suppliers are in compliance with Produce/PC Rule

Qualified Individual / Training

- General training requirements for personnel
- PC Qualified Individual
 - Has successfully completed training in developing and applying risk-based preventive controls
 - At least equivalent... standardized... recognized as adequate
 - Or otherwise qualified through job experience
 - Preventive Controls Alliance
 - Others?

FSMA: What's next?

- Use this time before compliance is required to figure out what you need to do: Are you covered? What trainings should you take? What upgrades or changes in practices might you need to make?
- FDA, USDA, NSAC, Cooperative Extension, and others (like your state department of agriculture) will be providing more information on how to comply with various provisions of the rules in the coming months/years.
- Farmers and eaters that submitted comments had the biggest impact on FDA's thinking. We will look to you again for your stories as the process unfolds – including as we work to secure additional funding to support trainings for farmers, local food processors, food hubs, etc.



What's next? Compliance Timelines

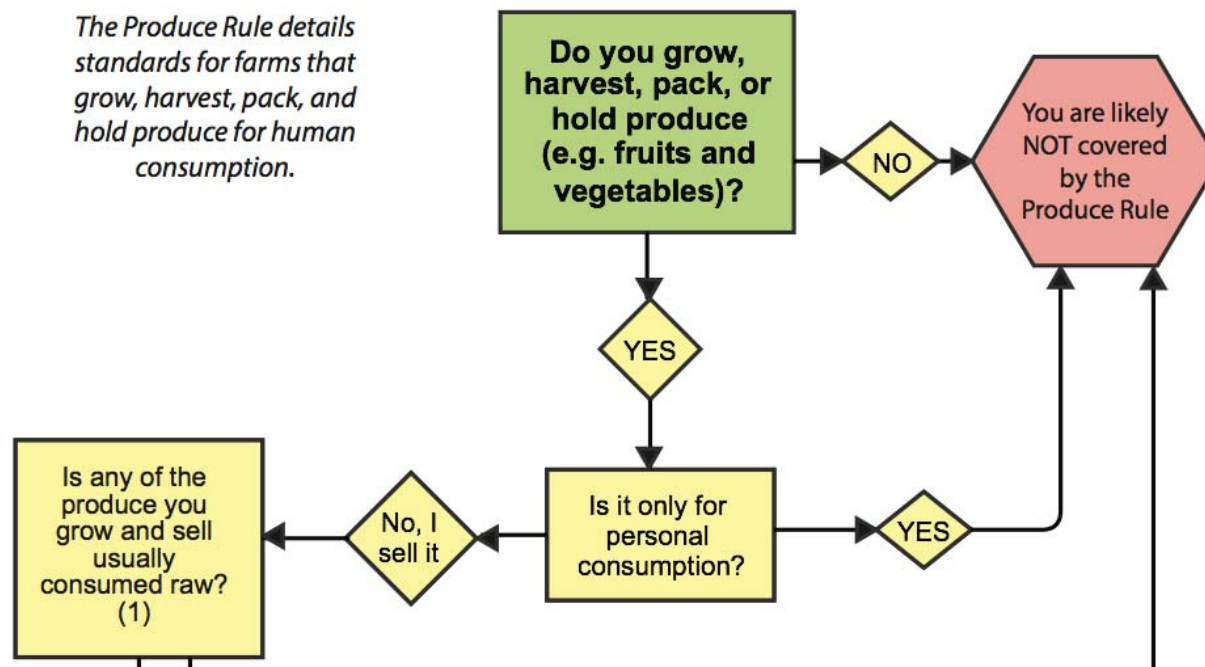
	Produce Rule		Preventive Controls	
	Gross annual produce sales (3 yr avg)	Years (from 1/26/16)	Gross annual food sales (3 yr avg)	Years (from 9/27/15)
Very Small Business	≤ \$250,000	4 + 2 for water	< \$1M	3
Small Business	≤ \$500,000	3 + 2 for water	< 500 employees	2
All Other (Large) Businesses	> \$500,000	2 + 2 for water	≥ \$1M ≥ 500 employees	1

GET THE DETAILED FLOWCHART HERE:

<http://sustainableagriculture.net/fsma>
(under *Who Is Affected?* section)

Am I Affected by the Proposed FSMA Produce Rule?

The Produce Rule details standards for farms that grow, harvest, pack, and hold produce for human consumption.



Questions?

<http://sustainableagriculture.net/fsma>

Sophia Kruszewski
NSAC Policy Specialist

sophia@sustainableagriculture.net

