

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.
- 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 REMINDERS

FACILITIES

- Compliance dates for the largest facilities are in effect as of Sept 2016/17.
- The compliance date for very small facilities is 9/17/18.

PRODUCE FARMS

- Compliance dates for the largest produce farms are in effect as of 1/26/18. Inspections begin in 2019.
- Compliance dates for small and very small farms are 1/28/19 and 1/27/20, respectively.

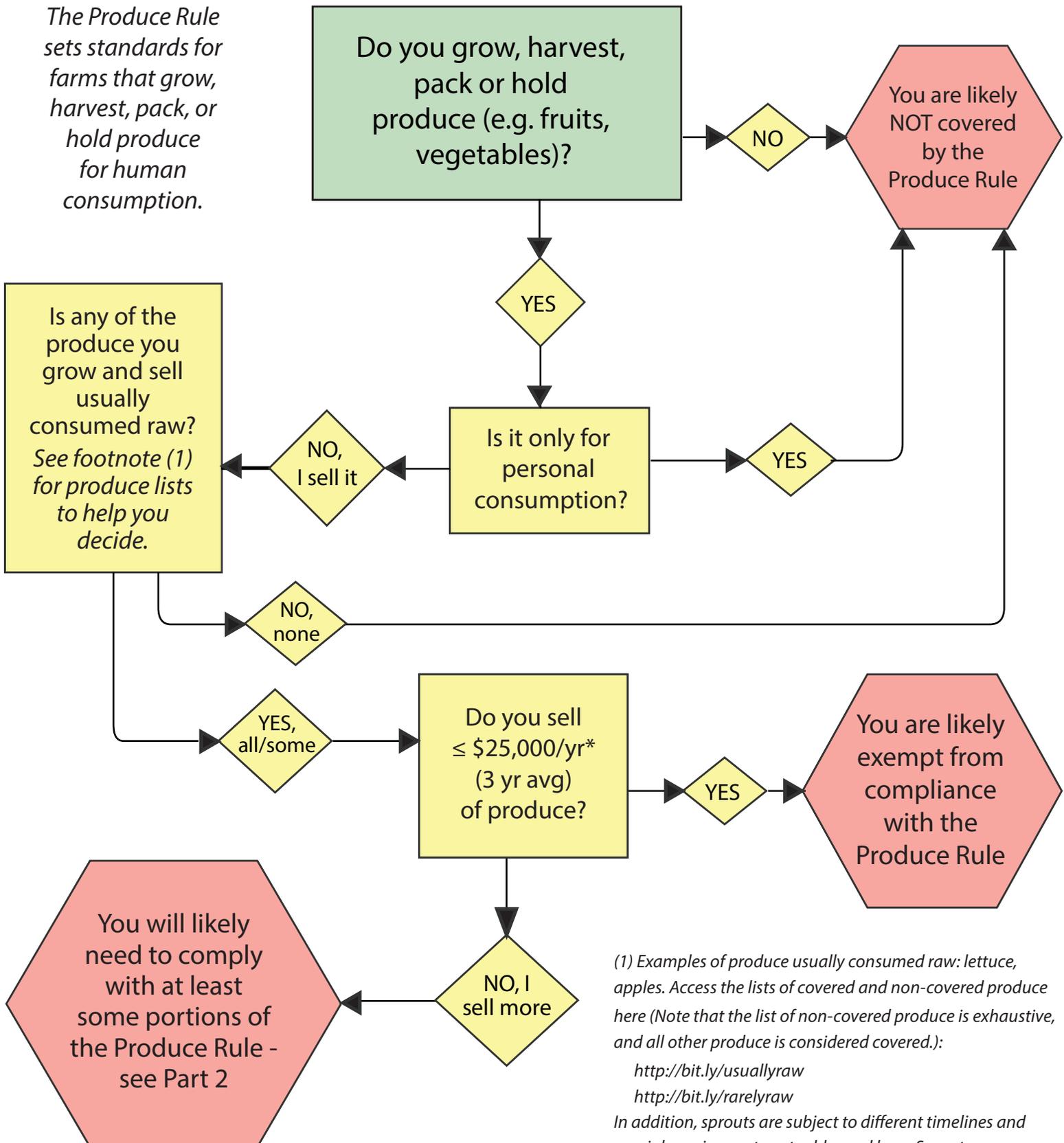
FDA continues to work out certain areas of the rule; some compliance dates continue to be adjusted, especially for irrigation water and requirements for packinghouses. Check our website frequently for updates: <http://sustainableagriculture.net/category/food-safety/>

See FDA's FSMA Compliance Timeline for more info: <http://bit.ly/FSMAcompliance>



Am I Affected by the FSMA Produce Rule?

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



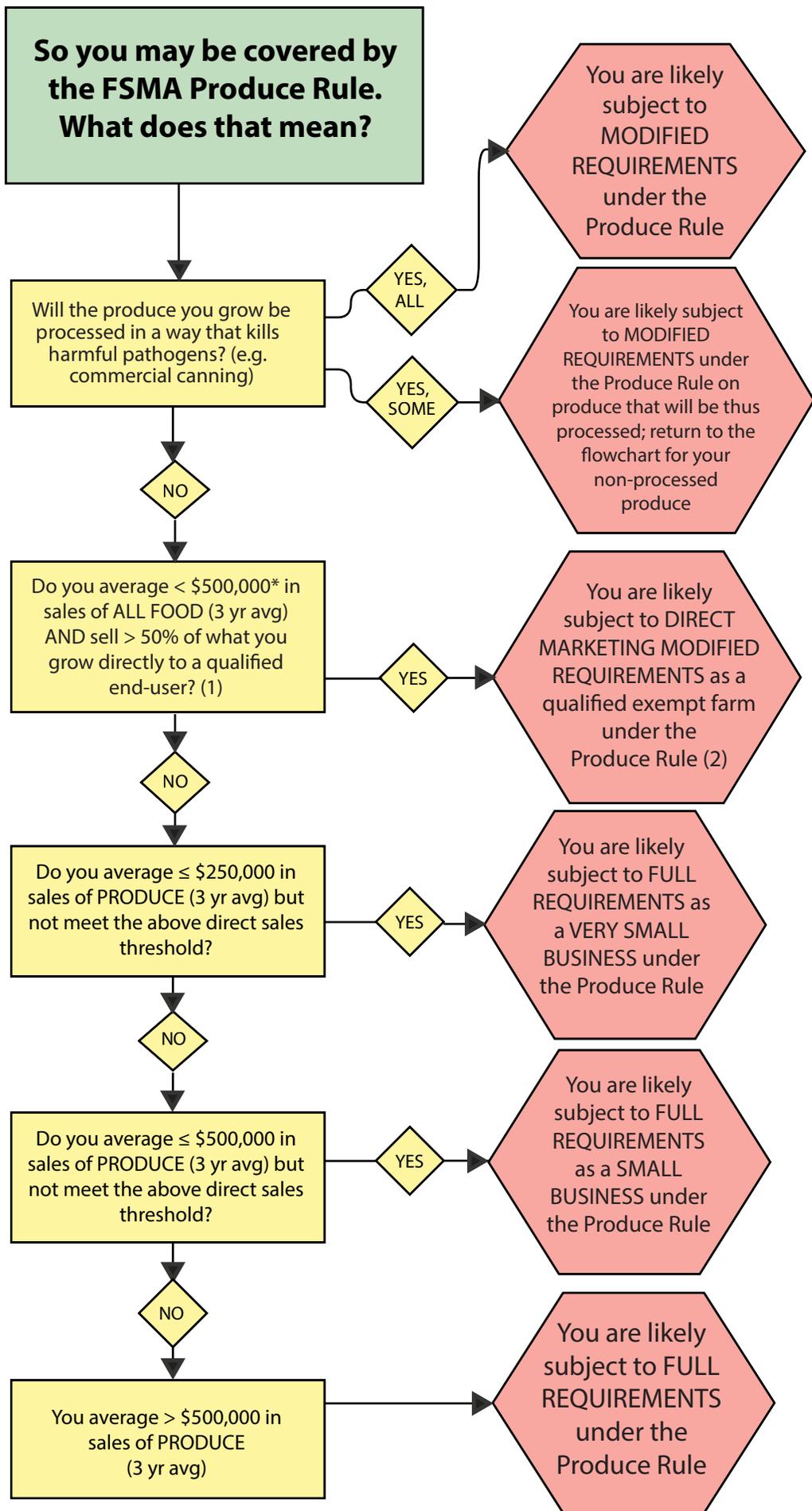
(1) Examples of produce usually consumed raw: lettuce, apples. Access the lists of covered and non-covered produce here (Note that the list of non-covered produce is exhaustive, and all other produce is considered covered.):

<http://bit.ly/usuallyraw>

<http://bit.ly/rarelyraw>

In addition, sprouts are subject to different timelines and special requirements not addressed here. Sprout growers should visit the Sprout Safety Alliance for more information: http://www.iit.edu/ifsh/sprout_safety

The FSMA Produce Rule - Part 2



What are MODIFIED REQUIREMENTS?

- Farms must comply with SOME Produce Rule measures under FSMA: certain recordkeeping requirements, compliance, and enforcement (3)
- Farms are NOT subject to other Produce Rule measures around water, soil amendments, etc (3)
- Qualified exempt 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?

- Fully covered farms must comply with ALL Produce Rule measures: recordkeeping; worker health, hygiene, and training; soil amendments; certain water testing measures; wild and domesticated animals; buildings and equipment (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>

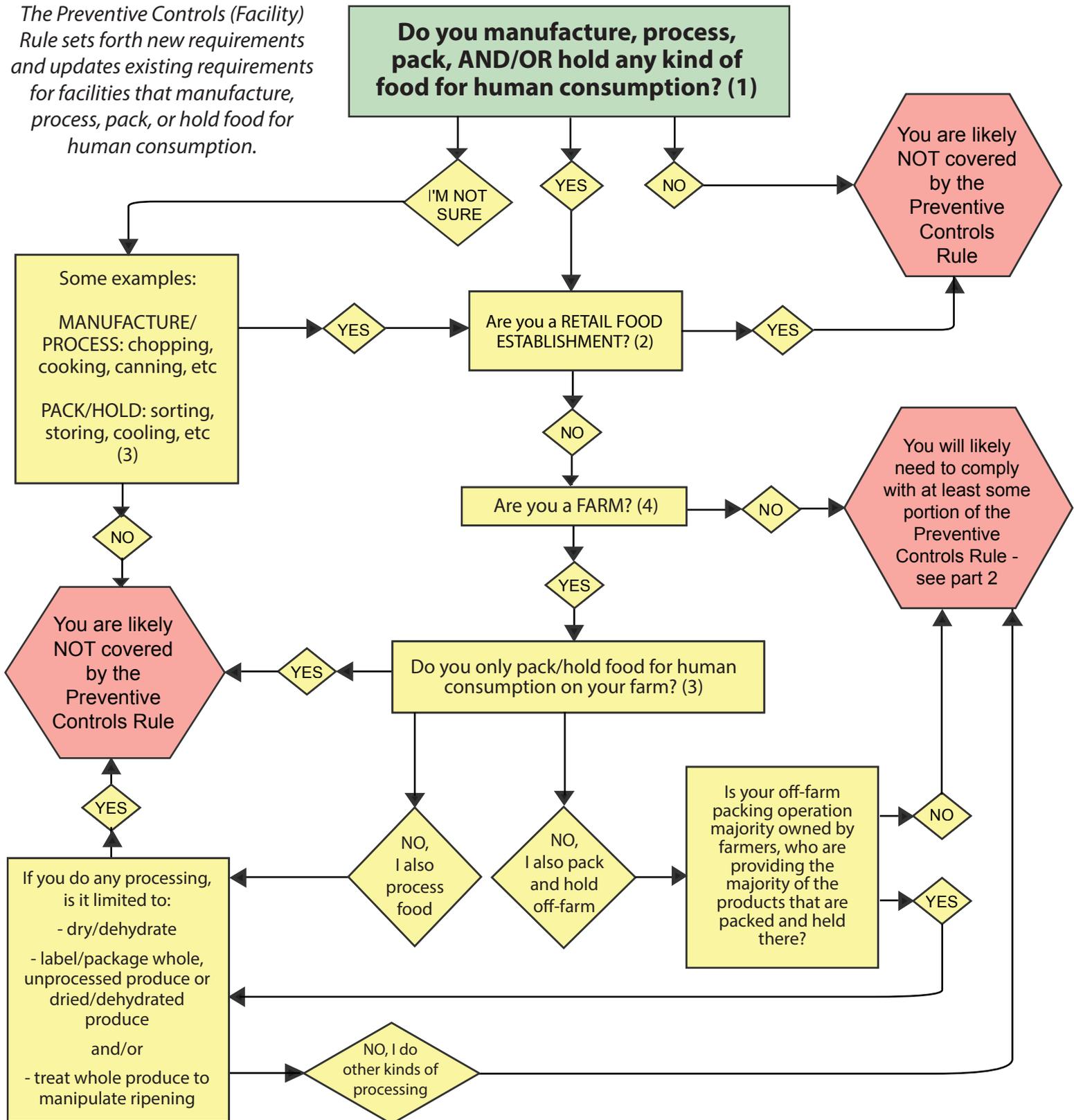
2) Direct Marketing Modified Requirements for qualified exempt farms are also known as the Tester-Hagan Exemption.

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> and <http://bit.ly/FSMAcompliance>

Am I Affected by the FSMA Preventive Controls (Facility) Rule?

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.



1) If you are manufacturing, processing, packing, or holding food **for personal consumption on farm only**, the Preventive Controls Rule does not apply.
 2) Retail Food Establishment: grocery stores, farm stands, and restaurants that sell the majority of their food directly to consumers; details: <http://bit.ly/nsacpcrule>
 3) Find definitions of manufacturing, processing, packing, and holding, along with examples of what "off-site" and "on-farm" mean, here: <http://bit.ly/nsacpcrule>
 4) Find details on 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>. Note also that FDA may be making changes to the rules to address operations that walk the line between a farm and a facility.

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 food covered by other regulations (e.g. juice, seafood, dietary supplements, alcohol)?

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

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 M,P,P, or H AND/OR I do some HIGH-RISK activities (2)

AND I have < \$1m/yr* in human food sales (3 yr avg)

AND I have ≥ \$1m/yr* in human food sales (3 yr avg)

You are likely subject to the PCR as a QUALIFIED FACILITY

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

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

WHAT ARE PCR REQUIREMENTS?

- FACILITIES EXEMPT FROM HARPC: must register with FDA and continue complying with already-existing rules and practices (like Current Good Manufacturing 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 and submit certain attestations; not required to develop full HARPC plans and procedures but must follow certain basic requirements (e.g. recordkeeping); if sales < \$1M*, 3 yrs to come into compliance (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: 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/nsacprule>
 3) Details on HARPC, including compliance timelines: <http://bit.ly/nsacprule>

* Inflation Adjusted Cutoffs *

Several FSMA rules have provisions in which a value is adjusted for inflation and averaged over three years. For the Produce Rule, these are the cutoffs for the de minimis exemption and the qualified exemption for direct marketing farms. For the PC Rule, this applies to qualified facilities. We note these cutoffs in the flowchart with asterisks (*) because each year the inflation-adjusted sales threshold is actually likely to be higher than the three-year average of \$25,000 in gross produce sales (de minimis exemption), \$500,000 in all food sales (qualified exempt farm), or \$1,000,000 in food sales (qualified facility).

FDA has a website where they list the inflation adjusted values relevant to all of the FSMA rules that have these kinds of sales thresholds or cutoffs, and will update the website in March of each year to reflect the most recent inflation-adjusted values.

The information listed here is updated as of 2018, and is relevant for using 2015-2017 sales records to demonstrate where you fall for compliance purposes in 2018. We intend to update this document annually to reflect the new inflation-adjusted cutoffs as FDA provides them. If you are using this document after 2018, be sure to check FDA's website to make sure you using the most up-to-date values: <http://bit.ly/FSMAinflation>

If you are trying to determine whether you satisfy the Produce Rule's de minimis exemption for 2018, you should average your past three years of produce sales (2015, 2016, and 2017), and then compare that number to the Produce Rule inflation-adjusted three-year average for 2015-17.

If you are assessing whether you satisfy the Produce Rule's qualified exemption for 2018, you should average your past three years of food sales (2015, 2016, and 2017), and then compare that number to the Produce Rule inflation-adjusted three-year average for 2015-17. If your sales are below that value, then you would qualify for the exemption (assuming you are also selling majority direct to a qualified end user).

A processor would follow the same process as outlined above for the Produce Safety Rule: for 2018, the facility would average the past three years' worth of human food sales (2015, 2016, and 2017) and then compare that averaged value to FDA's inflation-adjusted cutoff for 2015-2017.

Produce Safety Rule Inflation-Adjusted Cutoff for 2018 (based on 2015-17 average):

- *De minimis exemption:* \$26,999
- *Qualified Exemption:* \$539,982

Preventive Controls Rule Inflation-Adjusted Cutoff for 2018 (based on 2015-17 average):

- *Qualified Facility:* \$1,079,963



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