



# *Understanding Agricultural Law*

## Webinar Series

### *Understanding the Basics of*

# **PA Food Establishments & Cottage Food Regulations**

**September 27, 2024**





# ***Understanding Agricultural Law***

**A Legal Educational Series for General Practice Attorneys and Business  
Advisors Representing Agricultural and Rural Clients**

This webinar series is specifically tailored to create subject matter literacy and competence on fundamental issues of agricultural law for attorneys, advisors, and service providers to agricultural producers and agri-businesses.





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- Federal & State Conservation Programs
- Licensing & Regulation of Direct Agricultural Product Sales
- Agricultural Finance
- PA's "Clean & Green" Tax Assessment Program
- Animal Confinement Laws
- Conservation Easements
- Landowner Immunity Statutes
- The Farm Credit System
- Milk Pricing
- Pesticides
- Seed Laws
- Fair Labor Standards Act (FLSA)
- Perishable Agricultural Commodities Act (PACA)
- Food Labeling
- Organic Production
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# ***Understanding Agricultural Law Series***

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Oct. 25, 2024—*Understanding the Basics of* **Right to Repair Laws**

Nov. 22, 2024—*Understanding the Basics of* **Animal Disease Control/Quarantines**

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  - Please fill out form ASAP
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# Understanding the Basics of PA Food Establishments & Cottage Food Regulations





## Presentation Overview

- **Understanding Cottage Food Laws**
  - Definition of cottage food
  - FDA Model Food Code
- **State Cottage Food Laws**
  - A brief survey
- **Food Safety and Regulations**
  - FDA Model Food Code
  - Hazardous (TCS) v. Non-Hazardous Foods
  - TCS v. Non-TCS Foods
- **Pennsylvania Food Safety Laws**
  - The Retail Food Facility Safety Act & the Food Safety Act
  - PA Food Establishments
- **Pennsylvania “*less than a full commercial kitchen*” Regulations**
  - Limited Food Establishment (LFE) registration
  - Allowed homemade food products
  - Testing requirements
  - Labeling and safety standards



# Understanding Cottage Food Laws

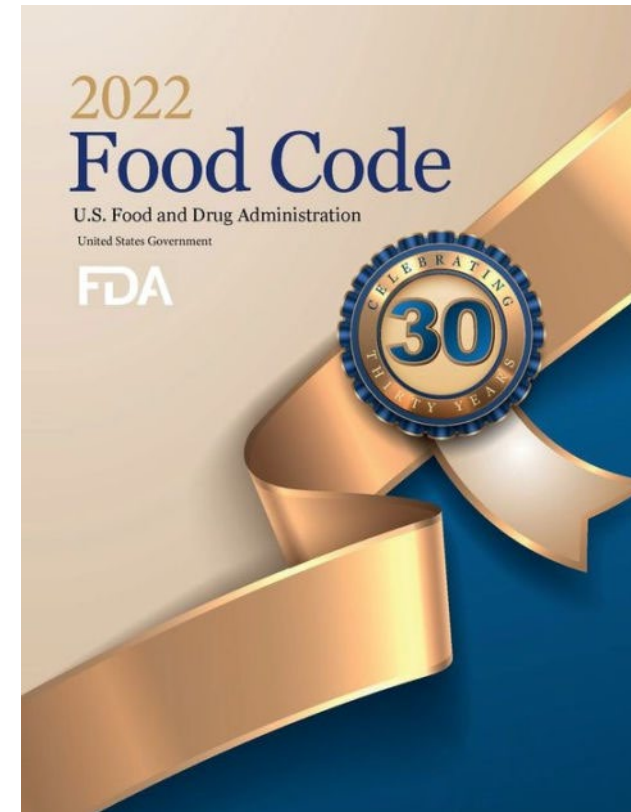
- What is a cottage food?
  - **Food prepared in a private home kitchen and sold directly to consumers**
- Pursuant to the FDA Food Code, Section 3-201.11, "Food prepared in a private home **may not be used or offered for human consumption in a food establishment.**"
- Pursuant to the FDA Food Code, Section 1-201.10(B), "**Food establishment** means an operation that (a) stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides food for human consumption ... (b) relinquishes possession of food to a consumer directly, or indirectly through a delivery service ..."
- **A few exceptions** include (1) stores selling only prepackaged, non-perishable foods; (2) produce stands selling whole, uncut fresh fruits and vegetables; (3) food processing plants; (4) home kitchens preparing non-perishable food for a service or function (e.g., bake sales), small daycare or bed-and-breakfasts; (5) private home receiving catered or home-delivered food.





# Understanding Cottage Food Laws

- Most states adopted the FDA Model Food Code and incorporated it into their own regulations.
  - **Pennsylvania incorporated almost verbatim the FDA Model Food Code**
  - [7 Pa. Code § 46]
- Some states **revised** their own regulations to allow the sale of **non-hazardous foods** made in private homes.





# State Cottage Food Laws—*A brief survey*

- **Delaware** [[16 Del. Admin. Code §§ 4458A. Cottage Food Regulations](#)]
  - **Allowed sales:** Cottage food establishments (CFEs) can sell homemade bakery goods, jams, jellies, and other fruit preserves, and candy products.
  - **Registration/licensing requirements:** Must register annually with the Delaware Division of Public Health (\$30 per CFE); farms processing non-TCS foods must apply for an On-Farm Home Food Processing License.
  - **Sales venue:** Direct sales only; online sales prohibited.
- **Maryland** [COMAR 10.15.03 et seq.]
  - **Allowed sales:** Non-TCS foods
  - **Registration/licensing requirements:** None
  - **Sales venue:** Direct and retail sales allowed
  - **Sales cap:** The sale of cottage food products must not exceed \$50,000.



# State Cottage Food Laws—*A brief survey*

- **New Jersey** [[N.J. Admin. Code § 8:24-11.1 et seq.](#)]
  - **Allowed sales:** Non-TCS foods
  - **Registration/licensing requirements:** Must submit a Cottage Food Operator Permit application (\$100 fee) to the New Jersey Department of Health.
  - **Sales cap:** The gross annual sales of cottage food products cannot exceed \$50,000.
- **New York** [[1 CRR-NY-276.3; 276.4](#)]
  - **Allowed sales:** Non-TCS foods
  - **Registration/licensing requirements:** Exempt from Article 20-C licensing but requires a Home Processor Registration.
  - **Sales venue:** Direct, indirect, and online sales allowed.



# State Cottage Food Laws—*A brief survey*

- **Virginia** [[Va. Code Ann. § 3.2-5130](#)]
  - **Allowed sales:** Non-TCS foods
  - **Registration/licensing requirements:** None
  - **Sales cap:** Honey (up to 250 gallons allowed annually); pickles (sales cannot exceed \$9,000 annually)
  - **Sales venue:** Direct sales only; online sales prohibited.
- **West Virginia** [W. Va. Code § 19-35-2 et seq; W. Va. Code R. § 64-102-2.3]
  - **Allowed sales:** Non-TCS foods, except acidified foods.
  - **Registration/licensing requirements:** None
  - **Sales venue:** Direct, retail and online sales allowed



# State Cottage Food Laws—*A brief survey*

- The National Agricultural Law Center (NALC), [“Cottage Food” Laws](#)
- The National Agricultural Law Center (NALC), [Update on Cottage Food Laws—2024 Proposed Legislation](#) (February 2024)
- Harvard Law School, Food Law and Policy Clinic, [Cottage Foods and Home Cooking: Fifty-State Survey of Laws](#) (Updated as of December 2021)
- Harvard Law School, Food Law and Policy Clinic, [Cottage Food Laws in the United States](#) (August 2018)





# Time/Temperature Control for Safety (TCS) Foods

- Pursuant to the FDA Food Code, Section 1-201.10(B), “**time/temperature control for safety food** (formerly “potentially hazardous food”) means a food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.”
  - TCS foods can pose a **public health risk** if not handled properly.
  - These foods are prone to spoilage and, if not maintained at safe temperatures, can support bacteria growth, leading to **foodborne illnesses**.
- TCS foods have a **pH level above 4.6** and **water activity greater than 0.85**.
- The temperature danger zones are **from 41°F to 135°F (5°C to 57°C)**.



# Key Factors Influencing TCS Foods

- **pH**
  - It is a quantitative measure of the acidity or alkalinity of a solution and measures on a scale from 1 to 14, with 7 being neutral.
  - A pH value less than 7 indicates an acidic solution—the lower the pH, the more acidic the solution.
  - Conversely, a pH value greater than 7 indicates an alkaline (basic) solution—the higher the pH, the more alkaline the solution.
  - And **the lower the pH (below 4.6), the safest the food is!**
- **Water activity (aw)**
  - It is the amount of water available that bacteria can use to grow.
  - **Foods with a low water activity (below 0.85) are less favorable to bacteria growth.**
  - Conversely, foods with a high water activity (above 0.85) promote it.



# Key Factors Influencing TCS Foods

- **Interaction of pH and aw**
  - The combination of acidity and water levels can influence bacterial growth and food safety
  - For example, high pH and high aw create an environment favorable to bacteria growth, but high pH with low aw restrict it.
- **Heat treatment**
  - It uses high temperatures to eliminate harmful bacteria and pathogens in food.
  - This can be achieved through cooking, pasteurization, etc.
  - For example, when hot smoking a fish, its internal temperature must be kept at or above 145°F (62.8°C) throughout the fish for at least 30 minutes.
- **Packaging**
  - Heat treatment followed by packaging provides an added layer of protection.



# TCS v. Non-TCS Foods

## **TCS Foods:**

- Raw or cooked meat, poultry, fish, seafood and eggs
- Dairy products
- Cooked vegetables, grains, legumes, and fruits
- Raw sprouts, cut melons, leafy greens, tomatoes, and garlic-in-oil mixtures

## **Non-TCS Foods:**

- Hard-boiled eggs with intact shells
- Commercially processed, hermetically sealed foods
- Foods with safe pH and water activity (aw) levels
- Products that have gone through product assessments
- Foods that do not support bacterial growth



# How the FDA Determines TCS Status

**Table A. Interaction of pH and  $A_w$  for control of spores in FOOD heat-treated to destroy vegetative cells and subsequently PACKAGED**

$A_w$ VALUES	PH: 4.6 OR LESS	PH: > 4.6 - 5.6	PH: > 5.6
$\leq 0.92$	Non-TCS food*	non-TCS food	non-TCS food
> 0.92 - 0.95	non-TCS food	non-TCS food	PA**
> 0.95	non-TCS food	PA	PA

\* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD

\*\* PA means Product Assessment required





# How the FDA Determines TCS Status

**Table B. Interaction of PH and  $A_w$  for control of vegetative cells and spores in FOOD not heat-treated or heat-treated but not PACKAGED**

$A_w$ VALUES	PH: < 4.2	PH: 4.2 - 4.6	PH: > 4.6 - 5.0	PH: > 5.0
< 0.88	Non-TCS food*	Non-TCS food	non-TCS food	non-TCS food
0.88 – 0.90	Non-TCS food	Non-TCS food	non-TCS food	PA**
> 0.90 – 0.92	Non-TCS food	Non-TCS food	PA	PA
> 0.92	Non-TCS food	PA	PA	PA

\* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD

\*\* PA means Product Assessment required



# How the FDA Determines TCS Status

## **Instructions for using the following Decision Tree and Table A and Table B:**

1. Does the operator want to hold the food without using time or temperature control?
  - a. No – Continue holding the food at  $\leq 5^{\circ}\text{C}$ ( $41^{\circ}\text{F}$ ) or  $\geq 57^{\circ}\text{C}$ ( $135^{\circ}\text{F}$ ) for safety and/or quality.
  - b. Yes – Continue using the decision tree to identify which table to use to determine whether time/temperature control for safety (TCS) is required.
2. Is the food heat-treated?
  - a. No – The food is either raw, partially cooked (not cooked to the temperature specified in section 3-401.11 of the Food Code) or treated with some other method other than heat. Proceed to step #3.
  - b. Yes – If the food is heat-treated to the required temperature for that food as specified under section 3-401.11 of the Food Code, vegetative cells will be destroyed although spores will survive. Proceed to step #4.
3. Is the food treated using some other method?
  - a. No – The food is raw or has only received a partial cook allowing vegetative cells and spores to survive. Proceed to step #6.
  - b. Yes – If a method other than heat is used to destroy pathogens such as irradiation, high pressure processing, pulsed light, ultrasound, inductive heating, or ozonation, the effectiveness of the process needs to be validated by inoculation studies or other means. Proceed to step #5.



# How the FDA Determines TCS Status

4. Is it packaged to prevent re-contamination?
  - a. No – Re-contamination of the product can occur after heat treatment because it is not packaged. Proceed to step #6.
  - b. Yes – If the food is packaged immediately after heat treatment to prevent re-contamination, higher ranges of pH and/or  $a_w$  can be tolerated because spore-forming bacteria are the only microbial hazard. Proceed to step #7.
5. Further product assessment or vendor documentation required.
  - a. The vendor of this product may be able to supply documentation that inoculation studies indicate the food can be safely held without time/temperature control for safety.
  - b. Food prepared or processed using new technologies may be held without time/temperature control provided the effectiveness of the use of such technologies is based on a validated inoculation study.



# How the FDA Determines TCS Status

6. Using the food's known pH and/or  $a_w$  values, position the food in the appropriate table.
  - a. Choose the column under "pH values" that contains the pH value of the food in question.
  - b. Choose the row under " $a_w$  values" that contains the  $a_w$  value of the food in question.
  - c. Note where the row and column intersect to identify whether the food is "non-TCS food" and therefore does not require time/temperature control, or whether further product assessment (PA) is required. Other factors such as redox potential, competitive microorganisms, salt content, or processing methods may allow the product to be held without time/temperature control but an inoculation study is required.
7. Use **Table A** for foods that are heat-treated and packaged **OR** use **Table B** for foods that are not heat-treated or heat-treated but not packaged.
8. Determine if the item is non-TCS or needs further product assessment (PA).

Source: [FDA Food Code 2022, Annex 3. Public Health Reasons/Administrative Guidelines](#)



## Product Assessment (PA)

- A “PA required” food is one where the combined acidity, water activity, and processing status do not clearly show if it needs time and temperature control for safety.
  - The FDA considers “PA required” foods as TCS foods **until proven otherwise**
- How to confirm if a “PA required” food is safe?
  - Inoculation study or some other acceptable evidence.
- The Conference for Food Protection (CFP) offers resources to help conduct inoculation studies and evaluate food safety
  - [Using NACMCF Parameters for Challenge Study Protocols for Retail Food Operators and Regulators](#)
- If a “PA required” food is not TCS, you can request a variance from the regulatory authority.





# Pennsylvania Food Safety Laws

**The Retail Food Facility Safety Act**, as revised by Act 106 of 2010 [3 Pa.C.S. §§ 5701-5714]

- Focuses on **retail facilities and restaurants**

**The Food Safety Act**, as revised by Act 106 of 2010 [3 Pa.C.S. §§ 5721-5737]

- Focuses on **food establishments**

**The Pennsylvania Food Code** [7 Pa. Code § 46]

- Pennsylvania has **incorporated almost verbatim the FDA Model Food Code**



# Retail Food Facility and Restaurant

## *What is a Retail Food Facility?*

### **7 Pa. Code § 46.3. Definitions**

**Retail Food Establishment.** “An establishment which stores, prepares, packages, vends, offers for sale or otherwise provides food for human consumption and which relinquishes possession of a food to a consumer directly, or indirectly, through a delivery service such as home delivery of grocery orders or delivery service provided by common carriers.”

“The term does not include dining cars operated by a railroad company in interstate commerce or a bed and breakfast homestead or inn.”

**Retail Food Facility.** “A public eating or drinking place or a retail food establishment.”



# Retail Food Facility and Restaurant

## 7 Pa. Code § 46.1141(a). License Requirement

**General requirement.** “A person may not operate a retail food facility without a valid license” issued by the PA Department of Agriculture or relevant authority.

- [PA Department of Agriculture; Retail Food Facilities and Restaurants](#)
- [Application Packet – Retail Food Facilities and Restaurants](#)



# Retail Food Facility and Restaurant

## *Retail Food Facility License Exemptions*

### **7 Pa. Code § 46.1141(b). License Requirement**

**Exemptions.** “The following retail food facilities are exempt from licensure requirements under the Retail Food Facility Safety Act but remain subject to the inspection provisions and all other provisions of the Retail Food Facility Safety Act:

- (1) A retail food facility in which only prepackaged, nonpotentially hazardous food or beverages are sold.**
- (2) A retail food facility that sells only raw agricultural commodities.
- (3) A retail food facility that is exempt from licensure by an order of the Secretary that has been published in the Pennsylvania Bulletin in accordance with section 5703(b)(1) of the Retail Food Facility Safety Act (related to license required) if the licensor is the Department.
- (4) A retail food facility that is exempt from licensure by an order of the local government unit or units having licensing authority in accordance with section 5703(b)(1) of the Retail Food Facility Safety Act if the licensor is an entity other than the Department.



# County/Local Health Departments

- There are many county and local health departments within Pennsylvania; you can find a full list of these departments on a [spreadsheet](#) located on the PDA's website.
- You may be in a jurisdiction where there might be specific retail food facility licensing requirements and enforcement procedures. Local authorities may have adopted their own food code or implemented provisions that differ from the FDA Food Code.
  - Counties: Allegheny, Bucks, Chester, Delaware, Erie, Montgomery, Philadelphia.
  - Municipalities: Examples are Reading, State College, Chambersburg, Scranton, Lancaster, Lebanon, Allentown, Bethlehem, Wilkes Barre, Williamsport, Easton, Sunbury, Pottsville, York, and many more.



# Commercial/Limited Food Establishments

## *What is a Food Establishment?*

### **7 Pa. Code § 46.3. Definitions**

**Food Establishments.** “A room, building or place or portion thereof or vehicle maintained, used or operated for the purpose of commercially storing, packaging, making, cooking, mixing, processing, bottling, baking, canning, freezing, packing or otherwise preparing, transporting or handling food.”

“The term excludes retail food facilities, retail food establishments, public eating and drinking places, and those portions of establishments operating exclusively under milk or milk products permits.”

Owners of food establishments must **register** with the PA Department of Agriculture.

- [Commercial Food Establishments Program](#)
  - [Application Packet – Commercial Food Establishment](#)
- [Limited Food Establishments Program](#)
  - [Application Packet – Limited Food Establishment](#)





# Limited Food Establishments

- Pennsylvania allows some “limited” types of food processing to occur in a “residential-style kitchen,” i.e., private home kitchen.
  - These foods must be **non-hazardous**.
- Home processors are **required to register** with the PA Department of Agriculture
- Additionally, home processors must consult with their local municipality to obtain **zoning approval** for operating a food business from their property. They must obtain zoning approval before submitting their registration application.
- They must submit a business plan and water testing and waste disposal information along with their registration application.
- Pennsylvania does not impose any restrictions on the total annual gross sales for limited food establishment operations.
- Direct, indirect, and online sales are allowed.
  - If home processors sell their foods at retail satellite locations (e.g., farmers’ market, fair, etc.) or retail store at the processing site, **a Retail Food Facility License may be required**.



# Allowed Cottage Food Products

**Non-TCS Foods that can be sold in Pennsylvania include, but are not limited to:**

- Baked goods, including breads, cakes, cookies, pies, etc.
- Vinegars
- Dry goods
- Dried herbs
- Dressings, sauces
- Acidified foods
- Butters, spreads
- Dehydrated foods
- Chocolate/fudge
- Honey
- Jams or jelly
- Candy
- Nut mixes
- Beef/meat jerky
- Maple syrup
- Beverage/drink/juice
- Spices/seasonings

Source: [Application Packet – Limited Food Establishment](#)



# Testing Requirements

- **Jams, Jellies and Similar Products**
  - Standard recipes: Home processors must follow approved recipes to avoid testing requirements
    - [The Ball Blue Book – Guide to Preserving](#)
    - [USDA Complete Guide to Home Canning – National Center for Home Food Preservation](#)
    - [Penn State Extension \(Home Food Preservation\)](#)
  - New/modified recipes: testing is required to ensure proper sugar content
    - Jams and jellies must have **at least 65% sugar content** and must follow **specific fruit-to-sugar ratios**
      - Fruit jellies: 45:55
      - Fruits preserves & jams: (i) berries: 47:55; (ii) pome fruits: 45:55
  - Fruit butters and artificially sweetened jellies must follow standardized sugar requirements (see [FDA standards of identity](#))
  - Conserves, marmalades, and spreads do not need sugar testing.



# Testing Requirements

- **Juices and Acidic and Fermented Beverages**
  - Home processors are allowed to sell acidic or fermented drinks (e.g., root beer, lemonade, kombucha, etc.) if their pH is below 4.6
  - Bottled or canned fermented drinks must be pasteurized at 180 °F.
  - See [Guidelines for Brewing-Bottling Kombucha](#)
  - Only juices with a pH of 4.6 or lower can be made in limited food establishments
    - Sales of juice are limited to the production site or satellite locations
  - Freshly brewed coffee and tea are considered TCS Foods and cannot be produced in limited food establishments.



# Testing Requirements

- **Canned acidic, acidified, and fermented foods**
  - **Types:** naturally acidic (fruits, tomatoes); acidified (salsa, chow—chow, pickled vegetables); fermented (kimchi, sauerkraut)
  - **Requirements:** food inspector must approve both the recipe and the process flow diagram; require lab testing to ensure pH is below 4.6 (**with a recommended  $\leq 4.2$** )
  - **pH testing:** laboratory testing is required to ensure the pH is below 4.6 (with a recommended  $\leq 4.2$ ); testing must occur 24 hours after cooling.
  - **Thermal processing:** hot-fill-hold, water bath/steam, or oil-based alternative.
  - See [Guidelines for Canning of Acid, Acidified, Fermented Food & Beverages](#)
- **Chocolate-covered fruits:**
  - Only allowed if the fruit has a **pH of 4.6 or below**
  - The fruit must remain **whole and intact**—no cutting or chopping allowed



# Labeling Requirements

## Key Elements of a Food Label

- **Principal Display Panel (PDP)**
  - Statement of identity
  - Net quantity of contents statement
- **Information Panel**
  - Ingredient list
  - Home processor information
  - Allergen information
  - Nutrient, health claims.
- For bakery items
  - **No labels required for bakery items** sold directly to consumers within the Commonwealth (e.g., farmers' market).
  - Ingredient information must be provided upon customer request.





# Health and Food Safety Standards

- **Pets**
  - Pets are **strictly prohibited** from entering areas where food is prepared or stored
  - Exception: limited food establishment registration may be possible if the kitchen is physically separated (e.g., by a door) and has its **own entrance/exit**.
- **Children**
  - **Children are not allowed** in the kitchen during food preparation.
- **Age Restrictions**
  - No specific age restrictions for workers, but all employees must have a **basic understanding of food safety and hygiene**.
- **Storage**
  - Cooking ingredients must be **stored separately from personal items** and be clearly labeled and protected.
  - Homemade processors must use **food-grade containers**.



***Thank you for joining us!***

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**CENTER MISSION AND BACKGROUND**

Center programs are funded in part by the Commonwealth of Pennsylvania through the Pennsylvania Department of Agriculture. The Center for Agricultural and Shale Law is a partner of the National Agricultural Law Center (NALC) at the University of Arkansas System Division of Agriculture, which serves as the nation's leading source of agricultural and food law research and information.

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