Regulatory Guidance for Best Practices





Cottage Foods April 2012











TABLE OF CONTENTS

	<u>Page</u>
INTRODUCTION	2
DEFINITIONS	2
PREREQUSITE REQUIREMENTS	3
LIMITATIONS	4
INSPECTION	5
COTTAGE FOOD PRODUCTS	6
FOOD LABELING	8
FREQUENTLY ASKED QUESTIONS	9
ACKNOWLEDGEMENTS	19

AFDO Regulatory Guidance for Best Practices Cottage Foods

INTRODUCTION

The popularity of farmers' markets has surged in recent years and, as a result, an increase in the desire of many individuals to establish a cottage food business. Locally-grown and produced food is becoming more prevalent today, but laws that govern these entities are non-uniform. Setting standards that preserve public health while still allowing for economic opportunity has become a difficult task for state and local officials.

This document provides guidance to government food safety regulatory officials for the oversight of cottage food operations and represents a consensus opinion of best practices and limitations on this somewhat controversial matter.

Note that the FDA Food Code; Section 3-201.11[B] states "Food prepared in a private home may not be used or offered for human consumption in a food establishment".

DEFINITIONS

- (1) "Cottage food operation" means a person who produces cottage food products only in the home kitchen of that person's primary domestic residence and only for sale directly to the consumer. A Cottage food operation shall not operate as a food service establishment, retail food store, or wholesale food manufacturer.
- (2) "Cottage food products" means non-potentially hazardous baked goods, jams, jellies, and other non-potentially hazardous foods produced at a cottage food operation.
- (3) "Domestic residence" means a single-family dwelling or an area within a rental unit where a single person or family actually resides. A domestic residence does not include any group or communal residential setting within any type of structure, or outbuilding, shed, barn, or other similar structure.

- (4) "Home kitchen" means a kitchen designed and intended for use by the residents of a home but that is also used by a resident for the production of cottage food products. It may contain one or more stoves or ovens, which may be a double oven, designed for residential use. It shall not include commercial types of equipment typically used for large wholesale manufacturing.
- (5) "Permitted area" means the portion of a domestic residence housing a home kitchen where the preparation, packaging, storage, or handling of cottage food products occurs.
- (6) "Potentially hazardous food (time/temperature control for safety food)" means a FOOD that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation.

PREREQUSITE REQUIREMENTS

- (1) All cottage food operations must be permitted annually by the regulatory authority on forms developed by that authority. The permit will identify a specific listing of the food products allowed to be produced by the cottage food operation.
- (2) Prior to permitting, the regulatory authority will examine the premises of the cottage food operation to determine it to be in substantial compliance with the requirements of this guidance document.
- (3) All cottage food operations permitted under this section must include a signed document attesting, by opting to become permitted, that the permitted cottage food operation expressly grants to the regulatory authority the right to enter the domestic residence housing the cottage food operation during normal business hours, or at other reasonable times, for the purposes of inspection including the collection of food samples.
- (4) A cottage food operation must comply with all applicable county and municipal laws and zoning ordinances that apply to conducting a business from one's home residence prior to permitting as a cottage food operation. Where required, the cottage food operation will provide written verification from a credible recognized source of the adequacy of their onsite wastewater system.

- (5) Any cottage food operation which has a private water supply must have the supply tested prior to permitting and at least annually thereafter and demonstrate through a written record of testing that the water supply is potable. The regulatory authority may require more frequent testing as deemed necessary.
- (6) Prior to permitting, the cottage food operation shall have attended and successfully completed a food safety training program that includes training in food processing and packaging, and that is recognized by the regulatory agency.

LIMITATIONS

- (1) The regulatory agency may set limitations of total annual gross sales for a cottage food operation. If gross sales exceed the maximum annual gross sales amount allowed, the cottage food operation must either obtain a food processing plant license or cease operations. The regulatory authority may request, in writing, documentation to verify the annual gross sales figure.
- (2) Products produced by a cottage food operation must be sold directly to the consumer. Direct sales at farmers markets, craft fairs, and charitable organization functions are permitted. Sales by internet, mail or phone order, or consignment, and sales to grocery stores and restaurants or at wholesale are prohibited. A cottage food operation may not operate as a food service establishment, retail food store, or wholesale food manufacturer.
- (3) A cottage food operation may only produce those specific food products listed on their permit. This permit shall be displayed at farmers markets, craft fairs, and charitable organization functions where cottage foods are sold.

INSPECTION

- (1) The regulatory authority may inspect at any time and whenever the regulatory authority has reason to believe the cottage food operation is in violation of these requirements or is operating in an unsanitary manner.
- (2) The regulatory authority may also inspect the permitted area of a cottage food operation in response to a foodborne illness outbreak, consumer complaint, or other public health emergency.
- (3) When conducting an inspection, the regulatory authority shall, at a minimum, inspect for the following:
 - That the permitted cottage food operation understands that only those specific foods identified on the permit for the cottage food operation may be produced;
 - b. That the permitted cottage food operation understands that no person other than the permittee, or a person under the direct supervision of the permittee, may be engaged in the processing, preparing, packaging, or handling of any cottage food products or be in the home kitchen during the preparation, packaging, or handling of any cottage food products;
 - c. That no preparation, packaging, or handling of cottage food products is occurring in the home kitchen concurrent with any other domestic activities such as family meal preparation, dishwashing, clothes washing or ironing, kitchen cleaning, or guest entertainment;
 - d. That no infants or small children are in the home kitchen during the preparation, packaging, or handling of any cottage food products; pets shall be excluded from the home;
 - e. That only normal, non-commercial types of kitchen equipment and utensils are used to produce cottage food products;
 - f. That all food contact surfaces, equipment, and utensils used for the preparation, packaging, or handling of any cottage food products are washed, rinsed, and sanitized before each use;
 - g. That all food preparation and food and equipment storage areas are maintained free of rodents and insects; and

- h. That all persons involved in the preparation and packaging of cottage food products:
 - (i) Are not going to work in the home kitchen when ill;
 - (ii) Wash their hands before any food preparation and food packaging activities; and
 - (iii) Avoid bare hand contact with ready-to-eat foods through the use of single-service gloves, bakery papers, tongs, or other utensils.

COTTAGE FOOD PRODUCTS

A cottage food operation is allowed to produce food items which do not require temperature control for safety. The following list of foods are examples of products that may be produced by a cottage food operation. Although not all inclusive, it provides for most types of approved cottage food products:

- Loaf breads, rolls, biscuits
- Cakes including celebration cakes (birthday, anniversary, wedding)
- Pastries and cookies
- Candies and confections
- Fruit pies
- Jams, jellies and preserves
- Dried fruits
- Dry herbs, seasonings and mixtures
- Cereals, trail mixes and granola
- Coated or uncoated nuts
- Vinegar and flavored vinegars
- Popcorn, popcorn balls, cotton candy

A cottage food operation is not allowed to produce food items which require temperature control for safety. Other food items which present a food safety risk such as acidified foods, low acid canned foods, garlic in oil, and fresh fruit or vegetable juices are not allowed as well. The following list of foods are examples of products that may not be produced at a cottage food operation. Although not all inclusive, it provides for most types of unapproved cottage food products:

- Fresh or dried meat or meat products including jerky
- Fresh or dried poultry or poultry products
- Canned fruits, vegetables, vegetable butters, salsas etc.
- Fish or shellfish products
- Canned pickled products such as corn relish, pickles, sauerkraut
- Raw seed sprouts
- Bakery goods which require any type of refrigeration such as cream, custard or meringue pies and cakes or pastries with cream cheese icings or fillings
- Tempered and/or molded chocolate or chocolate type products
- Milk and dairy products including hard, soft and cottage cheeses and yogurt
- Cut fresh fruits and/or vegetables
- Food products made from cut fresh fruits or vegetables
- Food products made with cooked vegetable products
- Garlic in oil mixtures
- Juices made from fresh fruits or vegetables
- Ice and/or ice products
- Barbeque sauces, ketchups and/or mustards
- Focaccia-style breads with vegetables and/or cheeses

FOOD LABELING

A cottage food operation may only sell cottage food products which are prepackaged with a label affixed that contains the following information (printed in English):

- The name and address of the cottage food operation;
- The name of the cottage food product;
- The ingredients of the cottage food product, in descending order of predominance by weight;
- The net weight or net volume of the cottage food product;
- Allergen information as specified by federal labeling requirements;
- Nutritional labeling as specified by federal labeling requirements is required if any nutrient content claim, health claim, or other nutritional information is provided; and
- The following statement printed in at least 10-point type in a color that provides a clear contrast to the background label: "Made in a Cottage Food Operation that is not Subject to Routine Government Food Safety Inspection."

A label sample is shown below.

MADE IN A COTTAGE FOOD OPERATION THAT IS NOT SUBJECT TO ROUTINE GOVERNMENT FOOD SAFETY INSPECTIONS

Chocolate Chip Cookies

Ashley Bryant 2550 Kingston Lane York, PA 17702

Ingredients: Enriched flour (Wheat flour, niacin, reduced iron, thiamine, mononitrate, riboflavin and folic acid), butter (milk, salt), chocolate chips (sugar, chocolate liquor, cocoa butter, butterfat (milk), soy lecithin, walnuts, sugar, eggs, salt, artificial vanilla extract, baking soda.

Contains: Wheat, eggs, milk, soy, walnuts

Net Wt. 3 oz.

FREQUENTLY ASKED QUESTIONS

Is there a limit to how much I can sell as a Cottage Food producer?

Some states have limitations in the amount of money a Cottage Food operation may make annually per household and operators that may be needed to maintain sales records and provide them to the regulatory inspector, upon request.

What types of Cottage Foods can I produce in my home?

Specific products are listed in the guidance document.

Will I need to meet local zoning or other laws?

Yes. Cottage Food Operators should contact their local unit of government to determine if there are local regulations that will affect their business. Note that it is possible, even in a state with a Cottage Food Law, for a local city or town government to ban home food production.

Can I utilize commercial type equipment such as large rotary mixers in my cottage food operation?

No. Typically a private home is not equipped with sinks required to effectively wash, rinse, and sanitize large commercial equipment.

Does my equipment, stove and/or refrigerator need to be NSF (a food equipment evaluation group) approved?

No. As a Cottage Food operator, you are not required to meet NSF standards for your equipment used to manufacture Cottage Food products.

Do I need to have a DBA?

A DBA (Doing Business As) may be a requirement of your county or local municipality.

The farmers market where I want to sell my products says I need a food license, even though I am a Cottage Food business. Can the market require a license?

Yes. Even though an entity may meet the requirements of a Cottage Food Operation and be permitted, some farmers markets or other direct marketing venues may require vendors to have a food establishment license or to meet other requirements. Local policies enacted by farmers market boards and other

local governing bodies are generally outside the scope of any Cottage Foods regulations.

Are there any special requirements regarding my home on-site well?

Yes. Only potable water from a properly constructed on-site well or municipal water system can be used. If a well is used, the well water should be tested, at least annually, for coliform bacteria and nitrates.

Water from wells with any of the following features should be avoided:

- Very shallow depth (< 25 ft)
- Producing cloudy water
- Located in below-ground pit
- Buried wellhead
- Missing cap or seal
- Opening around casing pipe
- Located in close proximity to septic system
- Dug well

A list of water testing laboratories may be available from the regulatory agency. Local Health Departments can provide consultation on drinking water quality and well construction.

Are there any concerns related to my home on-site wastewater (septic) system?

Depending on the nature and volume of the food products which will be manufactured for sale, there can be adverse effects to the existing system serving the home. For instance, adding significant bakery wastewater cannot only increase the total volume discharged, but may also result in the increase in the organic strength of the wastewater discharged to the drain field, leading to the possibility of accelerated system failure. The adequacy of the home system to handle additional wastewater loading should be evaluated by the local health department prior to initiating manufacturing. The health department can advise you if modifications to the existing system may be necessary.

Why are some products not allowed to be made and sold under the guidance document?

The Cottage Food guidance document allows food entrepreneurs to operate small food businesses and produce a variety of food products that are low risk from a food safety standpoint, if prepared properly in an unlicensed and uninspected kitchen, while protecting public health to the greatest extent possible. The allowable products list is based on the food safety risk level associated with certain types of food. People who operate a licensed and inspected food processing business have to meet certain requirements for training, food safety and handling. Since Cottage Food businesses are uninspected, it is necessary to limit food products allowed under the law to those that are considered low risk, or non-potentially hazardous.

Are pet treats covered in the guidance document?

No. The Cottage Food guidance document applies to human grade food only.

Can I produce and sell cooked vegetable products, like salsas, tomato sauces, spaghetti sauces, or focaccia bread with roasted vegetables?

No. Food products made with cooked vegetable products do not qualify under the Cottage Food guidance document. Manufacturers of cooked vegetable products like salsas and tomato sauces must meet significant federal and state training and licensing requirements. Cooked vegetables, whether fresh or canned, usually are made from a combination of low acid and acidified foods, and are considered a Potentially Hazardous Food. Cooked vegetables must be held either hot (above 135°F) or cold (below 41°F). They can't be stored at room temperature, which makes them ineligible for production in a cottage food operation.

Can I roast coffee beans in my home kitchen and sell them?

Yes. You can roast and sell whole bean coffee or ground coffee, as long as you meet all of the provisions of the Cottage Food guidance document (labeling, storage, etc.); however, since beverages are not allowed under the Cottage Food guidance document, you may not sell ready-made coffee.

Can I bake bread in a wood-fired oven?

Yes, as long as that oven is in your home kitchen.

Can I make and sell apple butter, pumpkin butter or other fruit butters?

No. Fruit butters have significantly less sugar than a traditional jam or jelly. It is the combination of acid, sugar, pectin and heat that assures the safety of jams/jellies. In fruit butters, the combination of sugar and pectin is not large enough to assure that the butter is safe. Additionally, with lower sugar and pectin levels, spoilage organisms are more likely to survive the cooking process, which would allow for a micro-environment to develop and allow for the growth of Clostridium botulinum.

Can I press and sell apple cider?

No. Apple cider is not a food allowed to be produced. Actually, no beverages are allowed to be produced under the Cottage Food guidance document.

Are honey and maple syrup covered under the guidance document?

No. Honey and maple syrup are not considered cottage foods, because state regulatory requirements and exemptions typically have some significant differences.

Can I make and sell dehydrated meat or poultry?

No. Meat and poultry are a potentially hazardous food and are not allowed under the Cottage Food guidance document exemptions.

I lease space in a retail building where I operate a small antique shop. As a Cottage Food baker, can I sell my own baked goods from my shop?

Yes, as long as they are labeled correctly and completely, and the label includes any allergens the product may contain. However, you can't sell other people's products (e.g., consignment) nor have other people sell your products (e.g., wholesalers).

Can I make and sell hard candies or lollipops?

Yes. Hard candies, lollipops and peppermint candies are allowed under the Cottage Food guidance document, as long as they are labeled correctly and completely, the label includes any allergens the product may contain, and all other provisions of the guidance are complied with.

Can I make and sell sweet breads, muffins or other baked goods made with fresh fruits and vegetables like zucchini, pumpkin, and strawberries?

Yes, as long as the fruits or vegetables are incorporated into the batter and properly baked, labeled and packaged. The baked goods may not be decorated or garnished with fresh fruits or vegetables.

Can I use homegrown fruits and vegetables in baked goods?

Yes. You should take care to thoroughly wash the homegrown produce and the fruits or vegetables must be incorporated into the batter and properly baked, labeled and packaged. The baked goods may not be decorated or garnished with fresh fruits or vegetables.

Can homegrown produce be canned and used for making baked goods, like sweet breads, at a later date?

No, but you can use commercially-canned products for baked goods, like canned pumpkin, cherry pie filling, etc. Most home-canned products are not approved for production under the Cottage Food Law, with the exception of jams and jellies.

Can I freeze homegrown produce and use it for making baked goods, like sweet breads, at a later date?

Yes, as long as the frozen fruits or vegetables are incorporated into the batter and properly baked, labeled and packaged. The baked goods may not be decorated or garnished with fresh or frozen fruits or vegetables.

Can I make and sell dry bread or "instant" bread mixes?

Yes. Dry bread mixes are an acceptable product to produce and sell under the Cottage Food guidance document, as long as you meet all requirements of the law.

Does my chocolate fountain business qualify as a Cottage Food business? I deliver and set up the fountain, and provide chocolate dipping sauce and items to dip (cut up fruit, pretzels, etc.) that I have prepared in my home kitchen.

The type of business you have described is a catering service or food service business and is not eligible to operate under the Cottage Food guidance document. Cottage Food products must be prepackaged and properly labeled prior to sale.

Do I have to put a label on my Cottage Foods?

Yes, you are required to label your Cottage Foods. The basic information that must be on the label is as follows:

- Name and address of the Cottage Food operation.
- Name of the Cottage Food product (All capital letters or upper/lower case are both acceptable).
- The ingredients of the Cottage Food product, in descending order of predominance by weight. If you use a prepared item in your recipe, you must list the sub ingredients as well. For example: soy sauce is not acceptable, soy sauce (wheat, soybeans, salt) would be acceptable. Please see the following label for further examples.
- The net weight or net volume of the Cottage Food product (must also include the metric equivalent; conversion charts are available online).
- Allergen labeling as specified in federal labeling requirements.
- The following statement: "Made in a cottage food operation that is not subject to routine government food safety inspection" (All capital letters or upper/lower case are both acceptable).

Hand-printed labels are acceptable if they are clearly legible, written with durable, permanent ink, and printed large enough to equal the font size requirements listed above.

What does allergen labeling, as specified in federal labeling requirements, mean?

It means you must identify if any of your ingredients are made from one of the following food groups: milk, eggs, wheat, peanuts, soybeans, fish (including shellfish, crab, lobster or shrimp) and tree nuts (such as almonds, pecans or walnuts). So, if you have an ingredient made with a wheat-based product, you have two options:

 Include the allergen in the ingredient list. For example, a white bread with the following ingredient listing: whole wheat flour, water, salt and yeast. In this example, the statement "whole wheat flour", meets the requirements of federal law. 2. Include an allergen statement ("Contains:") after the ingredient list. For example a white bread, with the following ingredients: whole wheat flour, water, sodium caseinate, salt and yeast. Contains wheat and milk.

The "Contains" statement must reflect all the allergens found in the product. In this example, the sodium caseinate comes from milk.

Are there any special requirements for tree nuts labeling for allergens?

Yes. If your Cottage Food has tree nuts as an ingredient, you must identify which tree nut you are using.

For example, if you made Nut Bread, an acceptable ingredient list would be: Ingredients: wheat flour, water, almonds, salt, yeast.

The following would not be acceptable:

Ingredients: flour, water, nuts, salt, yeast.

I am concerned that some of my product ingredients that are not allergens are "trade secrets" and listing all my ingredients would lead to unfair competition. Do I have to list all of my ingredients or can I protect my trade secrets?

According to federal regulations ($Food\ and\ Drug\ Administration\ (FDA)$, $21CFR\ 101.100g(1)(2)$), exceptions to labeling can be made. In particular, if the Commissioner of Food and Drugs finds that alleged secret ingredients are harmless, an exemption may be granted. You should contact the <u>FDA</u> to discuss and propose an exemption from labeling.

Do I have to include my home address on my product labeling or is a post office box sufficient?

You must use the physical address of your home kitchen on your product label, not a post office box. The purpose of including an address on product labels is to be able to locate the business in case of a recall or traceback associated with a foodborne illness complaint or outbreak. The Cottage Food guidance document specifies that the name and address of the business of the Cottage Food Operation must be included on the label.

Am I required to send my products to a laboratory to obtain an official ingredient list, or is it something I can put together on my own?

You are not required to have your product analyzed by a laboratory to obtain an official ingredient list. You must, however, list all ingredients, in descending order of predominance by weight. If you use a prepared item in your recipe, you must list sub-ingredients as well. For example, if you use soy sauce as an ingredient, listing soy sauce is not acceptable; soy sauce (wheat, soybeans, salt) is acceptable. Allergen labeling, as specified in federal labeling requirements, must also be included.

If I make and sell wedding cakes, how can I meet the labeling requirements, when I can't stick a label on the cake?

For wedding cakes, birthday cakes and other specialty cakes that are not easily packaged, you must include all labeling requirements on the invoice and deliver the invoice with the cake. Smaller cakes must be boxed, and the label must be included on the box.

Why can't I sell my Cottage Foods to my favorite restaurant or grocery store?

Because the kitchen is not routinely inspected, the safe food handling practices are not evaluated by any food safety official. Since the safe food handling practices are not being evaluated, the food is not considered an approved source for use in a restaurant or grocery store. Also, it is not possible for the final consumer to discuss your food safety practices with you, since you are not selling or serving the product to the consumer.

Can I make and sell products from my motor home kitchen, or cottage or summer home?

The Cottage Food guidance document applies only to non-potentially hazardous foods made in the kitchen of your primary residence. Second homes, vacation homes or motor homes do not qualify if they are not your primary residence.

Can I make products in a rented kitchen and sell them?

No. The Cottage Food guidance document applies only to non-potentially hazardous foods made in the kitchen of your primary residence. Even if the rented kitchen is a licensed facility, you would need a food establishment license to sell your products.

Can I make Cottage Food products in an outbuilding on my property, like a shed or a barn?

No. The guidance document requires the Cottage Food products be made in your kitchen and stored in your single family domestic residence.

Where can I store ingredients and finished products for my Cottage Food business?

Ingredients and finished Cottage Food products may be stored in your single family domestic residence where the Cottage Food products are made. This includes your kitchen, a spare room or a basement that is free of dampness/water, pests or other insanitary conditions. You may not use a garage, shed, barn or other outbuilding as a storage facility for your Cottage Food business.

Can nonprofit organizations produce and sell Cottage Foods?

No. Nonprofits do not have a single family domestic residence and, therefore, do not qualify as a Cottage Food business.

Can I sell my Cottage Foods over the Internet?

No. While you can advertise your product on the Internet, you cannot take orders over the Internet and then ship directly to consumers. Sales and product delivery must be directly from the producer to the consumer, in a person-to-person transaction, and not delivered by mail.

Can I sell my Cottage Foods to a wholesaler, broker or distributor?

No. Under the Cottage Food guidance document, it is not legal for a producer to sell to a wholesaler, broker or distributor who would then resell the product.

Can I advertise my Cottage Food products on my website?

Yes. You can use your website to advertise your products or market your business, but cannot take orders or sell products via your website.

Can I advertise my Cottage Food business in the newspaper or at trade shows?

Yes. Advertising is allowed; however, the actual sale must be made person-toperson between the producer and the consumer.

Is it possible to place my Cottage Food products in a store or restaurant on consignment?

No. Cottage Food products cannot be sold on consignment. The sale must be person-to-person, from the producer to the actual consumer.

Can I serve free samples of my Cottage Food Products?

Yes. As long as your product meets the requirements of the Cottage Food guidance document and is a non-potentially hazardous food, sampling is allowed. Samples must be pre-packaged in your home kitchen (e.g., if you sample bread, you can't cut it at the market, but can cut it in your home kitchen and individually wrap or package the bread samples into sample cups with lids). Although you do not need an individual label for each sample, you must have properly labeled packages of your product on display with the samples so your customer can review the ingredient list. Your product cannot be cooked or prepared in a way that makes it a potentially hazardous food/temperature control for safety food (e.g., you can't add a dried dip mix to sour cream or serve anything that can't be kept safely at room temperature - these examples would require a food license).

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