DEPARTMENT OF AGRICULTURE

Qualified Facility Guidance

Purpose of This Guidance

The purpose of this guidance document is to help you understand the requirements of a Qualified Facility under the Preventive Controls for Human Foods (PCHF) rule, also known as Title 21 of the Code of Federal Regulations, part 117 (or 21 CFR 117). The PCHF rule is the U.S. Food and Drug Administration's (FDA) primary food safety regulation that applies to food manufacturers and distributors. This document covers:

- How to file an attestation with the FDA.
- Your firm's responsibilities as a Qualified Facility.
- Guidance on how to identify the hazards for your products/processes.

Qualified Facilities are subject to 'modified requirements' (Subpart D of 21 CFR 117) and current good manufacturing practice requirements. Qualified Facilities are exempt from the requirements for hazard analysis and risk based preventive controls (Subpart C) and the requirements for a supply chain control (Subpart G).

The modified requirements provide an exemption from implementing a Food Safety Plan. However, a firm is still required to identify and control all hazards associated with food production and distribution.

Am I a qualified facility?

See Table 1 below for the definitions of Qualified Facility per 21 CFR 117 to help you determine if you are a Qualified Facility.

Table 1: Definitions of Qualified Facility per 21 CFR 117

A facility that is a very small business	**OR**	A facility to which both of the following apply
Part 117 defines "very small business" as a business, including any subsidiaries and affiliates, averaging less than $1,000,000, adjusted for inflation, per year, during the three-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale.		During the three-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; AND The average annual monetary value of all food sold during the three-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

What is attestation?

By attesting, it means you are confirming that your facility is implementing preventive controls to address the hazards associated with your food and that your facility meets the definition of a Qualified Facility. This confirmation is submitted to the FDA on the Qualified Facility Attestation Form for Human Food Facility (or Form FDA 3942a). It is your firm's responsibility to determine your status.

When, where, and how do I attest?

1. The Qualified Facility Attestation Form for Human Food Facility (Form FDA 3942a) should be submitted as soon as possible once you determine you are a Qualified Facility.
2. You are required to re-submit Form FDA 3942a to the FDA every two years during the food facility biennial registration renewal period (even years) beginning on October 1 and ending on December 31.
3. Submit the Form FDA 3942a electronically at the FDA Industry Systems Portal via the Qualified Facility Attestation Module. Facilities must have a valid food facility registration to submit their attestation (the facility registration module is located on the same page as the qualified facility attestation module).
4. When completing Form FDA 3942a, be sure to check the first box in Section 4 – Compliance with 21 CFR 117.201:

> I, as the owner, operator, or agent in charge of the facility have identified the potential hazards associated with the food being produced, am implementing preventive controls to address the hazards, and am monitoring the performance of the preventive controls to ensure that such controls are effective.
>
> Note: Section 4 also contains a second option; but Minnesota adopts the FDA regulations, so our state requirements are the same as FDA's and your facility needs to meet the requirements listed in the first option.

Your Responsibilities as a Qualified Facility

Records maintenance

Part 117 requires that you keep records you rely upon to support the attestations you made on Form FDA 3942a. However, it does not specify the types of records that you must keep.

In addition to the records that you use for your calculations of annual sales, you should also keep supporting records regarding your food safety practices and compliance.

These records to further support your attestation may vary depending on how you comply with 21 CFR 117.201(a)(2). You should keep records documenting the following:

- The identification of potential hazards (biological, chemical, and physical),
- The preventive controls you have in place to control those hazards (examples: cleaning/sanitation, cooking, visual inspection, labeling, employee training), and
- The implementation and monitoring of your preventive controls (examples: batch records, pre-operational inspections, finished product labels, cleaning and sanitation records).

Identifying hazards

Identify and evaluate known or foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility. These hazards are known to be, or have the potential to be, associated with the facility or the food.

Table 2: Hazards to Consider

Type of Hazard	Description of Examples
Biological hazards	Microbiological hazards such as pathogenic bacteria, parasites, including environmental pathogens such as Listeria and Salmonella, and other pathogens.
Chemical hazards	Radiological hazards, pesticides and drug residues, natural toxins (such as mycotoxins), decomposition, unapproved food or color additives, and food allergens.
Physical hazards	Stones, glass, and metal fragments.

Table 3: Factors to Consider

Factors to Consider	Description
Formulation of the food	Certain ingredients such as acids and preservatives inhibit growth of, or even kill, microorganisms of public health significance. Some ingredients may contain allergens.
Condition, function, and design of the facility and equipment	Equipment with close-fitting parts may be difficult to clean and allow pathogens to become established. Equipment with metal-to-metal contact may generate metal fragments.
Sanitation, including employee hygiene	Ready-to-eat foods may be subject to contamination from the environment or from food handlers.
Raw materials and other ingredients	Contaminated ingredients can introduce hazards such as pathogens or toxins.
Transportation practices	Failure to adequately control temperature during transportation could make a food unsafe if the product requires time and temperature controls to ensure safety.
Manufacturing/processing procedures	Improper cooling or holding of certain foods can result in germination of pathogenic spore forming bacteria or production of toxins by certain pathogenic bacteria.
Packaging and labeling activities	Packaging in glass can result in glass fragments in food. Labeling of food allergens is critical for allergic consumers.
Storage and distribution	Some foods require refrigerated storage to maintain safety.
Intended or reasonably foreseeable use	It is reasonably foreseeable that some foods intended to be cooked will be eaten without cooking (e.g., cookie dough, soup mixes used to prepare dips).

Factors to Consider	Description
Environmental pathogens	Environmental pathogens may contaminate a ready-to-eat food exposed to the environment prior to packaging.

It is recommended that you review the FDA Hazards Guide: Hazard Analysis and Risk-Based Preventive Controls for Human Food to help identify the hazards associated with your product and process.

Important reminders

Although Qualified Facilities are exempt from the preventive controls requirements in Subparts C and G of 21 CFR 117, the following requirements in 21 CFR 117 do apply to Qualified Facilities:

1. Subpart A – General Provisions: Consists of definitions, exemptions, applicability, and requirements for qualified individuals
2. Subpart B – Current Good Manufacturing Practices
3. Subpart D – Modified Requirements: Includes the modified requirements that apply to a Qualified Facility and a facility solely engaged in the storage of unexposed packaged food
4. Subpart F – Records Requirements: Includes requirements for employee training records and record retention

Resources

Qualified Facility Attestation Form for Human Food Facility (PDF) (www.fda.gov/media/115813/download)

FDA Industry Systems (www.access.fda.gov)

FDA Hazards Guide: Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry (PDF) (www.fda.gov/media/99581/download)

What You Need to Know About the FDA Regulation: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR Part 117): Guidance for Industry Small Entity Compliance Guide (PDF) (https://www.fda.gov/media/100921/download)

Processors Food Safety Toolkit: A resource collection to help very small and small food processors get started with Preventive Controls for Human Food (PCHF) and Good Manufacturing Practices (GMPs)(www.pchf.necafs.org)

Examples Using the FDA Hazards Guide

The following pages contain an example of how a firm may identify the potential hazards associated with their product/process using the FDA Hazards Guide.

It is the responsibility of a Qualified Facility to identify and control the hazards associated with their products and processes. Persons may find some of the principles and recommendations in this guidance helpful in manufacturing, processing, packing, and holding human food.

Example 1

Biological Hazards Table 1A (FDA Hazards Guide): Information that you should consider for potential ingredient or other food-related biological hazards for Bakery Items.

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*Shigella* spp.	*S. aureus*	*Giardia lamblia*	*Trichinella spiralis*	Example Products
Unbaked Bakery Items - Ready-To-Bake (RTB)	4	Fruit pies/cobblers	Frozen						X	X	X		X			Apple/Cherry/Peach Cobbler; Apple, Cherry/ Mixed Berries/etc. Pies
Unbaked Bakery Items - Ready-To-Bake (RTB)	5	Custard pies	Frozen						X	X	X		X			Pumpkin and Sweet Potato Pies
Fully-Baked Without Filling, No Topping/Frosting	6	Bread, Whole/Pre-sliced	Shelf-Stable, Refrigerated or Frozen						X	X						Breads (e.g., White, Wheat, Rye, Oat Bran, Pumpernickel), Cheese Breads, Raisin Breads; Cornbread, Plain or Flavored Biscuits, Bagels, Rolls, Croissants, Pita Bread, Pumpkin Bread
Fully-Baked Without Filling, No Topping/Frosting	7a	Cakes/Muffins/Brownies/ Doughnut	Shelf-Stable						X	X						Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes
Fully-Baked Without Filling, No Topping/Frosting	7b	Cakes/Muffins/Brownies/ Doughnut	Refrigerated						X	X						Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes

Biological hazard summary and example controls

In the section from Table 1A above, Pathogenic E. coli and Salmonella spp. are the two hazards identified for fully-baked without filling, no topping/frosting category. Baking (heat treating), Supplier Guarantee (if using ingredients that are treated to eliminate the biological hazards) are potential options for mitigating this hazard.

If you are adding a topping such as nuts or dusting with flour after the product has been baked, you will need to evaluate the ingredient for food safety.

Example 2

Chemical Hazards Table 2A (FDA Hazards Guide): Information that you should consider for potential ingredient or other food-related chemical hazards for Bakery Items.

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Unbaked Bakery Items - Ready-To-Bake (RTB)	4	Fruit pies/cobblers	Frozen					X				Apple/Cherry/Peach Cobbler; Apple, Cherry/ Mixed Berries/etc. Pies
Unbaked Bakery Items - Ready-To-Bake (RTB)	5	Custard pies	Frozen					X				Pumpkin and Sweet Potato Pies
Fully-Baked Without Filling, No Topping/Frosting	6	Bread, Whole/Pre-sliced	Shelf-Stable, Refrigerated or Frozen					X				Breads (e.g., White, Wheat, Rye, Oat Bran, Pumpernickel), Cheese Breads, Raisin Breads; Cornbread, Plain or Flavored Biscuits, Bagels, Rolls, Croissants, Pita Bread, Pumpkin Bread
Fully-Baked Without Filling, No Topping/Frosting	7a	Cakes/Muffins/Brownies/ Doughnut	Shelf-Stable					X				Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes
Fully-Baked Without Filling, No Topping/Frosting	7b	Cakes/Muffins/Brownies/ Doughnut	Refrigerated					X				Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes

Chemical hazard summary and examples controls:

Using the excerpt from Table 2A above, Mycotoxins/Natural toxins (aflatoxin, vomitoxin) are the main hazards identified for fully-baked without filling, no topping/frosting category. Working with an approved supplier and contacting them for a letter of guarantee could help mitigate this hazard along with monitoring storage conditions of raw grains.

Mycotoxins are a by-product of fungi and mold. They are chemically stable, can survive processing and are generally a supply chain and/or storage issue.

Example 3

Process Hazards Table 3A (FDA Hazards Guide): Information that you should consider for potential process-related biological, chemical, and physical hazards for Bakery Items.

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	formation due to poor formulation control	formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Fully-Baked Without Filling, No Topping/Frosting	6	Bread, Whole/Pre-sliced	Shelf-Stable, Refrigerated or Frozen	X				X		X	X	X	X		Breads (e.g., White, Wheat, Rye, Oat Bran, Pumpernickel), Cheese Breads, Raisin Breads; Cornbread, Plain or Flavored Biscuits, Bagels, Rolls, Croissants, Pita Bread, Pumpkin Bread
Fully-Baked Without Filling, No Topping/Frosting	7a	Cakes/Muffins/Brownies/ Doughnut	Shelf-Stable	X				X		X	X	X	X		Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes
Fully-Baked Without Filling, No Topping/Frosting	7b	Cakes/Muffins/Brownies/ Doughnut	Refrigerated	X				X		X	X	X	X		Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes
Fully-Baked Without Filling, No Topping/Frosting	7c	Cakes/Muffins/Brownies/ Doughnut	Frozen	X				X		X	X	X	X		Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes

Process hazard summary and control examples:

There are multiple hazards identified for the fully-baked without filling, no topping/frosting category. The following list provides potential hazard mitigation strategies for each.

- Bacterial pathogen survival of a lethal treatment: monitoring of the heat treatment (baking temperature/time), validation study of heat treatment to kill E. coli and salmonella.
- Recontamination with environmental pathogens: employee handling practices (hand washing, illness policy, limiting bare hand contact); sanitation practices (cleaning and sanitizing of food contact surfaces)
- Undeclared allergens - incorrect label: ingredient labeling to include allergens of concern (monitoring of finished product label to verify allergens are declared on the label) and ensuring the correct label is applied to the product.
- Undeclared allergens - cross-contact: sanitation practices (cleaning of equipment between products with unlike allergens); employee practices (handwashing and changing gloves between handling different products).
- Chemical hazards due to mis-formulation (ex. sulfites, yellow #5): ensure employees follow the recipes, use of approved ingredients.
- Metal: monitoring equipment for failures (chipping, flaking, broken metal parts) and/or metal detection.