

What is the *Food Safety Modernization Act* and what does it mean for my farm or food business?

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 Rule — these are the two main FSMA rules that impact 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.

3) Remember: the FSMA rules are NOT yet final; details may change before they are finalized and implemented. This means they are not yet being enforced.

4) 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 in their proposed form. **This is not legal advice.** Each operation is different, and your obligations under FSMA could change based on the specifics of your operation and the requirements contained in the final rules. And remember, regardless of your coverage under these rules, **food safety is everyone's responsibility -- from field to fork.**

More FSMA Information:

<http://sustainableagriculture.net/fsma>



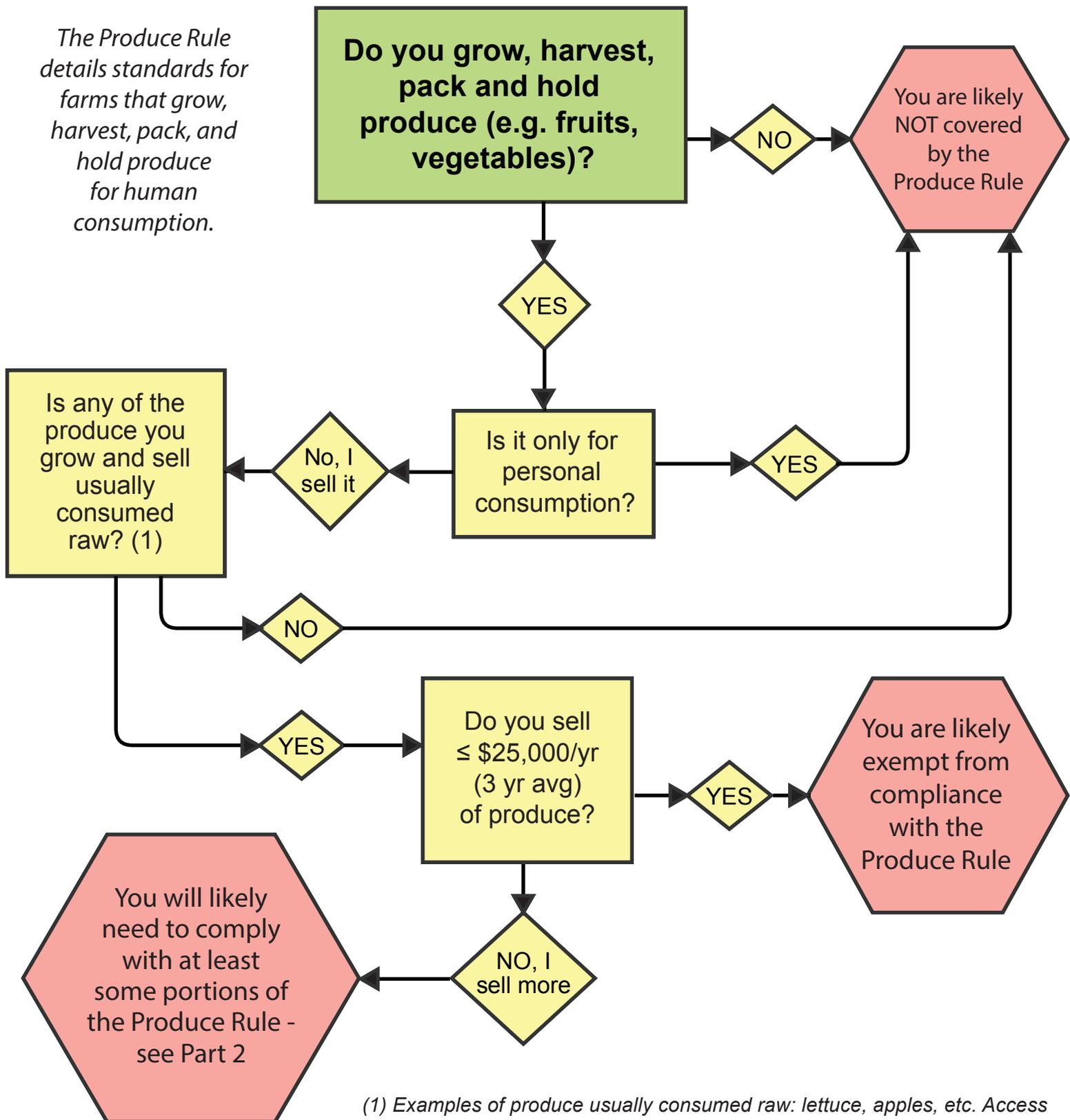
National Sustainable Agriculture Coalition

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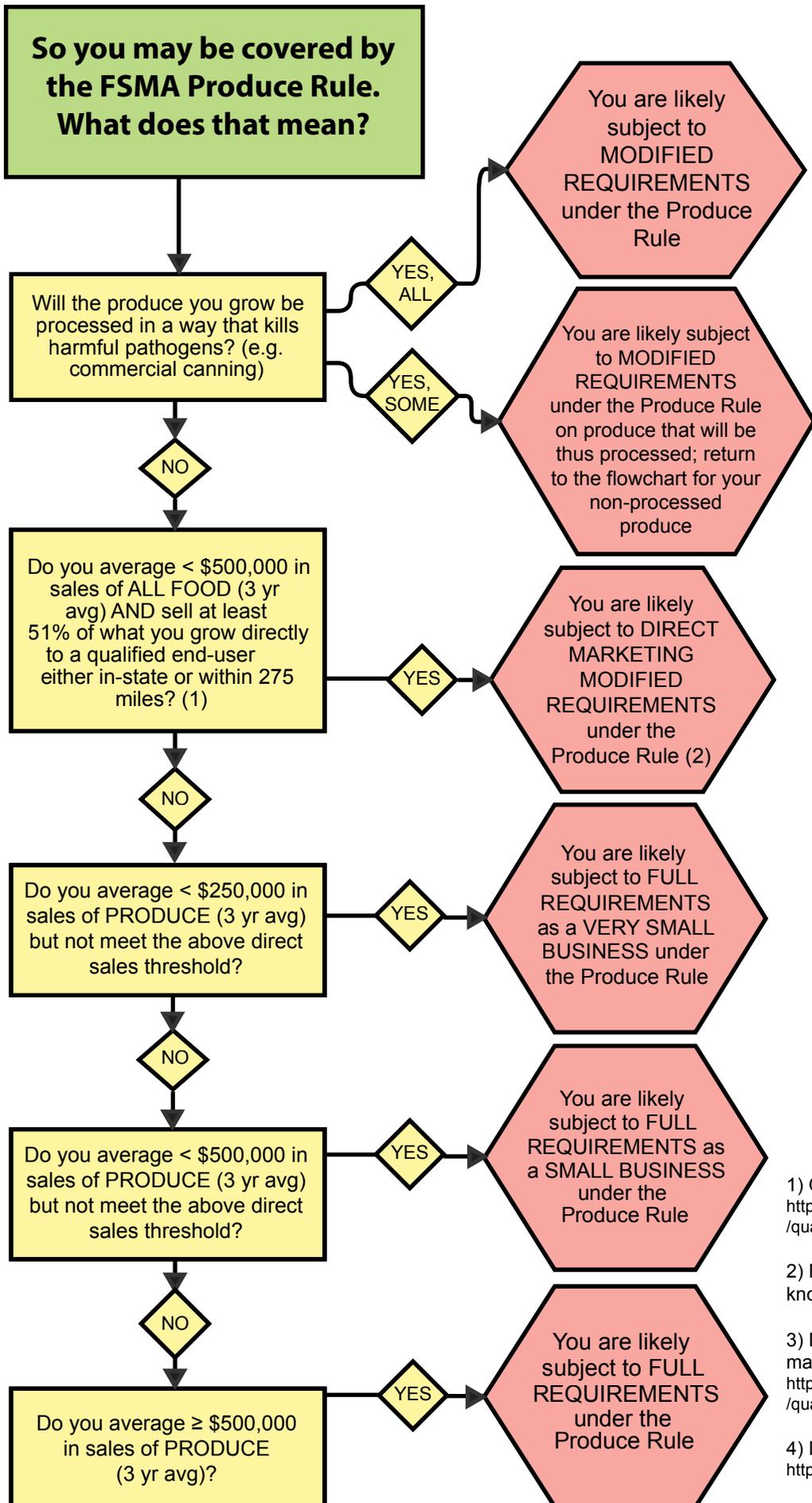
Am I Affected by the Proposed FSMA Produce Rule?

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



(1) Examples of produce usually consumed raw: lettuce, apples, etc. Access the full list of covered produce here (Note that the list will not be finalized until FDA finalizes the proposed rules and is subject to change): <http://sustainableagriculture.net/fsma/who-is-affected/>

The FSMA Produce Rule - Part 2



What are MODIFIED REQUIREMENTS?

Remember: all farms have a duty to grow safe food, regardless of their status under FSMA rules.

- 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?

- Farms have 2 years to comply with ALL Produce Rule measures under FSMA: recordkeeping, compliance, enforcement, soil amendments, hygiene, etc, plus 2 additional years to comply with water measures (4)
- SMALL BUSINESSES: all of the above but with 3 yrs to comply, plus 2 additional yrs for water (4)
- VERY SMALL BUSINESSES: all of the above but with 4 yrs to comply, plus 2 additional yrs for water (4)

1) Qualified End-User: a consumer, restaurant, etc. <http://sustainableagriculture.net/fsma/learn-about-the-issues/qualified-exemptions-and-modified-requirements>

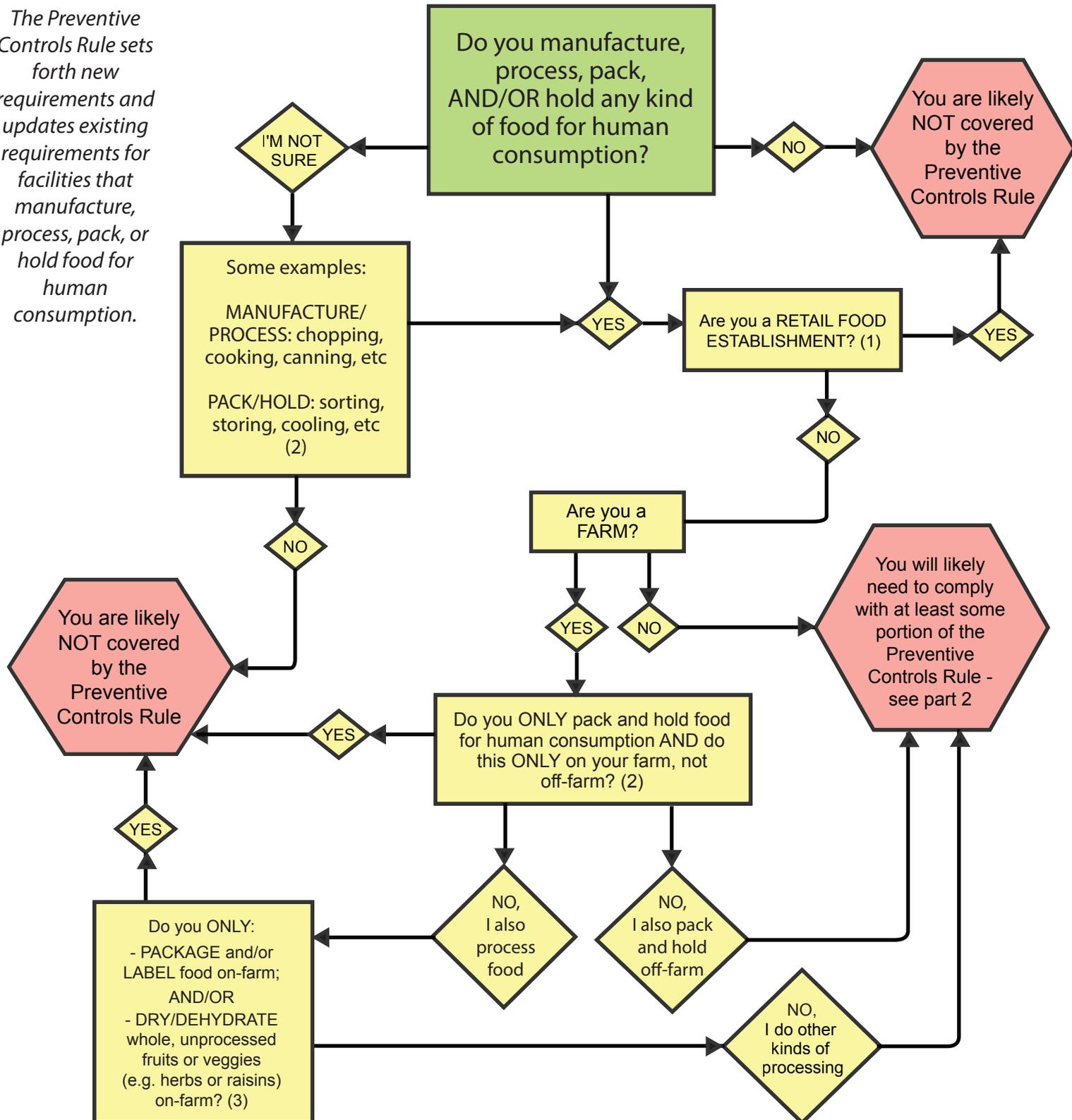
2) Direct Marketing Modified Requirements are also known as the Tester-Hagan Exemption.

3) Details on recordkeeping, enforcement, direct market labeling, and all levels of compliance: <http://sustainableagriculture.net/fsma/learn-about-the-issues/qualified-exemptions-and-modified-requirements>

4) Details on compliance timeframes: <http://sustainableagriculture.net/fsma/who-is-affected>

Am I Affected by the Proposed FSMA Preventive Controls Rule?

The Preventive Controls Rule sets forth new requirements and updates existing requirements for facilities that manufacture, process, pack, or hold food for human consumption.



1) Retail Food Establishment: establishments such as grocery stores, farm stands, and restaurants that sell the majority of their food directly to consumers; details: <http://sustainableagriculture.net/fsma/learn-about-the-issues/direct-to-consumer-marketing-preventive-controls-rule/>

2) Find definitions of manufacturing, processing, packing, and holding, along with examples of activities and what "off-site" and "on-farm" mean, here: <http://sustainableagriculture.net/fsma/learn-about-the-issues/do-i-operate-a-facility/>

3) Find more details on packaging, labeling, dehydrating, and other on-farm activities that do and don't trigger the "facility" definition at the same link as above.

The FSMA Preventive Controls Rule - Part 2

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

Do you **ONLY** manufacture juice, seafood, supplements, alcohol, or low-acid canned foods?

NO

YES

Do you **ONLY** hold (store) RAW AGRICULTURAL COMMODITIES (1) other than fruits and vegetables destined for further processing?

NO

YES

Do you **ONLY** hold (store) packaged food that is not exposed to the environment and does not need refrigeration?

NO

YES

Do you sell < \$1 million/yr (3 yr avg) of human food OR do you have < 500 employees?

NO

YES

Is all of the human food you MANUFACTURE, PROCESS, PACK, or HOLD a LOW-RISK activity and done ON-FARM? (2)

NO, I do some OFF-FARM M,P,P, or H -OR- I do some HIGH-RISK activities (2)

You are likely exempt from HARPC requirements under the PCR; see sidebar

You are likely subject to the PCR as a QUALIFIED FACILITY

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

WHAT ARE PCR REQUIREMENTS?

Remember: all farms and facilities have a duty to provide safe food, regardless of their status under FSMA rules.

- FACILITIES EXEMPT FROM HARPC: must register with FDA and comply with already-existing rules and practices, but do not need to develop Hazard Analysis and Risk-Based Preventive Controls (HARPC) plans and procedures. (3)

- QUALIFIED FACILITIES: must register with FDA; eligible for modified requirements, including labeling and recordkeeping but not required to develop full HARPC plans and procedures. (3)

- FACILITIES SUBJECT TO FULL REQUIREMENTS: must register with FDA; must develop full HARPC plans and procedures laid out under the PCR; facilities have 1 year to come into compliance. (3)

- FULL REQUIREMENTS as a SMALL BUSINESS: Same as above but with 2 years to come into compliance. (3)

1) Raw Agricultural Commodity: any 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://sustainableagriculture.net/fsma/learn-about-the-issues/do-i-operate-a-facility/>

3) Details on HARPC: <http://sustainableagriculture.net/fsma/overview-and-background/what-is-the-preventive-controls-rule/>