Am I affected by new FOOD SAFETY RULES under the FOOD SAFETY MODERNIZATION ACT?  
A Flowchart for Farmers and Food Businesses

How to Use This Flowchart:

1) There are 2 sections: one for the Produce Rule and one for the Preventive Controls (Facility) Rule — these are the two main FSMA rules for businesses that grow and process food for people to eat. Start with PART 1 of each. If you find out at the end of Part 1 that you may be affected, proceed to Part 2 for details.

2) FARMERS: some farms may not be subject to either rule, some farms may be subject to just the Produce Rule, and some farms may be subject to BOTH the Produce Rule and the Preventive Controls Rule. You should read PART 1 of both to be sure.

3) This flowchart is intended to help you determine whether and to what extent your farm or food business MIGHT be impacted by the FSMA rules. This is not legal advice. Each operation is different, and your obligations under FSMA could change based on the specifics of your operation.

Timing Reminder: all farms have at least two years - until January 2018 - to come into compliance with the Produce Rule. Many smaller farms will have three or four years. And most smaller processors will have two to three years to come into compliance with the Preventive Controls (Facility) Rule (Sept 2017 or 2018).

More FSMA Information:  
http://sustainableagriculture.net/fsma

National Sustainable Agriculture Coalition  
Prepared by the National Sustainable Agriculture Coalition  
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Am I Affected by the FSMA Produce Rule?

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

Do you grow, harvest, pack and hold produce (e.g. fruits, vegetables)?

YES

Is it only for personal consumption?

NO, I sell it

NO, none

YES, all/some

Do you sell \( \leq 25,000 \text{/yr (3 yr avg)} \) of produce?

YES

NO, I sell more

You are likely NOT covered by the Produce Rule

You are likely exempt from compliance with the Produce Rule

Is any of the produce you grow and sell usually consumed raw? (1)

NO,

none

YES, all/some

You will likely need to comply with at least some portions of the Produce Rule - see Part 2

(1) Examples of produce usually consumed raw: lettuce, apples. Access the lists of covered and non-covered produce here:
(Note that the list of non-covered produce is exhaustive, and all other produce is considered covered.)
The FSMA Produce Rule - Part 2

So you may be covered by the FSMA Produce Rule. What does that mean?

Will the produce you grow be processed in a way that kills harmful pathogens? (e.g. commercial canning)

- YES, ALL
- YES, SOME
- NO

Do you average < $500,000 in sales of ALL FOOD (3 yr avg) AND sell > 50% of what you grow directly to a qualified end-user? (1)

- YES
- NO

Do you average ≤ $250,000 in sales of PRODUCE (3 yr avg) but not meet the above direct sales threshold?

- YES
- NO

Do you average ≤ $500,000 in sales of PRODUCE (3 yr avg) but not meet the above direct sales threshold?

- YES
- NO

Do you average > $500,000 in sales of PRODUCE (3 yr avg)?

- YES
- NO

What are MODIFIED REQUIREMENTS?

- Farms must comply with SOME Produce Rule measures under FSMA: recordkeeping, compliance, and enforcement (3)
- Farms are NOT subject to other Produce Rule measures around water, soil amendments, etc (3)
- Farms under DIRECT MARKETING MODIFIED REqs: all of the above + must label all food at point of sale; also subject to withdrawal measures (3)

What are FULL REQUIREMENTS?

- Under full requirements, farms must comply with ALL Produce Rule measures: recordkeeping; worker health, hygiene, and training; soil amendments; water testing; wild and domesticated animals; buildings and equipment, etc (4)
- SMALL BUSINESSES: 3 years to comply; 5 years for water testing (4)
- VERY SMALL BUSINESSES: 4 years to comply; 6 years for water testing (4)
- ALL OTHER BUSINESSES: 2 years to comply; 4 years for water testing (4)

1) What is a “qualified end user”? Either an individual (in any location) or a retail food establishment located in-state or within 275 miles. More details: http://bit.ly/nsacproduce

2) Direct Marketing Modified Requirements are also known as the Tester-Hagan Exemption.

3) Details on recordkeeping, enforcement, direct market labeling, and all levels of compliance: bit.ly/nsacproduce

4) Details on requirements and compliance timeframes: http://bit.ly/fsmapr1
The Preventive Controls (Facility) Rule sets forth new requirements and updates existing requirements for facilities that manufacture, process, pack, or hold food for human consumption.

**Do you manufacture, process, pack, AND/OR hold any kind of food for human consumption?**

- **I'M NOT SURE**
- **YES**
- **NO**

**Are you a RETAIL FOOD ESTABLISHMENT?**

- **YES**
- **NO**

**Are you a FARM?**

- **YES**
- **NO**

**Do you only pack/hold food for human consumption on your farm?**

- **YES**
- **NO**

**Is your processing limited to:**

- dry/dehydrate and/or label/package whole unprocessed produce (e.g. herbs, raisins)
- treat whole produce to manipulate ripening

**Is your off-farm packing operation majority owned by farmers, who are providing the majority of the products that are packed and held there?**

- **NO**
- **YES**

**Is your processing limited to:**

- dry/dehydrate and/or label/package whole unprocessed produce (e.g. herbs, raisins)
- treat whole produce to manipulate ripening

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1) Retail Food Establishment: grocery stores, farm stands, and restaurants that sell the majority of their food directly to consumers; details: http://bit.ly/nsacpcrule
2) Find definitions of manufacturing, processing, packing, and holding, along with examples of what “off-site” and “on-farm” mean, here: http://bit.ly/nsacpcrule
3) Details FDA's “farm” definition and on packaging, labeling, dehydrating, other on-farm activities that do and don't trigger the “facility” definition: http://bit.ly/nsacpcrule
The FSMA Preventive Controls (Facility) Rule - Part 2

So you may be covered by the Preventive Controls Rule. What does that mean?

- Do you ONLY manufacture juice, seafood, supplements, alcohol, or low-acid canned foods?
  - **YES**
  - You are likely exempt from HARPC requirements under the PCR
  - **NO**

- Do you ONLY hold (store) raw agricultural commodities (1) OTHER THAN FRUITS AND VEGETABLES destined for further processing?
  - **YES**
  - **NO**

- Do you ONLY hold (store) packaged food that is not exposed to the environment and does not need refrigeration?
  - **YES**
  - **NO**

- Of the human food you sell, including food you may MANUFACTURE, PROCESS, PACK, or HOLD, do you sell ≥ $1 million/yr (3 yr avg) OR have < 500 employees?
  - **YES**
  - **NO**

  - If you have ≥ $1 m/yr in human food sales (3 yr avg) AND < 500 employees, you are likely subject to FULL REQUIREMENTS as a SMALL BUSINESS under the PCR
  - If you have ≥ $1m/yr in human food sales (3 yr avg) AND ≥ 500 employees, you are likely subject to FULL REQUIREMENTS under the PCR

- Is all of the human food you MANUFACTURE, PROCESS, PACK, or HOLD a LOW-RISK activity and done ON-FARM? (2)
  - **YES**
  - **NO**

  - NO, I do some OFF-FARM AND/OR I do some HIGH-RISK activities (2)

What does that mean?

You are likely subject to the PCR as a QUALIFIED FACILITY

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1) Raw Agricultural Commodity: a food in its raw and natural state (e.g. raw grains)
2) Details on low-risk vs high-risk activities and off-farm vs on-farm: http://bit.ly/nsacpcrule
3) Details on HARPC, including compliance timelines: http://bit.ly/nsacpcrule