

# Selling Honey in Pennsylvania

**Honey is regulated by the Bureau of Food Safety which is part of the PA Department of Agriculture**

## Laws Affecting Sale of Honey:

### 1. "Honey Sale and Labeling"

Act 184 of 1974 (3 Pa. C.S.A. §§ 311 – 318)

### 2. "The Retail Food Facility Safety Act" & "The Food Safety Act"

Act 106 of 2011 (3 Pa. C.S.A. §§ 5701 – 5737)

**House Bill 2565** – Amends Act 106 to exempt retail food facilities and food establishments from registering their honey products with the Department of Agriculture when 100% of the products being offered are produced or processed on location.

## General Guidelines:

***1. As long as honey is made, processed, and sold on the same farm, the honey producer is exempt from the \$35 Food Safety Registration Fee.***

- All Home Food Processor guidelines will still apply.
- "On the farm" could be a true farm, a single family home, an apartment, or residential property. It is the site in which the honey is processed and produced.

## **No Food Safety Registration Application is required.**

- While **NOT** in the Food Safety "system," the honey producer **CAN** be inspected if there is a complaint.

## ***2. If honey producer sells off-site of his or her "farm":***

(Off site locations include stores, farmers' markets, internet, craft shows, restaurants, ag fairs, etc.)

- Then, he or she **MUST** fill out a Food Safety Application AND **FOLLOW** the "Guidelines for the Sanitary Operation of Honey Extracting Facilities."
- There is still NO \$35 fee if honey was made and processed on the "farm." There will be routine inspections of the processing site.
- **If NO fee is paid, there is NO registration issued. The Law exempts the on-farm honey processor from a fee but not potential inspection. The Food Safety Inspector is not inspecting**

honey processors that are only selling on farm, but Food Safety Inspectors are inspecting honey processors that sell their honey off premises or sell to other businesses. The application is so the honey producers are entered into the Food Safety data base, and the Food Safety Inspectors can do the inspections. It also assures if another local health inspector finds the product for sale, we can affirm that it is from an inspected approved source.

**\*If selling honey off-site of the "farm" for three days or less in a calendar year, a retail license is not required. If selling more than four calendar days in a year, a license may be required. If the only product sold is bottled honey, then the retail location would be exempt from a license fee. If other foods are sold in addition to honey, a license may be required, and a \$14 temporary license, good for 14 days cumulative in a calendar year, could be obtained. (The 14 days can be all at one time or added up throughout the year.)**

### **Frequently Asked Questions:**

***1. What if I raise, process and sell my honey on site ("farm"), but I need to buy in and sell another beekeeper's honey to keep up with the demand for honey? It is PA honey and I bottle it on my farm.***

You need to register with Food Safety, pay the \$35 registration fee, and you will be inspected. You are not exempt because the honey is not produced and processed on the same site.

***2. I have well water. Since I do not use water in the production of the honey, just for the clean-up, can I buy and use bottled water rather than getting my well water tested (which costs a fair amount of money)?***

Food Safety's Response: "He could use water from any approved source, so yes, bottled water would work (spring or distilled); although, he will need to have a means for hand washing as well as cleanup... which will require heating the water. Well water testing is not that expensive... perhaps \$10-\$15 per year for coliforms..... seems to me he would spend that on bottled water , as well as whatever he would need to get the warm water to a hand wash sink setup...."

***3. What if I sell other food products grown on my farm?***

This does **NOT** exempt you from any other Food Safety Rules and Regulations. It only applies to honey. You must follow the Food Safety Rules for other products as appropriate.

***4. What if I am selling my honey in another state?***

You **MUST** register with Food Safety.

You **MUST** pay the \$35 registration fee.

You **WILL** be inspected by a Food Safety Inspector about every 24 months.

**5. What if I belong to a club and we have an extracting site (honey house) that many members use?**

The site **MUST** be registered.

The \$35 Food Safety Registration fee **MUST** be paid.

Although the “club or organization” can be listed as the “owner” on the registration, the name of an actual PERSON, who is responsible for the honey house operation (perhaps the club president) must be listed with the owner information. The beekeepers that come to that site do **NOT** need to register, but must be able to show that honey was processed there through some type of recordkeeping.

**The owner/operator should keep a log with names and dates of beekeepers extracting honey at that site.**

**6. What if honey is made and processed on the “farm”, and then wholesaled?**

You **MUST** register with Food Safety.

You do **NOT** have to pay the \$35 registration fee.

You **WILL** be inspected by a Food Safety Inspector about every 24 months.

**7. What if a beekeeper gives or sells his or her honey to family or friends. The family or friends then sell the honey to someone else. The beekeeper may or may not know that this is being done. Which rules apply in this situation? Is the original beekeeper liable to any problems?**

Food Safety Staff reply: “If they give to family and friends it is supposed to be for their personal use. If the product is resold in anyway then the honey processor should be registered. Depending on who the family and/or friends are selling to, they may or may not be ‘found’. I would suggest to the honey processor that if they are concerned this is happening they may want to label their product “Not for Resale”.”

**8. What if I want to have the statement, “Reg. Penna. Dept. Agr.” or the “PA Preferred” on my honey bottle?**

You **MUST** register with Food Safety.

You **MUST** pay the \$35 registration fee.

You **WILL** be inspected by a Food Safety Inspector.

**9. What is PA Preferred?**

PA Preferred is a state-supported agricultural marketing program. The Pennsylvania Department of Agriculture launched the PA Preferred program to identify and promote food and agricultural products grown, produced and processed in Pennsylvania. Please see the Pennsylvania Department of Agriculture’s website for additional information ([www.agriculture.state.pa.us](http://www.agriculture.state.pa.us)) or contact Ashlee Dugan at [asdugan@pa.gov](mailto:asdugan@pa.gov). “Every

application has a story....” and each product and producer will be evaluated to determine eligibility. Sometimes even if 100% of a beekeeper’s honey is NOT made by the bees while they are in PA, they will qualify. So, if you have questions, please email Ashlee!

### **10. What are the benefits of being a PA Preferred member?**

It promotes PA agriculture.

It is FREE.

It can be used as a marketing tool to help with sales.

Many Pennsylvanians want to buy and use local products.

### **11. What should be on a PA honey or pollen label?**

-Common name (example: Honey or Pollen)

-Ingredient(s) (example: Honey or Pollen)

-Manufacturing or processing address

-Net weight of the honey or pollen

Honey is the common name and it is a single ingredient, so label should say “HONEY”. Honey with something added to it, like corn syrup, legally must say “Honey Product”, “Honey Food”, or something to that effect.

Address of the processor or distributor. If from extracting site used by others, enter “code” or date of extraction too.

There must be enough of an address so that the site could be found using a public search.

-Business Example: Bees’ Gold, Harrisburg, PA

- Individuals’ Example: John and Jane Beekeeper, Main Street, Harrisburg, PA (or PO Box 1, Harrisburg, PA)

You may wish to put “Do not feed to infants under 1 year of age” on your label, but it is not required.

Infant botulism is caused by *Clostridium* bacteria which thrive in soil and dust. This can also contaminate certain foods, including honey. (Symptoms and signs of infant botulism include muscle weakness, poor sucking, a weak cry, constipation, and floppiness -decreased muscle tone.) Even pasteurized honey can contain viable botulism spores because the honey must be boiled to kill the spore. Because of this, infants under 1 year should not eat food with honey listed as an ingredient, even if the food is cooked. The intestines usually contain enough acid in people over 1 year of age to destroy any toxins produced by botulism bacteria found in honey.

### **12. Important to remember:**

**Do NOT make claims that honey or pollen will absolutely cure specific or nonspecific diseases, problems, etc. unless you are registered with the Food and Drug Administration! Honey and pollen are not registered as a “drug”.**

**13. I keep my bees in Town A, PA but I process the honey from them in Town B, PA. Is it a problem if I put my business name & Town A, PA on my label but add a sticker saying it was processed in Town B, PA? Basically, I don't want people to see the label & assume that I keep the bees in Town B, & not in Town A. Someone told me that they are pretty sure I can't have Town A on the label, but to me, as long as I include the address where it is processed, it doesn't seem like it would matter. Help!**

Food Safety's Response: "The name and address of the processor or distributor does not need to be the location of the processing site.... It could be a corporate or 'headquarters' address - as long as the address leads us to a competent owner or manager who can then tell us where the product is from. For example all the Hershey chocolate bars say Distributed by Hershey Chocolate Company, Hershey, PA.... but very little of the product is actually made there.... It could be made anywhere in the world even. They have plants in Mexico and Canada even.... But if you give them the lot code from a candy bar, they can tell exactly what processing facility the product was from.... We may not know looking at the code, but as long as a competent person at the labeled address can answer that question, it meets the labeling requirements. So basically the beekeeper can use any name and address they want, as long as it leads us to them as the owner and they can tell us where the product was processed. They also do not need to distinguish which honey bee colony product came from either, unless they want to do that for a trace back purpose of their own."

**14. What should I expect from a Food Safety Inspection?**

Inspectors prefer to do inspection while extracting is occurring.  
 Inspectors like clean, unbroken equipment.  
 Inspectors may or may not call first.  
 Inspectors will usually leave a business card if no one is on site.  
 Inspections will usually last 15 minutes or more.

**15. My honey house was recently inspected. The Food Safety Inspector asked me questions about lot numbering, tracking, and written plans. These questions did not show up on the inspection report given to me. Is this a PA Department of Agriculture (PDA) or a Food and Drug Administration (FDA) regulation? Should I be doing something else in my record keeping?**

Some of these questions have to do with PDA's compliance with the Manufactured Food Regulatory Program Standards from the FDA. Those standards require PDA to maintain information on a firm's type of food products, size, geographic distribution, and food safety systems in place to assess potential public health risk, assign inspection frequencies, and target educational materials and outreach.

Other questions are related to the new FDA regulation – Preventative Control Rules for Human Food (PC Rule), which by Law, PDA has adopted as PA regulation for Food Establishments. This regulation is still a

“work in progress” and it will NOT directly affect most small ‘on-farm’ beekeepers. The PC Rule did update and make changes to the current Good Manufacturing Practices (basic Sanitation and Food Safety standards). The biggest changes in the PC Rule relate to requirements for trained staff, formal Food Safety Plans, and associated recordkeeping. The questions you were asked about lot numbering, tracking, and written plans are included in the facility record in the PDA data base for your honey house. **If you do not know the answers to these questions when the Food Safety Inspector asks, it is perfectly fine to say that you do not know the answer.** The questions are asked to help the Food Safety Inspectors determine who will eventually be included in the Preventative Control Rules for Human Food regulations, and to what extent they must comply with those regulations.

For this new FDA regulation, businesses are put into three categories with three different compliance dates:

- Large Businesses: firms that do not meet either of these categories (they have 500 or more employees AND have over \$1 million in sales) – Compliance Date was September 19, 2016
- Small Businesses: firms with less than 500 employees (and over \$1 million in sales) – Compliance Date is September 19, 2017
- Very Small Businesses: firms with less than \$1 million in sales. Compliance Date is September 19, 2018

**Businesses processing honey – a low risk food - on their farm where the honey was produced, and with less than one million dollars in sales, will most likely be exempt from the full requirements of the Preventive Control Rule for Human Food (PC Rule). Businesses that are processing honey from bees that are not strictly from “on farm,” may be subject to “modified” requirements of the PC Rule.**

PDA’s Food Safety staff is waiting for FDA guidelines and clarification on “modified” requirements for certain businesses, to include those which have “off the farm processing” of honey. The guidelines and requirements may include and involve some recordkeeping, labeling requirements, a recall plan, etc.

There is training and information available through Penn State and on their website at

<http://extension.psu.edu/food/safety/food-safety-modernization-act>

PDA Food Safety also has information on their website (<http://www.EatSafePA.com>) for businesses (go to the Manufacturing.

FDA FSMA information can be found at

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>

### ***16. Interested in more information about the Food and Drug Administration (FDA) ?***

Go to their website at [www.fda.gov](http://www.fda.gov) and click on “Food” (found in the top menu bar). The menu on the right side of the next page will offer a number of pages including information on: “Popular Topics”, “Food Safety”, “Food Businesses”, and “Contact FDA”.

## Questions for Food Safety?

Please contact:

**Sheri Morris, Program Manager**

(717) 787-5289 [shmorris@pa.gov](mailto:shmorris@pa.gov)

OR

**Abdellah El Hajjam, Manufactured Food Program Specialist**

(717) 772-5208 [aelhajjam@pa.gov](mailto:aelhajjam@pa.gov)

You can find your regional Food Safety office at <http://www.EatSafePA.com> and clicking on "Contact PDA Regional Offices".

Prepared by Karen Roccasecca, State Apiarist, PA Dept. of Agriculture, 717-346-9567, [kroccasecc@pa.gov](mailto:kroccasecc@pa.gov)  
<http://www.agriculture.state.pa.us>

This information is designed as guidelines. Please contact Food Safety for additional information.

Revised: October 2016

## FSMA's Final Rule on *Preventive Controls* for Human Food

### ❖ Who is Subject to FDA's new FSMA Preventive Controls Rule?

The Food Safety Modernization Act (FSMA), which became law in 2011, requires firms that manufacture, process, pack or hold human food and that must register with FDA under 2002 BT Act to ALSO follow the Preventive Controls (PC) Rule's new food safety requirements found in **21 CFR Part 117**. To learn more about who must register their firms with FDA, visit the FDA website at: <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm2006831.htm>

The Preventive Controls rule is now final, and compliance dates for some businesses begin as early as September 2016. For more information about the FDA's FSMA Final Rule for PC for Human Food, please visit: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>

The Pennsylvania Department of Agriculture (PDA) will adopt the new federal regulations as dictated by the Food Safety Act (3 Pa. C.S.A. §5733(f)) and will enforce all applicable provisions as of the effective compliance date. As Pennsylvania regulation, all PDA registered firms will be expected to comply with the applicable portions of the PC Rules regardless of FDA registration status, unless specifically exempted in the Rule. During inspection of food establishments, PDA will evaluate the required food safety plans and make sure the plans are being implemented properly.

The new *PC Rule* requires food establishments to follow updated good manufacturing practices (*cGMPs*), and establish and implement a comprehensive Hazard Analysis and Risk-Based Preventive Controls (*HARPC*) plan.

### ❖ FSMA's Food Safety Plan Requirements

Firms that are subject to the regulations must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. This includes a written food safety plan that covers:

- **Hazard analysis:** What are the known or reasonably foreseeable biological, chemical, and physical hazards that occur naturally, are unintentionally introduced, or are intentionally introduced, that could affect the safety of the food.
- **Preventive controls:** Measures that are required to minimize or prevent the identified hazards, including:
  - Process Controls,
  - Food Allergen Controls,
  - Sanitation Controls,
  - Supplier-Chain Controls — a risk-based approach to ensure suppliers are not providing food establishments with raw materials or ingredients that pose a significant risk to the final product made by the firm.
  - Recall Plan—It must include steps and methods to be used to notify the direct recipients of the food about the recall and the public about any hazard, and to verify that the recall is carried out as well as procedures to appropriately dispose of the recalled food in the food establishment and by all recipients.
  - Other Appropriate Controls
- **Oversight and management of preventive controls:**
  - Monitoring: to provide assurance that preventive controls are consistently performed.
  - Corrective Actions and Corrections: to quickly identify and correct a minor isolated problem that occurs during food production.
  - Verification: to ensure that preventive controls are consistently implemented and effective.
- **Recordkeeping:** Documentation of compliance with the food safety plan to include but not limited to monitoring, corrective actions and verification activities. Required records shall be made available to the regulatory authority.



**Pennsylvania Department of Agriculture**  
**Bureau of Food Safety & Laboratory Service**  
**717-787-4315**  
[www.EatSafePA.com](http://www.EatSafePA.com)

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❖ **When would Food Establishments need to comply (if not exempted)?**

<i>Business Size</i>	<i>Description</i>	<i>Compliance Date</i>
<b>Very small</b>	<\$1M total annual sales of food (3 year avg.)	September 16, 2018
<b>Small</b>	<500 full-time equivalent employees	September 16, 2017
<b>Large</b>	All other businesses	September 16, 2016

✍ Implementing Supply-Chain Program has differing compliance dates based upon when the food establishments' suppliers must comply with the PC Rule.

❖ **What Food Establishments are exempt from the FSMA's PC rule?**

- Food establishments that manufacture products covered by separate regulations including juice, seafood, dietary supplements, alcoholic beverages, or *Low-acid canned foods*.
- Establishments such as grain elevators and warehouses that are solely engaged in storing agricultural commodities (other than fruits and vegetables) intended for further processing.
- Establishments, such as warehouses, that only store packaged foods that are not exposed to the environment and for which refrigeration is not required for safety.
- Establishments that are small or very small on-farm businesses that conduct certain low-risk manufacturing and processing, packing, or holding activities (*e.g., making jams/jellies, honey, maple syrup, candy, soft drinks, etc.*)
- Farms are not covered by the new requirements, unless they trigger the "establishment" definition.

❖ **What Food Establishment is subject to or qualifies for the modified PC requirements?**

*(This may apply to most PDA Limited Food Establishments)*

- ✚ A very small business not meeting the "on-farm" OR the "low-risk activity" criteria.
- ✚ An establishment that has less than \$500,000 in gross annual sales (3 years average) AND the majority of the food is sold directly to a "qualified end-user," then it must maintain certain records and must certify that:
  - a. *It qualifies for modified requirements AND,*
  - b. *It is implementing/monitoring preventive controls*  
*OR, it is complying with applicable State food safety law.*
- ✚ An establishment that is solely engaged in the holding of packaged food not exposed to the environment but requires time/temperature control for safety (TCS food); the firm must:
  - a) *Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin production by, pathogens AND,*
  - b) *Monitor the temperature controls with adequate frequency to provide assurance that the temperature controls are consistently performed AND,*
  - c) *Take appropriate corrective actions to correct any loss of temperature control that may impact the safety of the refrigerated packaged food AND,*
  - d) *Verify that temperature controls are consistently implemented AND,*
  - e) *Establish and maintain records (subject to the requirements of Part 117, subpart F) documenting the above monitoring, corrective actions, and verification activities.*

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❖ **Updated Current Good Manufacturing Practice (cGMP)**

The PC Rule also updates Current Good Manufacturing Practice (cGMP) requirements. Updates include:

- ✓ Clarifications on protections against cross-contact of food by allergens,
- ✓ Deletion of certain nonbinding provisions (language containing recommendations),
- ✓ Some previously nonbinding provisions are now modified to be binding provisions.  
*(An example is education and training, in which management is now required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties. These employees must have the necessary combination of education, training, and/or experience necessary to manufacture, process, pack, or hold clean and safe food. Individuals must receive training in the principles of food hygiene and food safety, including the importance of employee health and hygiene).*

Establishments that are exempt or subject to modified requirements in the new requirements for Hazard Analysis and Risk-Based Preventive Controls (HARPC) would generally be subject to cGMP requirements.

❖ **How does a “preventive controls plan” compare to a HACCP plan?**

The general concepts are very similar. However, these “preventive controls plans” also cover monitoring, records, and corrective actions for items that are considered pre-requisite programs in HACCP, including food allergen controls, sanitation controls, and a recall plan. Preventive controls plans do NOT have a requirement for a Critical Limit as in HACCP plans.

❖ **Assistance to Industry**

The FDA FSMA Technical Assistance Network (TAN) is now operational and providing technical assistance to industry regarding FSMA implementation. Inquiries may be submitted through a web form accessible at [www.fda.gov/fsma](http://www.fda.gov/fsma) select “Contact FDA about FSMA” and then Submit Inquiry.

The FDA is developing several guidance documents on subjects that include:

- *Hazard Analysis & Preventive Controls,*
- *Environmental Monitoring,*
- *Food Allergen Controls,*
- *Validation of Process Controls,*
- *A Small Entity Compliance Guide that explains the actions a small or very small firm must take to comply with the rule.*

The PDA will communicate and work with firms, especially small and very small businesses, to understand and comply with the new PC Rules during their ongoing routine inspections. PDA will communicate available training opportunities as they are available.

**REMEMBER**

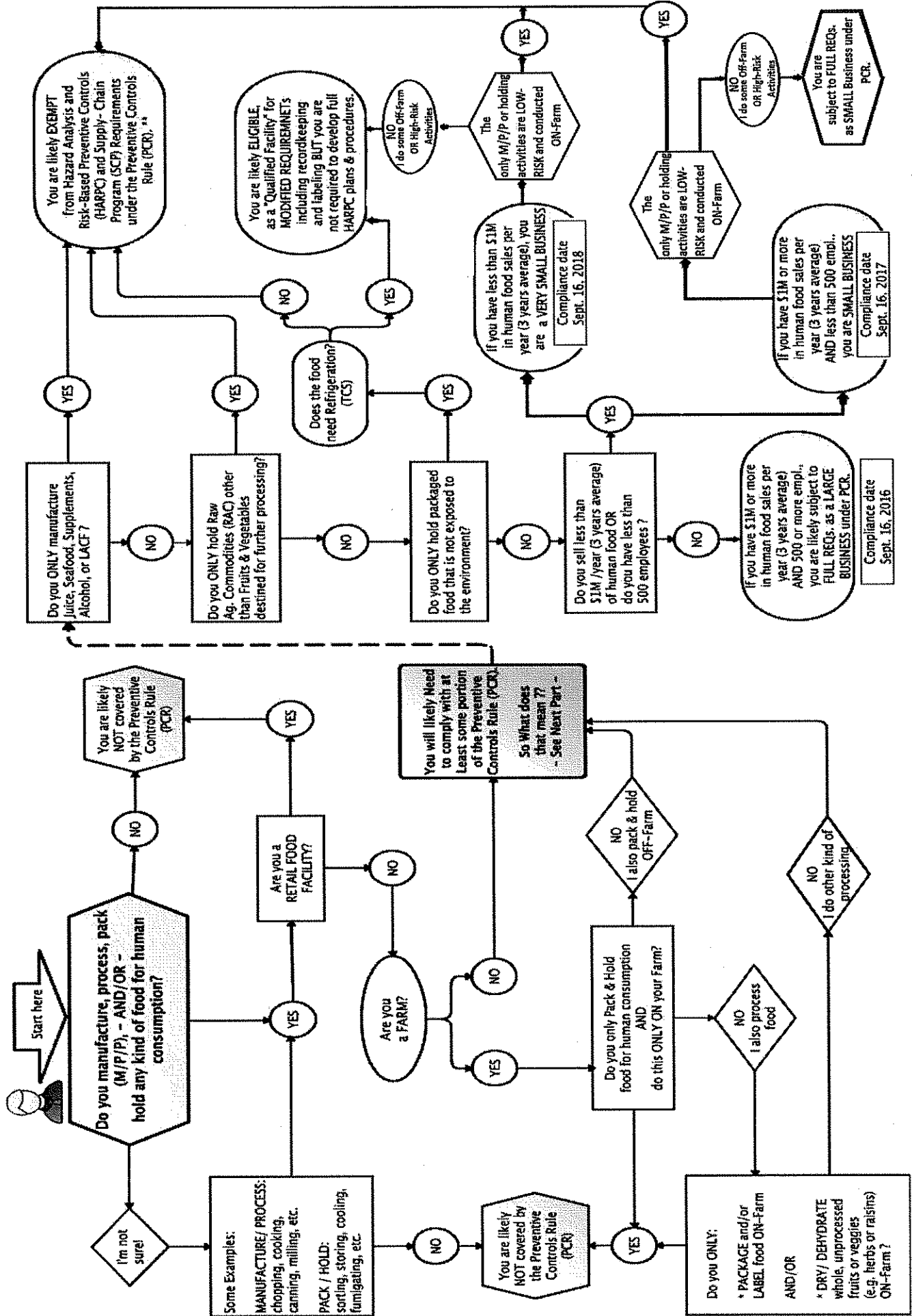
**Regardless of your status under FSMA rules, food safety is everyone’s responsibility  
-- From field to fork --**



See the Flow Chart in the back of this sheet to determine whether you are affected by the FSMA PC Rule.



# AM I AFFECTED BY THE FSMA PREVENTIVE CONTROLS RULE ?



\*\* Establishments exempt from HARPC and SCP Requirements MUST still comply with already-existing rules and practices (cGMPs, Part 120, 123, etc.), but DO NOT need to develop HARPC plans and SCP procedures.