Ministero della Salute

DIREZIONE GENERALE PER L'IGIENE E LA SICUREZZA DEGLI ALIMENTI E DELLA NUTRIZIONE
Ufficio 2

Regioni e Province Autonome
di Trento e Bolzano
Servizi Veterinari
Loro Sedi

p. c. Associazioni di categoria
Loro Sedi

Oggetto: esportazione di prodotti alimentari verso gli Stati Uniti d'America secondo la normativa FDA- Food Safety Modernization Act: Current Good Manufacturing Practice

Le Autorità Statunitensi di FDA stanno emanando diverse norme sul settore della sicurezza alimentare. Tra queste, appare utile fornire alle imprese che intendono esportare, le linee guida relative alla Current Manufacturing Practice che FDA sta completando per le piccole imprese (meno di 500 dipendenti) e che dovrebbero chiarire alcuni ambiti applicativi della norma che entrerà in vigore a partire dal 18 settembre 2017. In allegato si riporta la bozza di tale documento e di seguito un estratto di alcune parti della stessa. Per gli approfondimenti si prega di voler fare riferimento al testo in inglese allegato alla presente.

E' importante sottolineare che il Food Safety Modernization Act **non si applica** alle aziende che producono carni e prodotti a base di carni, ovoprodotti e pescegatto. Tali alimenti sono disciplinati da un altro ente governativo statunitense appartenente al Dipartimento dell'Agricoltura (USDA-FSIS).

La Current Good Manufacturing Practice, in linea generale, **prevede alcune esenzioni** in quanto alcuni alimenti sono già disciplinati per alcuni aspetti dal Code of Federal Regulation. Si riportano di seguito degli esempi:

ALIMENTI	NORMA
Prodotti della pesca	21 CFR 123
Succhi di frutta	21 CFR 120
Alimenti in scatola a bassa acidità	21 CFR 113
Integratori alimentari	21 CFR 111
Bevande alcoliche	21 CFR 117.5 (j)
Depositi	21 CFR 117.7

Infine, la norma **si applica** sia alle aziende che producono in ambito nazionale (USA) sia a quelle che desiderano esportare i loro prodotti verso detto Paese Terzo.

I regolamenti richiedono che ogni azienda abbia un piano di autocontrollo scritto che deve essere preparato da personale qualificato (PCQI).

Il PCQI può ritenersi qualificato qualora soddisfi almeno **uno** dei seguenti requisiti:

1 ha frequentato un corso di formazione specifico;
2 ha un curriculum ed un esperienza lavorativa nel settore dei controlli dei processi produttivi per alimenti

Di seguito l'estratto della norma:

*"Preventive controls qualified individual means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA **or** is otherwise qualified through job experience to develop and apply a food safety system".*

Tale piano deve includere:

1. Un'analisi dei pericoli

L'azienda deve identificare, valutare tutti i potenziali pericoli che potrebbero ragionevolmente verificarsi per ogni tipo di prodotto fabbricato, confezionato o mantenuto nello stabilimento per determinare se vi sono pericoli che possono essere contenuti da azioni preventive di controllo. I pericoli possono verificarsi naturalmente o intenzionalmente e devono essere identificati se compromettono la sicurezza dell'alimento.

2. Misure preventive di controllo

Sono controlli effettuati che possono minimizzare o prevenire l'insorgenza dei pericoli identificati.

Tali misure possono suddividersi in:

A. Controlli a livello dei punti Critici (CCP)
B. Controlli, che non sono CCP, ma sono necessari per garantire la sicurezza del prodotto

Ovviamente tali controlli dipendono dal processo di lavorazione in atto presso lo stabilimento e dall'alimento stesso e possono suddividersi in:

A. Controlli di processo (monitoraggio di parametri quali Temperatura di cottura e refrigerazione, pH etc...)

B. Controlli della contaminazione crociata per gli allergeni e corretta etichettatura
C. Controlli relativamente alle procedure di sanificazione per minimizzare o prevenire l'insorgenza di pericoli quali i contaminanti ambientali. Le procedure di sanificazione devono essere tali da includere le superfici destinate a venire a contatto con gli alimenti, gli utensili e le attrezzature, prevenire problemi da contaminazioni crociate di allergeni o di materie prime con i prodotti finiti. Tali sanificazioni non sono quelle generali dello stabilimento ma riguardano le procedure utilizzate nello stabilimento per controllare l'insorgenza dei pericoli.
D. Verifiche sui fornitori per accertarsi che i pericoli siano stati precedentemente identificati e controllati.
E. Procedure di tracciabilità e ritiro e richiamo del prodotto dal mercato.

3. Se, appropriato, un sistema di sorveglianza dei fornitori realizzato sulla base dell'analisi del rischio

L'approvvigionamento da fornitori qualificati è necessario nel momento in cui gli stabilimenti produttori hanno identificato, nelle materie prime utilizzate, dei pericoli che possono essere controllati dall'impianto fornitore prima dell'arrivo di detta materia prima presso lo stabilimento.

4. Procedure di rintracciabilità che consentano i ritiro delle merci
5. Procedure di monitoraggio ed implementazione delle misure preventive di controllo

Come previsto anche dalla legislazione Europea, tali procedure devono prevedere almeno:

A. Il controllo del personale, in termini di "stato sanitario" e disposizione degli indumenti di lavoro
B. La verifica delle adeguate strutture e manutenzione degli stabilimenti produttivi e delle are limitrofe
C. La verifica dell'adeguate procedure di sanificazione degli ambienti e delle attrezzature, comprensive delle sostanze utilizzate per la sanificazione e il magazzinaggio di materiale tossico, programmi di derattizzazione e controllo degli infestanti, sanificazioni delle superfici a contatto e non a contatto e stoccaggio delle attrezzature/utensili puliti
D. Il controllo sull'approvvigionamento dell'acqua, dei punti d'acqua/tubazioni presenti nello stabilimento
E. La verifica della gestione dei rifiuti e del materiale di categoria 1,2, e 3
F. La verifica delle attrezzature ed utensili in uso presso le ditte. A tale proposito si ricorda che le attrezzature devono essere costruite e mantenute in modo tale da essere facilmente sanificabili, avere superfici a contatto che siano resistenti alla corrosione, di materiale non tossico. Gli strumenti di misura e di controllo devono essere accurati e adeguatamente mantenuti.
G. La verifica sui processi produttivi deve garantire che tutte le operazioni condotte nel processo di fabbricazione dell'alimento siano adeguate per evitare eventuali contaminazioni. Tutti gli alimenti contaminati devono essere segregati e trattati in modo tale da eliminare la fonte della contaminazione.
H. La verifica delle condizioni di stoccaggio e trasporto in modo tale che gli alimenti vengano protetti da eventuali fonti di contaminazione determinate da allergeni, contaminati biologici, chimici o fisici.

6. Procedure in grado di verificare che i controlli preventivi sono implementati in maniera efficacie per minimizzare o prevenire i pericoli identificati.

Si pregano gli Enti in indirizzo di informare di quanto sopra ed allegato tutti gli operatori interessati.

IL DIRETTORE GENERALE
(Dr. Giuseppe Ruocco)

Allegato1 FDA Regulation: Current Good Manufacturing Practice

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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

Additional copies are available from:
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
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(Tel) 240-402-1700
http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm or
http://www.regulations.gov

You may submit either electronic or written comments regarding this guidance at any time. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the Docket No: FDA-2011-N-0920 listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
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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[1]

Small Entity Compliance Guide

This guidance represents the Food and Drug Administration's (FDA or Agency) current thinking on this topic. It does not establish any rights for any person and does not bind FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance using the contact information on the title page.

I. INTRODUCTION

The FDA Food Safety Modernization Act of 2011 (FSMA) directs the Food and Drug Administration (FDA) as the food regulatory agency of the U.S. Department of Health and Human Services to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety regulation. On September 17, 2015, FDA published the final rule *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food* (PCHF rule) (80 FR 55907).

This final rule became effective on November 16, 2015. It creates new requirements for the production of human food by registered food facilities, and revises previous requirements. Compliance dates are staggered – see "When Do I Have to Comply with the Rule?"

[1] This guidance has been prepared by the Office of Food Safety and the Office of Analytics and Outreach in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

The PCHF rule also revised the definition of 'farm' and expanded it to cover more operations. Operations defined as farms are not subject to the PCHF rule. See Definitions, page 40.

We have prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. Law 104-121). The intent of this guide is to inform domestic and foreign food facilities about the PCHF regulation and enable them to better understand the requirements of the rule. The rule is binding and has the full force and effect of law.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendation, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

Purpose of this Compliance Guide

This guide was developed to inform domestic and foreign food facilities about the PCHF regulation and how to comply with it. It contains important information that may affect your firm.

Key Requirements

1. **Covered facilities must establish and implement a food safety system that includes an analysis of hazards and implementation of risk-based preventive controls. (21 CFR, Part 117, subpart C)**

   The rule requires a written food safety plan for all covered facilities unless an exemption applies. The written plan must be prepared by (or its preparation overseen by) a "preventive controls qualified individual" (see Definitions, page 45) and must include (21 CFR 117.126):

   - A hazard analysis
   - Preventive controls
   - A risk-based supply chain program, if appropriate
   - A recall plan, if there are any hazards associated with the food
   - Procedures for monitoring the implementation of the preventive controls
   - Procedures for verifying that the preventive controls are consistently implemented and are effectively minimizing or preventing the identified hazards

2. **Manufacturing/processing facilities must have a risk-based supply chain program for those raw materials and other ingredients for which a hazard has been controlled before receipt (a supply-chain-applied control) (21 CFR Part 117, subpart G).**

The risk-based supply-chain program is flexible, with separate compliance dates.

3. **Covered facilities must meet updated Current Good Manufacturing Practice (CGMP) requirements (21 CFR, Part 117, subpart B).**

II. WHO MUST COMPLY WITH THE RULE?

The requirements of this rule apply to businesses – either in the U.S. or any other country – that are required to register with FDA as food facilities because they manufacture/process, pack, or hold food for consumption in the U.S.

III. KEY TERMS USED IN PART 117

The PCHF rule uses a substantial number of terms in very specific ways. A full list of these terms appears in this guide on page 39. The terms defined here and below in **Section IV. Who is Exempt from the Requirements for Hazard Analysis and Risk-Based Preventive Controls or Subject to Modified Requirements?** will help you determine if your business is subject to the rule.

Table 1--Key Terms Used in Part 117

Term	Definition
Facility	Any establishment, structure, or structures under one ownership at one general physical location, or a mobile facility traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the U.S.
Manufacturing/Processing	Making food from one or more ingredients, or creating, preparing, treating, modifying or manipulating food, including food crops or ingredients
Packing	Placing food into a container other than a container that directly contacts the food and that the consumer receives, including incidental activities to ensure the safe or effective packing of that food such as sorting, culling, grading, and weighing or conveying.
Holding	Storage of food, including activities ensuring the safe or effective storage of a food such as fumigating food during storage, and drying/dehydrating raw agricultural commodities (when the drying/dehydrating does not create a distinct commodity, e.g., drying/dehydrating hay or alfalfa). Holding also includes activities necessary for the distribution of food such as blending of a raw agricultural commodity or breaking down pallets.

IV. WHO IS EXEMPT FROM THE REQUIREMENTS FOR HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS OR SUBJECT TO MODIFIED REQUIREMENTS?

Table 2--Exemptions and Modified Requirements for Part 117

Exemption or Modified Requirement	Conditions
Qualified Facilities – businesses (when including the sales by any subsidiaries, affiliates, and any entity of which the facility is a subsidiary or affiliate) with average annual sales of less than $500,000 with at least half the sales to consumers or to local retailers or restaurants or Indian reservation (within the same state or within 275 miles) or very small businesses as defined below. *Very small businesses* (including any subsidiaries or affiliates) averaging less than $1,000,000 (adjusted for inflation) -- in both sales of human food *plus* the market value of human food that is manufactured, processed, packed, or held without sale (e.g. held for a fee), per year during the 3-year period preceding the current calendar year. (21 CFR 117.5(a))	To be eligible for modified requirements, a qualified facility is required to notify FDA about its status; and attest that it is either: 1. Addressing identified hazards through preventive controls and monitoring the preventive controls; or 2. Complying with applicable *non-Federal* food safety regulations, and notifying consumers of the name and complete business address of the facility where the food was manufactured or processed. A qualified facility must submit these notifications to FDA during the same two year timeframe that the facility is required to update its facility registration. An otherwise Qualified Facility that does NOT notify FDA is subject to the requirements for Hazard Analysis and Preventive Controls.
Low-risk, on-farm activities performed by small businesses (less than 500 full-time equivalent employees) or very small businesses as defined above. (21 CFR 117.5(g) and (h))	For specific information on which activities are covered, see page 20.
Activities covered by the seafood HACCP requirements of 21 CFR part 123. (21 CFR 117.5(b))	The facility must be in compliance with part 123
Activities that are subject to the juice HACCP requirements of 21 CFR part 120. (21 CFR 117.5(c))	The facility must be in compliance with part 120
Activities that are subject to the "low-acid canned food" requirements of 21 CFR part 113. (21 CFR 117.5(d))	The exemption applies only with respect to microbiological hazards regulated under part 113, *and* the facility must be in compliance with part 113.

Exemption or Modified Requirement	Conditions
Manufacturing, processing, packing, or holding of a dietary supplement covered by the Current Good Manufacturing Practices (CGMP) requirements of 21 CFR part 111. (Note: this exemption does not apply to dietary ingredients) (21 CFR 117.5(e))	The facility must be in compliance with part 111, *and* with requirements for serious adverse event reporting for dietary supplements
Activities of a facility that are subject to Standards for Produce Safety, section 419 of the Federal Food, Drug, & Cosmetic Act. (21 CFR 117.5(f))	See FDA's Produce Safety Rule at (21 CFR part 112) for a description of these activities (https://www.federalregister.gov/articles/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption)
Alcoholic beverages regulated by the Alcohol and Tobacco Tax and Trade Bureau (TTB) of the U.S. Treasury Department. (21 CFR 117.5(i))	Non-alcoholic beverage foods in prepackaged form and that constitute not more than 5 percent of the overall sales of the facility are also exempt.
Facilities that only store raw agricultural commodities -- *other than fruits and vegetables* -- intended for further distribution or processing. (21 CFR 117.5(j))	Storage of raw agricultural commodities that are fruits and vegetables is not exempt.
Facilities that only store packaged food that is not exposed to the environment (21 CFR 117.7)	Modified requirements apply for the storage of packaged food that must be refrigerated for safety.

Note: A facility that manufactures/processes, packs, or holds only a food contact substance or pesticide is NOT required to register with FDA and is NOT required to comply with the Preventive Controls for Human Foods Regulation.

V. WHAT FOODS ARE COVERED BY THIS REGULATION?

Table 3--Foods covered by Part 117

CGMP Requirements (subparts A, B and F)	Hazard Analysis and Risk-based Preventive Controls Requirements (subparts A, C, D, E, F, and G)
Ingredients for dietary supplements and dietary supplements	Ingredients for dietary supplements
Infant formula	Infant formula
Beverages (including alcoholic beverages and bottled water)	Beverages except for alcoholic beverages and juices covered under 21 CFR 120

CGMP Requirements (subparts A, B and F)	Hazard Analysis and Risk-based Preventive Controls Requirements (subparts A, C, D, E, F, and G)
Fruits and vegetables[2]	Fruits and vegetables[3]
Fish and other seafood	Exempt; covered under 21 CFR 123
Dairy products	Dairy products
Baked goods	Baked goods
Snack foods	Snack Foods
Candy	Candy
Acid, acidified, and low-acid canned foods	Acid, acidified, and low-acid canned foods except low-acid canned foods covered under 21 CFR 113 that only have microbiological hazards
Game meat	Game meat

Note: A facility that manufactures/processes, packs, or holds only a food contact substance or pesticide is NOT required to register with FDA and is NOT required to comply with the Preventive Controls for Human Foods Regulation.

VI. WHEN DO I HAVE TO COMPLY WITH THE RULE?

Table 4--Compliance Dates for Part 117

Size and Type of Business	Compliance Date
Qualified facilities (including very small businesses) as defined above	September 17, 2018, except that the compliance date for a facility to retain records to support its status as a qualified facility is January 1, 2016
Small businesses, i.e., a business with fewer than 500 full-time equivalent employees	September 18, 2017

[2] The CGMPs do not apply to farms; activities of "farm mixed-type facilities that fall within the farm definition; establishments solely engaged in the holding and/or transportation of raw agricultural commodities; and establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts (without additional manufacturing/processing, such as roasting nuts). They do apply when a farm or farm mixed-type facility dries/dehydrates raw agricultural commodities that are covered produce to create a distinct commodity (compliance can also be achieved by following applicable requirements for packing and holding in the produce safety standards).

[3] Hazard Analysis and Preventive Control requirements do not apply to farms conducting activities on produce covered by the Produce Safety Rule. Farms conducting activities on produce covered by the Produce Safety Rule will be required to comply with that rule. (https://www.federalregister.gov/articles/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption).

Businesses producing grade ‘‘A’’ milk and milk products under the Pasteurized Milk Ordinance (for those products only)	September 17, 2018
All other businesses	September 19, 2016

Note: Separate compliance dates have been established for the supply-chain program provisions. Refer to the Compliance Dates For The Requirements Of The Supply−Chain Program section on page 16.

VII. HAZARD ANALYSIS

You must identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards (hazards that are known to be, or have the potential to be, associated with the facility or the food) for each type of food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control. These hazards may occur naturally, may happen unintentionally, or may be intentionally introduced for economic gain, and must be identified if they affect the safety of the food. This analysis must be written and included in your food safety plan (21 CFR 117.130).

A. What must Hazard Identification consider?

Table 5--Hazards that must be considered (21 CFR 117.130(b))

Type of Hazard	**Description**
Biological hazards	Microbiological hazards such as parasites, environmental pathogens, and other pathogens
Chemical hazards	Radiological hazards, substances such as pesticide and drug residues, natural toxins (such as mycotoxins), decomposition, unapproved food or color additives, and food allergens
Physical hazards	Stones, glass, and metal fragments

B. What must your Hazard Evaluation include?

The hazard evaluation must include consideration of the severity of the illness or injury caused, if the identified hazards were to occur and the probability that the hazards will occur without preventive controls. The evaluation must consider the effect on the safety of the finished food for the intended consumer (21 CFR 117.130(c)).

Table 6--Factors the Hazard Evaluation Must 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 sporeforming 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).
Environmental pathogens	Environmental pathogens may contaminate a ready-to-eat food exposed to the environment prior to packaging

VIII. PREVENTIVE CONTROLS

Your written plan must specify controls to ensure that identified hazards will be minimized or prevented (21 CFR 117.135). Preventive controls may include controls for processes, food allergens, and sanitation, as well as supply-chain safety, and a recall plan. Included are:

- Controls at critical control points (CCPs), if there are any CCPs; and
- Controls, other than those at CCPs, which are also necessary for food safety.

The types of preventive controls you use will depend on the facility and the food:

1. Process controls are the procedures, practices, and processes to ensure the control of operations such as heat processing, acidifying, irradiating, and refrigerating foods. When applicable to a process control, you must specify the parameter that is monitored (e.g., the temperature, the pH of the food) and the minimum or maximum value that ensures control (e.g., a minimum of 165°F (for a heat treatment), a maximum of 41°F (for refrigerated storage)). (21 CFR 117.135(c)(1))

2. Food allergen controls are the procedures for ensuring protection of food from allergen cross-contact (preventing the unintentional incorporation of an allergen in a food) — including during storage, handling, and use — and correctly labeling the finished food if it contains any of the eight major food allergens (milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, soybeans). (21 CFR 117.135(c)(2))

3. Sanitation controls are the procedures to ensure the facility's sanitation practices are adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards. Sanitation controls must address the cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment, and prevention of allergen cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces; and from raw product to processed product. Note that sanitation controls do not include all sanitation procedures used in the facility, only those that are used to control hazards. (21 CFR 117.135(c)(3))

4. Supply-chain controls are activities taken to verify that suppliers that are controlling hazards are doing so effectively. This will be covered in section IX. Risk-based Supply Chain Safety Program for Manufacturing/Processing Facilities. (21 CFR 117.135(c)(4))

5. A recall plan is necessary for any food with a hazard requiring a preventive control. It must be written and must include steps to take (and who is responsible for taking them) to (21 CFR 117.139):

    - Notify your direct customers,
    - Notify the public, if necessary,
    - Check the effectiveness of the recall, and
    - Dispose of the food appropriately.

A. Oversight And Management Of Preventive Controls

The rule provides flexibility in the steps needed to ensure that preventive controls are effective and to correct problems that may arise. These procedures are designed to provide assurance that preventive controls are consistently performed.

Table 7--Preventive Control Management Components

Function	Explanation
Monitoring (21 CFR 117.145)	You must have written procedures for monitoring each preventive control, including how often these procedures are to be performed.
Corrective actions and corrections (21 CFR 117.150)	Steps taken to identify and correct a problem that occurs during food production. Corrective actions include steps to identify a problem with preventive control functioning, reduce the likelihood the problem will recur, evaluate the affected food for safety, and prevent it from entering commerce. Corrective actions must be documented in records. Corrections that don't include all these steps may be taken in certain situations, such as for minor problems that don't affect the safety of the food.
Verification & Validation (21 CFR 117.155 and 21 CFR 117.160)	These are activities to ensure that preventive controls are consistently applied and effective in controlling the hazards. It's critical to verify that controls are carried out and, where necessary, to validate with scientific evidence that a control measure effectively controls an identified hazard. Verification activities include calibration (or accuracy checks) of process monitoring and verification instruments (such as thermometers) and reviewing records to verify that monitoring is being conducted and appropriate corrective actions are taken (if necessary).
Product testing and environmental monitoring (21 CFR 117.165 (a)(2) and (a)(3))	These are verification activities, but are only required when appropriate to the food, the facility, the nature of the preventive control, and the role of that control in the facility's food safety system. Environmental monitoring generally would be required if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control.
Records (21 CFR 117.126 and 21 CFR 117.190)	Records may be originals, true copies – i.e., reproductions of originals – or electronic Two types of records are required— • Records of your food safety plan itself, i.e., hazard analysis and preventive controls development; recall plan; and monitoring, corrective action and verification procedures • Implementation records, i.e., monitoring data, corrective actions taken, validation documentation, verification activity records, supply-chain program execution, and personnel training

B. When is a Preventive Control Not Required?

You are not required to implement a preventive control for an identified hazard if any of the following circumstances apply (21 CFR 117.136):

(1) You determine and document that the type of food (e.g., raw agricultural commodities such as cocoa beans, coffee beans, and grains) could not be consumed without application of an appropriate control. (For example, cocoa beans must be roasted to make cocoa products, and to achieve the desired characteristics of the beans the roasting process will achieve an adequate time and temperature that controls the hazard of *Salmonella* associated with the raw cocoa beans).

(2) You rely on your customer who is subject to the requirements for hazard analysis and risk-based preventive controls to ensure that the identified hazard will be significantly minimized or prevented and you:

- Disclose in documents accompanying the food, in accordance with trade practice, that the food is "not processed to control [identified hazard]"; and
- Annually obtain from your customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard.

(3) You rely on your customer who is not subject to the requirements for hazard analysis and risk-based preventive controls (e.g., because the customer is a qualified facility subject to modified requirements, a foodservice establishment, or some other business not subject to the requirements) to provide assurance the customer is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements and you:

- Disclose in documents accompanying the food, in accordance with trade practice, that the food is "not processed to control [identified hazard], and
- Annually obtain from your customer written assurance that your customer is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements.

(4) You rely on your customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and you:

- Disclose in documents accompanying the food, in accordance with trade practice, that the food is "not processed to control [identified hazard]"; and

- Annually obtain from your customer written assurance that your customer:
  - Will disclose in documents accompanying the food, in accordance with trade practice, that the food is "not processed to control [identified hazard]"; and
  - Will only sell to another entity that agrees, in writing, that it will:
    - Follow identified procedures that will significantly minimize or prevent the identified hazard – if the entity is covered by hazard analysis and risk-based preventive controls requirements – or, if it is not so covered, it will manufacture, process, or prepare the food in accordance with applicable food safety requirements, or
    - Obtain a similar written assurance from the entity's customer.

(5) You have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food product you distribute and you document the implementation of that system.

IX. RISK-BASED SUPPLY-CHAIN PROGRAM FOR MANUFACTURING/PROCESSING FACILITIES

If a manufacturing/processing facility has identified in its raw materials and ingredients a hazard that requires a control and that control is applied in the supply chain before receipt, the facility must have a supply-chain program (21 CFR 117.405). Manufacturing/processing facilities that control all identified hazards with their own preventive controls, or who follow requirements applicable when relying on a commercial customer to control hazards, do not need to have a supply-chain program for such foods.

Food facilities covered by the regulation are responsible for ensuring that raw materials and other ingredients for their products are received only from approved suppliers, or — if received on a temporary basis from unapproved suppliers — ensuring those materials are subject to verification activities before being accepted for use.

A. Requirements

The supply-chain program must be written (21 CFR 117.405(b)) and must include:

- Using approved suppliers (21 CFR 117.410(a)(2), 117.415(a)(1), and 117.420);
- Determining appropriate supplier verification activities (including determining the frequency of conducting the activity) (21 CFR 117.410(a)(2) and 117.425);
- Conducting supplier verification activities (21 CFR 117.410(a)(3), 117.430 and 117.435);

- Documenting supplier verification activities (21 CFR 117.410(a)(4) and 117.475); and
- When applicable, verifying a supply-chain-applied control applied by an entity other than the receiving facility's supplier and documenting that verification, or obtaining documentation of an appropriate verification activity from another entity, reviewing and assessing that documentation, and documenting the review and assessment (21 CFR 117.410(a)(5) and 117.475).

When a supply-chain-applied control is applied by an entity other than the receiving facility's supplier (e.g., when a non-supplier applies controls to certain produce, because growing, harvesting, and packing activities are under different management), the receiving facility must (21 CFR 117.405(c)):

- Verify the supply-chain-applied control; or
- Obtain documentation of an appropriate verification activity from another entity, review and assess the entity's applicable documentation, and document that review and assessment.

Other entities in the supply chain, such as a broker or distributor, can conduct supplier verification activities, but the receiving facility (the manufacturer/processor) must review and assess the entity’s documentation verifying control of the hazard and document this review (21 CFR 117.415(a)).

Supplier verification activities may be (21 CFR 117.410(b):

- onsite audits;
- sampling and testing of raw materials and other ingredients;
- review of the supplier’s relevant food safety records; and
- other appropriate supplier verification activities.

Approving suppliers and determining the appropriate supplier verification activities (and their frequency) are based on the risk associated with the raw material or other ingredient and supplier performance (21 CFR 117.410(d)).

B. Compliance Dates For The Requirements Of The Supply−Chain Program

Separate compliance dates have been established for the supply-chain program provisions so that a food facility will not be required to comply with the supply-chain program provisions before its supplier is required to comply with the PCHF rule or the produce safety rule (if applicable).

Table 8--Compliance dates for the Requirements of the Supply-Chain Program (Subpart G)

Type of Facility	Compliance Date
Receiving facility is a small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule	September 18, 2017
Receiving facility is a small business and its supplier will be subject to the human preventive controls rule or the produce safety rule	September 18, 2017 or 6 months after the supplier is required to comply with the applicable rule, whichever is later
Receiving facility is not a small or very small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule	March 17, 2017
Receiving facility is not a small or very small business and its supplier will be subject to the human preventive controls rule or the produce safety rule	6 months after the supplier is required to comply with the applicable rule

X. EDUCATION AND TRAINING

Companies subject to this rule must ensure that their food safety system is developed and applied by an individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system (21 CFR 117.4).

In addition, each individual (including temporary and seasonal personnel) engaged in (or supervising) manufacturing, processing, packing, or holding food covered by this rule must (21 CFR 117.4(b)):

- Be a qualified individual, i.e., have the education, training, or experience (or a combination of these) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties; and
- Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility, and the individual's assigned duties.

Additional qualifications for supervisory personnel: Responsibility for ensuring compliance by individuals with the requirements of this rule must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination of these) necessary to *supervise* subordinates in the production of clean and safe food (21 CFR 117.4(c)).

Records documenting the required training in the principles of food hygiene and food safety must be established and maintained (21 CFR 117.4(d)).

XI. INFORMATION FOR QUALIFIED FACILITIES

A. How Can I Tell If My Business is a Qualified Facility?

To be a qualified facility (see definitions in 21 CFR 117.3), a business must either be:

- A very small business (a business, including any subsidiaries and affiliates, averaging less than **$1,000,000**, adjusted for inflation, per year, during the 3-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 (e.g., held for a fee); or

- A facility (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) to which both of the following apply:

    - During the 3-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 (consumers, or local restaurants and retail food establishments not more than 275 miles from the facility) 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 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

In determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011 (21 CFR 117.201(a)(1)).

B. How Do I Tell FDA That My Business Is A Qualified Facility?

- The information can be submitted to FDA in one of two ways (21 CFR 117.201(b)):

    - Electronically — Go to http://www.fda.gov/furls and follow the instructions. FDA encourages electronic submission.

    - Mail — You must use Form FDA 3942a (21 CFR 117.201(b)(2)). Send the completed paper Form FDA 3942a to the U.S. Food and Drug Administration (HFS-681), 5001 Campus Drive, College Park, MD 20740. We recommend that you submit a paper copy only if your facility does not have reasonable access to the Internet. To obtain a copy of this form:

- Download it from http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/QualifiedFacilityAttestation/default.htm, or
- Write to the U.S. Food and Drug Administration (HFS-681), 5001 Campus Drive, College Park, MD 20740, or
- Request a copy by phone at 1-800-216-7331 or 301-575-0156

C. What Other Information Must A Qualified Facility Provide FDA?

- You must attest that you either:
  - Have identified potential hazards associated with the food being produced, are implementing preventive controls to address the hazards, and are monitoring the performance of the preventive controls to ensure that such controls are effective (21 CFR 117.201(a)(2)(i)); or
  - Are in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulation of foreign countries. This attestation may be based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight (21 CFR 117.201(a)(2)(ii)).

D. When Must I Tell FDA That My Business Is A Qualified Facility?

The attestation verifying that your business is a qualified facility must be submitted to FDA initially (21 CFR 117.201(c)(2)(i))—

- By December 17, 2018, for a facility that begins manufacturing, processing, packing, or holding food before September 17, 2018, or
- Before beginning operations, for a facility that begins manufacturing, processing, packing, or holding food after September 17, 2018.

Beginning in 2020, your attestation must be submitted to FDA every 2 years during the period beginning on October 1 and ending on December 31 (21 CFR 117.201(c)(2)(ii)).

The determination whether a facility satisfies the definition of qualified facility must be made annually no later than July 1 of each calendar year (21 CFR 117.201(c)(1)). When the status of a facility changes from "qualified facility" to "not a qualified facility" based on the annual determination:

- The facility must notify FDA of that change in status using Form FDA 3942a by July 31 of the applicable calendar year (21 CFR 117.201(c)(3)), and

- The facility must comply with the requirements for hazard analysis and preventive controls no later than December 31 of the applicable year, unless otherwise agreed to by FDA and the facility (21 CFR 117.201(d)).

E. Withdrawal of a Qualified Facility Exemption

FDA may withdraw a qualified facility exemption —

- In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility (21 CFR 117.251(a)(1)); or
- If FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility (21 CFR 117.251(a)(2)).

Before FDA issues an order to withdraw a qualified facility exemption, FDA —

- May consider one or more other actions to protect the public health or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, suspension of registration, refusal of food offered for import, seizure, and injunction (21 CFR 117.251(b)(1));
- Must notify the owner, operator, or agent in charge of the facility, in writing, of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the facility to respond in writing, within 15 calendar days of the date of receipt of the notification, to FDA's notification (21 CFR 117.251(b)(2)); and
- Must consider the actions taken by the facility to address the circumstances that may lead FDA to withdraw the exemption (21 CFR 117.251(b)(3)).

XII. WHAT ON-FARM LOW-RISK ACTIVITIES BY SMALL OR VERY SMALL BUSINESSES ARE EXEMPT FROM HAZARD ANALYSIS AND PREVENTIVE CONTROLS?

Certain manufacturing, processing, packing and holding activities are not subject to the requirements for hazard analysis and risk-based preventive controls when they are **conducted on-farm by small or very small businesses, <u>if</u>** these are the **only activities they conduct that would be subject to the requirements for hazard analysis and risk-based preventive controls.** The exemption only applies to the low-risk activity/food combinations listed in the regulation. In addition, the modified requirements for a very small business also would <u>*not*</u> apply to very small on-farm businesses conducting these low-risk, on-farm manufacturing, processing,

packing and holding activities. The terms that apply with respect to the foods associated with the activity/food combinations are listed below, followed by the exemptions for on-farm packing and holding of food and the exemptions for on-farm manufacturing/processing of food. Some foods that are considered fruits and vegetables (i.e., coffee bean, cocoa beans, fresh herbs, peanuts, sugar cane, sugar beets, tree nuts, seeds for direct consumption) were considered separately.

Table 9--Activity/Food Combinations (21 CFR 117.5(g)(2))

Activity/Food Combination Term	**Description and/or Examples**
Dried/dehydrated fruit and vegetable products	Includes only products such as raisins and dried legumes made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling.
Other fruit and vegetable products	Includes those products that have undergone one or more of the following processes: acidification, boiling, canning, coating with things other than wax/oil/resin, cooking, cutting, chopping, grinding, peeling, shredding, slicing, or trimming. Examples include flours made from legumes (such as chickpea flour), pickles, and snack chips made from potatoes or plantains. Examples also include dried fruit and vegetable products made with additional manufacturing/processing (such as dried apple slices; pitted, dried plums, cherries, and apricots; and sulfited raisins). This category **does not include** dried/dehydrated fruit and vegetable products made without additional manufacturing/processing such as raisins and dried legumes. This category also **does not include** products that require time/temperature control for safety, such as fresh-cut fruits and vegetables.
Peanut and tree nut products	Includes such products as roasted peanuts and tree nuts, seasoned peanuts and tree nuts, and peanut and tree nut flours.
Processed seeds for direct consumption	Include such products as roasted pumpkin seeds, roasted sunflower seeds, and roasted flax seeds.
Dried/dehydrated herb and spice products	Includes only processed food products as dried intact herbs made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling.

Activity/Food Combination Term	Description and/or Examples
Other herb and spice products	Includes those processed food products such as chopped fresh herbs, chipped or ground dried herbs (including tea), herbal extracts (e.g., essential oils, extracts containing more than 20 percent ethanol, extracts containing more than 35 percent glycerin), dried herb- or spice infused honey, and dried herb- or spice-infused oils and/or vinegars. This category **does not include** dried/dehydrated herb and spice products made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling. This category also **does not include** products that require time/temperature control for safety, such as fresh herb-infused oils.
Grains	Includes barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat and oilseeds for oil extraction, such as cotton seed, flax seed, rapeseed, soybeans, and sunflower seed.
Milled grain products	Includes such products as flour, bran, and corn meal.
Baked goods	Includes such products as breads, brownies, cakes, cookies, and crackers. This category **does not include** products that require time/temperature control for safety, such as cream-filled pastries.
Other grain products	Include such products as dried cereal, dried pasta, oat flakes, and popcorn.

A. On-Farm Packing Or Holding Of Food

1. What Packing or Holding Activities On a Farm Mixed–Type Facility are Within the Definition Of "Farm" and not Subject to the Requirements for Hazard Analysis and Preventive Controls?

There are packing and holding activities that are within the "farm" definition and so are not subject to the requirements for hazard analysis and preventive controls when performed on a farm or a farm mixed–type facility (see "Farm" and "Mixed-Type Facility" in Definitions, Pages 40 and 43) and therefore do not need to be specified in the exemption. Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins, and drying/dehydrating fresh herbs to produce dried herbs) and packaging and

labeling such commodities, without additional manufacturing/processing (such as chopping and slicing) are within the "farm" definition. (See 21 CFR 117.5(g)(1).)

2. What Low-Risk Packing or Holding Activity/Food Combinations are Exempt from Hazard Analysis and Preventive Controls if Performed On a Farm By a Small or Very Small Business and Are the Only Activities That Would Be Subject To the Requirements or Hazard Analysis and Preventive Controls?

The requirements for hazard analysis and risk-based preventive controls do not apply to on-farm packing or holding of food by a small or very small business if the packing and holding activities are limited to packing (or re-packing) (including weighing or conveying incidental to packing or re-packing); sorting, culling, or grading incidental to packing or storing; and storing (ambient, cold and controlled atmosphere) of these foods (21 CFR 117.5(g)(3)):

- ***Baked goods*** — e.g., bread and cookies
- ***Candy*** — e.g., hard candy, fudge, maple candy, maple cream, nut brittles, taffy, and toffee
- ***Roasted cocoa beans and cocoa products***
- ***Roasted coffee beans***
- ***Game meat jerky***
- ***Gums, latexes, and resins*** that are processed foods
- ***Pasteurized honey***
- ***Jams, jellies, and preserves***
- ***Milled grain products*** — e.g., flour, bran, and corn meal
- ***Molasses and treacle***
- ***Oils*** — e.g., olive oil and sunflower seed oil
- ***Other fruit and vegetable products*** — e.g., flours made from legumes; pitted, dried fruits; sliced, dried apples; snack chips
- ***Other grain products*** — e.g., dried pasta, oat flakes, and popcorn
- ***Other herb and spice products*** — e.g., chopped or ground dried herbs, herbal extracts
- ***Peanut and tree nut products*** — e.g., roasted peanuts and tree nut flours
- ***Processed seeds for direct consumption*** — e.g., roasted pumpkin seeds

- ***Soft drinks and carbonated water***
- ***Sugar***
- ***Syrups*** — e.g., maple and agave syrups
- ***Trail mix and granola***
- ***Vinegar***
- ***Any other processed food that does not require time/temperature control for safety*** — e.g., vitamins, minerals, and dietary ingredients, such as bone meal, in powdered, granular, or other solid form.

B. On-Farm Manufacturing/Processing Of Food

1. What Food Manufacturing/Processing Activities on a Farm Mixed–Type Facility Are Within the Definition Of "Farm" And are not subject to the requirements for Hazard Analysis and Preventive Controls?

There are manufacturing/processing activities that are within the "farm" definition and so are not subject to the requirements for hazard analysis and preventive controls when performed on a farm or a farm mixed–type facility (see "Farm" and "Mixed-Type Facility" in Definitions, Pages 40 and 43) and therefore do not need to be specified in the exemption.

These include (21 CFR 117.5(h)(1)):

- Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins, and drying/dehydrating fresh herbs to produce dried herbs) and packaging and labeling such commodities, without additional manufacturing/processing (such as chopping and slicing)
- Treatment to manipulate ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling the treated raw agricultural commodities, without additional manufacturing/processing
- Packaging and labeling raw agricultural commodities without additional manufacturing/processing.

2. What Low-Risk Food Manufacturing/Processing Activities Are Exempt From Hazard Analysis And Preventive Controls If Performed On A Farm By A Small Or Very Small Business And Are The Only Activities That Would Be Subject To The Requirements For Hazard Analysis And Preventive Controls?

The requirements for hazard analysis and risk-based preventive controls do not apply to on-farm manufacturing/processing of food by a small or very small business if the

manufacturing/processing activities are limited to the following low-risk manufacturing/processing activity/food combinations (21 CFR 117.5(h)(3)):

- Boiling gums, latexes, and resins
- Chopping, coring, cutting, peeling, pitting, shredding, and slicing acid fruits and vegetables that have a pH less than 4.2 (e.g., cutting lemons and limes), baked goods (e.g., slicing bread), dried/dehydrated fruit and vegetable products (e.g., pitting dried plums), dried herbs and other spices (e.g., chopping intact, dried basil), game meat jerky, gums/latexes/resins, other grain products (e.g., shredding dried cereal), peanuts and tree nuts, and peanut and tree nut products (e.g., chopping roasted peanuts)
- Coating dried/dehydrated fruit and vegetable products (e.g., coating raisins with chocolate), other fruit and vegetable products except for non-dried, non-intact fruits and vegetables (e.g., coating dried plum pieces, dried pitted cherries, and dried pitted apricots with chocolate are low-risk activity/food combinations but coating apples on a stick with caramel is not a low-risk activity/food combination), other grain products (e.g., adding caramel to popcorn or adding seasonings to popcorn provided that the seasonings have been treated to significantly minimize pathogens, peanuts and tree nuts (e.g., adding seasonings provided that the seasonings have been treated to significantly minimize pathogens), and peanut and tree nut products (e.g., adding seasonings provided that the seasonings have been treated to significantly minimize pathogens)
- Drying/dehydrating (that includes additional manufacturing or is performed on processed foods) other fruit and vegetable products with pH less than 4.2 (e.g., drying cut fruit and vegetables with pH less than 4.2), and other herb and spice products (e.g., drying chopped fresh herbs, including tea)
- Extracting (including by pressing, by distilling, and by solvent extraction) from dried/dehydrated herb and spice products (e.g., dried mint), fresh herbs (e.g., fresh mint), fruits and vegetables (e.g., olives, avocados), grains (e.g., oilseeds), and other herb and spice products (e.g., chopped fresh mint, chopped dried mint)
- Freezing acid fruits and vegetables with pH less than 4.2 and other fruit and vegetable products with pH less than 4.2 (e.g., cut fruits and vegetables)
- Grinding/cracking/crushing/milling baked goods (e.g., crackers), cocoa beans (roasted), coffee beans (roasted), dried/dehydrated fruit and vegetable products (e.g., raisins and dried legumes), dried/dehydrated herb and spice products (e.g., intact dried basil), grains (e.g., oats, rice, rye, wheat), other fruit and vegetable products (e.g., dried, pitted dates), other grain products (e.g., dried cereal), other herb and spice products (e.g., chopped dried herbs), peanuts and tree nuts, and peanut and tree nut products (e.g., roasted peanuts)

- Labeling baked goods that do not contain food allergens, candy that does not contain food allergens, cocoa beans (roasted), cocoa products that do not contain food allergens), coffee beans (roasted), game meat jerky, gums/latexes/resins that are processed foods, honey (pasteurized), jams/jellies/preserves, milled grain products that do not contain food allergens (e.g., corn meal) or that are single-ingredient foods (e.g., wheat flour, wheat bran), molasses and treacle, oils, other fruit and vegetable products that do not contain food allergens (e.g., snack chips made from potatoes or plantains), other grain products that do not contain food allergens (e.g., popcorn), other herb and spice products (e.g., chopped or ground dried herbs), peanut or tree nut products, (provided that they are single-ingredient, or are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration, or both (e.g., roasted or seasoned whole nuts, single-ingredient peanut or tree nut flours)), processed seeds for direct consumption, soft drinks and carbonated water, sugar, syrups, trail mix and granola (other than those containing milk chocolate and provided that peanuts and/or tree nuts are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration), vinegar, and any other processed food that does not require time/temperature control for safety and that does not contain food allergens (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form)
- Making baked goods from milled grain products (e.g., breads and cookies)
- Making candy from peanuts and tree nuts (e.g., nut brittles), sugar/syrups (e.g., taffy, toffee), and saps (e.g., maple candy, maple cream)
- Making cocoa products from roasted cocoa beans
- Making dried pasta from grain
- Making jams, jellies, and preserves from acid fruits and vegetables with a pH of 4.6 or below
- Making molasses and treacle from sugar beets and sugarcane
- Making oat flakes from grain
- Making popcorn from grains
- Making snack chips from fruits and vegetables (e.g., making plantain and potato chips)
- Making soft drinks and carbonated water from sugar, syrups, and water

- Making sugars and syrups from fruits and vegetables (e.g., dates), grains (e.g., rice, sorghum), other grain products (e.g., malted grains such as barley), saps (e.g., agave, birch, maple, palm), sugar beets, and sugarcane

- Making trail mix and granola from cocoa products (e.g., chocolate), dried/dehydrated fruit and vegetable products (e.g., raisins), other fruit and vegetable products (e.g., chopped dried fruits), other grain products (e.g., oat flakes), peanut and tree nut products, and processed seeds for direct consumption, provided that peanuts, tree nuts, and processed seeds are treated to significantly minimize pathogens

- Making vinegar from fruits and vegetables, other fruit and vegetable products (e.g., fruit wines, apple cider), and other grain products (e.g., malt)

- Mixing baked goods (e.g., types of cookies), candy (e.g., varieties of taffy), cocoa beans (roasted), coffee beans (roasted), dried/dehydrated fruit and vegetable products (e.g., dried blueberries, dried currants, and raisins), dried/dehydrated herb and spice products (e.g., dried, intact basil and dried, intact oregano), honey (pasteurized), milled grain products (e.g., flour, bran, and corn meal), other fruit and vegetable products (e.g., dried, sliced apples and dried, sliced peaches), other grain products (e.g., different types of dried pasta), other herb and spice products (e.g., chopped or ground dried herbs, dried herb- or spice-infused honey, and dried herb- or spice-infused oils and/or vinegars), peanut and tree nut products, sugar, syrups, vinegar, and any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form)

- Packaging baked goods (e.g., bread and cookies), candy, cocoa beans (roasted), cocoa products, coffee beans (roasted), game meat jerky, gums/latexes/resins that are processed foods, honey (pasteurized), jams/jellies/preserves, milled grain products (e.g., flour, bran, corn meal), molasses and treacle, oils, other fruit and vegetable products (e.g., pitted, dried fruits; sliced, dried apples; snack chips), other grain products (e.g., popcorn), other herb and spice products (e.g., chopped or ground dried herbs), peanut and tree nut products, processed seeds for direct consumption, soft drinks and carbonated water, sugar, syrups, trail mix and granola, vinegar, and any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form)

XIII. UPDATED AND CLARIFIED CURRENT GOOD MANUFACTURING PRACTICE (CGMP)

A. Personnel (21 CFR 117.10)

The management of the establishment must take reasonable measures and precautions to ensure:

- ***Disease control*** − Any person who has or appears to have any abnormal **source of microbial contamination** (e.g., illness, open lesions, including boils, sores, or infected wounds) that reasonably could contaminate food, food-contact surfaces, or food-packaging materials must be excluded from any operations which could result in such contamination until the condition is corrected (unless conditions such as open lesions, boils and infected wounds are adequately covered).

  Personnel must be instructed to report such health conditions to their supervisors.

- ***Cleanliness*** − All persons **working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices** while on duty as necessary to protect against allergen cross-contact and against contamination of food. Methods for cleanliness include:

  (1) **Wearing suitable outer garments**, in a manner that protects against allergen cross-contact and against the contamination of food, food-contact surfaces, or food-packaging materials.

  (2) Maintaining **adequate personal cleanliness**.

  (3) **Washing hands thoroughly** (and sanitizing when necessary to protect against undesirable microorganisms) in an adequate hand-washing facility before starting work, after any absence from the work station, and at any other time when the hands may have become soiled or contaminated.

  (4) **Removing unsecured jewelry** or other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized if food is manipulated by hand. If hand jewelry cannot be removed, it may be covered by material which effectively protects against contamination of the food, food-contact surfaces, or food-packaging materials.

  (5) **Maintaining gloves in an intact, clean, and sanitary condition** if used in food handling.

  (6) **Wearing effective hair restraints** where needed, including hair nets, headbands, caps, beard covers, etc.

  (7) **Storing clothing or other personal belongings** away from areas where food is exposed or where equipment or utensils are washed.

  (8) **Confining eating food, chewing gum, drinking beverages, or tobacco use** to areas away from where food may be exposed or where equipment or utensils are washed.

(9) **Taking any other necessary precautions to protect against allergen cross-contact and contamination of food, food-contact surfaces, or food-packaging materials** with microorganisms or foreign substances, including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

B. Plant and Grounds (21 CFR 117.20)

- ***Grounds*** — the grounds around a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds must include:

  (1) **Properly storing equipment, removing litter and waste, and cutting weeds or grass** within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests.

  (2) **Maintaining roads, yards, and parking lots** so that they do not constitute a source of contamination in areas where food is exposed.

  (3) **Adequately draining areas that may contribute contamination** to food by seepage, foot-borne filth, or providing a breeding place for pests.

  (4) **Operating systems for waste treatment and disposal** so that they do not constitute a source of contamination in areas where food is exposed.

  (5**) If the plant grounds are bordered by grounds not under the operator's control** and not maintained in the manner described in paragraphs (1) through (4) of this section, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

- ***Plant construction and design*** — the plant must be **suitable in size, construction, and design to** facilitate maintenance and sanitary operations for food-production purposes – manufacturing, processing, packing, and holding food. The plant must:

  (1) Provide **space for the placing of equipment and storage of materials** adequate for maintenance, sanitary operations, and the production of safe food.

  (2) Allow for adequate precautions **to reduce the potential for allergen cross-contact and for contamination of food, food-contact surfaces, or food-packaging material**s with microorganisms, chemicals, filth, and other extraneous material. The potential for allergen cross-contact and for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which allergen cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow systems, dust control systems, enclosed systems, or other effective means.

(3) Allow for adequate precautions **to protect food in installed outdoor bulk vessels** by any effective means, including —

- Using protective coverings
- Controlling areas over and around the vessels to eliminate harborage for pests
- Checking on a regular basis for pests and pest infestation
- Skimming fermentation vessels when necessary

(4) Be **constructed so that** –

- Floors, walls, and ceilings may be adequately cleaned, kept clean, and kept in good repair,
- Drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials, and
- Aisles or working spaces are provided between equipment and walls and are adequately clear and wide enough to allow employees to perform their duties and to protect against contaminating food, food-contact surfaces, or food-packaging materials with clothing or personal contact.

(5) Provide **adequate lighting** in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned. Light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation must be shatter-resistant or otherwise protect against food contamination in case of glass breakage.

(6) Provide **adequate ventilation or control equipment to minimize dust, odors and vapors** (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces.

(7) Provide, where necessary, **adequate screening or other protection against pests**.

C. Sanitary Operations (21 CFR 117.35)

- *General maintenance* − **buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition** and must be kept in repair

adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a way that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

- *Substances used in cleaning and sanitizing, and storage of toxic materials –*

  Cleaning compounds and sanitizing agents must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement must be verified by any effective means, including purchase of these substances under a letter of guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed −

  - Those required to maintain clean and sanitary conditions,
  - Those necessary for use in laboratory testing procedures,
  - Those necessary for plant and equipment maintenance and operation, and
  - Those necessary for use in the plant's operations.

  Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

- *Pest control* − **Pests must not be allowed** in any area of a food plant.
  - Guard, guide, or pest-detecting dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials.
  - Effective measures must be taken to **exclude pests from the manufacturing, processing, packing, and holding areas** and to protect against the contamination of food on the premises by pests.
  - The **use of pesticides to control pests** in the plant is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

- *Sanitation of food-contact surfaces* − All **food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned** as frequently as necessary to protect against allergen cross-contact and against contamination of food.

  (1) **Food-contact surfaces used for manufacturing/processing, packing, or holding low-moisture food** must be in a clean, dry, sanitary condition before use.

When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In **wet processing**, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into food, all food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary.

(3) **Single-service articles** (such as utensils intended for one-time use, paper cups, and paper towels) must be stored, handled, and disposed of in a way that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

- *Sanitation of non-food-contact surfaces* − Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.

- *Storage and handling of cleaned portable equipment and utensils* − Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored in a location and manner that protects food-contact surfaces from allergen cross-contact and from contamination.

D. Sanitary Facilities and Controls (21 CFR 117.37)

Each plant must be equipped with adequate sanitary facilities and accommodations including:

- *Water supply* − The water supply must be **adequate for the intended operations and must be derived from an adequate source**. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

- *Plumbing* − Plumbing must be of adequate size and design and adequately installed and maintained to:

  (1) Carry **adequate quantities of water to required locations** throughout the plant.

  (2) Properly **carry sewage and liquid disposable waste** from the plant.

(3) **Avoid contaminating food, water supplies, equipment or utensils**, or creating an unsanitary condition.

(4) Provide **adequate floor drainage** in all areas where floors are subject to flooding-type cleaning or where normal operations cause water or other liquid waste on the floor.

(5) Provide that there is not **backflow from, or cross-connection between, piping systems** that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

- *Sewage disposal* **–** Dispose sewage into an **adequate sewerage system** or dispose it through other suitable means.
- *Toilet facilities* − Each plant must provide employees with **adequate, readily accessible toilet facilities**. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.
- *Hand-washing facilities* − Each plant must ensure that an **employee's hands are not a source of contamination** of food, food-contact surfaces, or food-packaging materials by providing hand-washing facilities that are adequate, convenient, and furnish running water at a suitable temperature.
- *Rubbish and offal disposal* − **Convey, store, and dispose of rubbish and any offal** so as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces.

E. Equipment and Utensils (21 CFR 117.40)

- *All plant equipment and utensils used in manufacturing, processing, packing, or holding food must —*

(1) Be designed and of such material and workmanship that they are **adequately cleanable, and must be adequately maintained** to protect against allergen cross-contact and contamination.

(2) Be designed, constructed, and used appropriately to **avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water**, or any other contaminants.

(3) Be installed so as to **facilitate cleaning and maintenance** of the equipment and of adjacent spaces.

(4) Have **food-contact surfaces that are corrosion-resistant** when in contact with food.

(5) Have food-contact surfaces **made of nontoxic materials and designed to withstand the environment** of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures, and

(6) Be maintained so **that food-contact surfaces are protected from allergen cross-contact and from being contaminated by any source**, including unlawful indirect food additives.

- ***Seams*** on food-contact surfaces **must be smoothly bonded or maintained** so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.

- *Equipment* in areas where food is manufactured, processed, packed, or held that does not come into contact with food must be **so constructed that it can be kept in a clean and sanitary condition.**

- *Holding, conveying, and manufacturing systems*, including gravimetric, pneumatic, closed, and automated systems, must be of a **design and construction that enables them to be maintained in an appropriately clean and sanitary condition**.

- *Each freezer and cold storage compartment* used to store and hold food capable of supporting growth of microorganisms **must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device** so installed as to show the temperature accurately within the compartment.

- *Instruments and controls* used for **measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions** that control or prevent the growth of undesirable microorganisms in food must be accurate and precise and adequately maintained, and adequate in number for their designated uses.

- *Compressed air or other gases* mechanically **introduced into food or used to clean food-contact surfaces or equipment must be treated** in such a way that food is not contaminated with unlawful indirect food additives.

F. Processes and Controls (21 CFR 117.80)

- *General* -

(1) Conduct all **operations in the manufacturing, processing, packing, and holding of food – including operations involved in receiving, inspecting, transporting, and segregating –** consistent with adequate sanitation principles.

(2) Use **appropriate quality control operations** to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.

(3) Place overall sanitation of the plant under **the supervision of one or more competent individuals** assigned responsibility for this function.

(4) Take adequate precautions to ensure that **production procedures do not contribute to allergen cross-contact or to contamination** from any source.

(5) Use **chemical, microbial, or extraneous-material testing procedures** where necessary to identify sanitation failures or possible allergen cross-contact and food contamination.

(6) **Reject all food that has become contaminated** to the extent that it is adulterated, or if appropriate, treat or process the food to eliminate the contamination.

- *Raw Materials and Other Ingredients*

  (1) Assure that **raw materials and other ingredients are clean and suitable for processing into food by inspection, segregation, or other methods as necessar**y. Store them under conditions that protect against allergen cross-contact and against contamination and that will minimize deterioration. Wash or clean raw materials as necessary to remove soil or other contamination. For washing, rinsing, or conveying food, only use water that is safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not cause allergen cross-contact or increase the level of contamination of the food.

  (2) Either **make certain that raw materials and other ingredients do not contain levels of microorganisms that may make the food injurious** to the health of humans, or pasteurize or otherwise treat them during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.

  (3) Ensure that **raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins** comply with FDA regulations for poisonous or deleterious substances before these raw materials or other ingredients are incorporated into finished food.

  (4) Ensure that **raw materials, other ingredients, and rework that is susceptible to contamination with pests, undesirable microorganisms, or extraneous materia**l comply with applicable FDA regulations for natural or unavoidable defects if they are to be used in manufacturing food.

  (5) Hold raw materials, other ingredients, and rework in bulk, or in **containers designed and constructed so as to protect against allergen cross-contact and against contamination**. Hold them at the temperature and relative humidity and in a manner necessary to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such.

(6) Keep **frozen raw materials** and other ingredients frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and other ingredients from becoming adulterated.

(7) Hold **liquid or dry raw materials and other ingredients received and stored in bulk form** so that they are protected against allergen cross-contact and against contamination.

(8) **Identify raw materials and other ingredients that are food allergens**, as well as rework that contains food allergens, and hold them in a manner that prevents allergen cross-contact.

- *Manufacturing Operations —*

  (1) **Maintain equipment and utensils and food containers** in an adequate condition through appropriate cleaning and sanitizing, as necessary. When necessary, take equipment apart for thorough cleaning.

  (2) Conduct all food manufacturing, processing, packing, and holding under the conditions and controls necessary **to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food**.

  (3) Hold food that can support the rapid growth of undesirable microorganisms at **temperatures that will prevent the food from becoming adulterated** during manufacturing, processing, packing, and holding.

  (4) Ensure that measures such as **sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling a_w** that are taken to destroy or prevent the growth of undesirable microorganisms are adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.

  (5) **Handle work-in-process and rework** in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.

  (6) Take effective measures to **protect finished food from allergen cross-contact and from contamination by raw materials, other ingredients, or refuse**. When raw materials, other ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in allergen cross-contact or contaminated food. Protect food transported by conveyor against allergen cross-contact and against contamination as necessary.

(7) **Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work-in-process, rework, or other food** must be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.

(8) Take adequate **measures to protect against the inclusion of metal or other hazardous material in food.**

(9) **Food, raw materials, and other ingredients that are adulterated**:

- Must be disposed of in a manner that protects against the contamination of other food; or
- If the adulterated food is capable of being reconditioned, it must be:
  - Reconditioned using a method that has been proven effective; or
  - Reconditioned and reexamined and found no longer to be adulterated before being incorporated into other food.

(10) Perform steps such as **washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming** so as to protect food against allergen cross-contact and against contamination. Protect food from contaminants that may drip, drain, or be drawn into the food.

(11) When **heat blanching** is required in the preparation of food capable of supporting microbial growth, heat the food to the required temperature, hold it at this temperature for the required time, and then either rapidly cool the food or pass it to subsequent manufacturing without delay. Growth and contamination in blanchers by microorganisms that grow at high temperatures must be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.

(12) Treat or maintain **batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations** that are held and used repeatedly over time so that they are protected against allergen cross-contact and against contamination, and minimizing the potential for the growth of undesirable microorganisms.

(13) Perform **filling, assembling, packaging, and other operations** so that the food is protected against allergen cross-contact, contamination and growth of undesirable microorganisms.

(14) Food, such as **dry mixes, nuts, intermediate moisture food, and dehydrated food** that relies principally on the control of a_w for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.

(15) Monitor and maintain **food, such as acid and acidified food**, that relies principally on the control of pH for preventing the growth of undesirable microorganisms at a pH of 4.6 or below.

(16) **When ice is used in contact with food**, make it from water that is safe and of adequate sanitary quality. Ice must be used only if it has been manufactured in accordance with current good manufacturing practice.

G. Warehousing and Distribution (21 CFR 117.93)

Store and transport food under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container**.**

H. Defect Action Levels (21 CFR 117.110)

- The manufacturer, processor, packer, and holder of food must utilize quality control operations at all times that reduce natural or unavoidable defects to the lowest level currently feasible.

- The mixing of a food containing defects at levels that render the food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food. For examples of defect action levels that may render food adulterated, see the Defect Levels Handbook, which is accessible at http://www.fda.gov.

XIV. HOLDING AND DISTRIBUTION OF HUMAN FOOD BY-PRODUCTS FOR USE AS ANIMAL FOOD

Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor must be held under conditions that will protect against contamination, including the following (21 CFR 117.95(a)):

- Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food

- Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash
- During holding, human food by-products for use as animal food must be accurately identified

In addition:

- Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed (21 CFR 117.95(b)).
- Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against contamination of the human food by-products for use as animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food (21 CFR 117.95(c)).

XV. DEFINITIONS

Acid foods or acidified foods: Foods that have an equilibrium pH of 4.6 or below.

Adequate: That which is needed to achieve the intended purpose in keeping with good public health practice.

Affiliate: Any facility that controls, is controlled by, or is under common control with another facility.

Allergen cross-contact: The unintentional incorporation of a food allergen into a food.

Audit: The systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess a supplier's food safety processes and procedures.

Batter: A semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

Blanching, except for tree nuts and peanuts: A prepackaging heat treatment of foodstuffs for an adequate time and at an adequate temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

Correction: An action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).

Critical control point: A point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

Defect action level: A level of a non-hazardous, naturally occurring, unavoidable defect at which FDA may regard a food product "adulterated" and subject to enforcement action under section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act.

Environmental pathogen: A pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment so that food may be contaminated and may cause foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Examples of environmental pathogens for the purposes of this part include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic sporeforming bacteria.

Facility: A domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of this chapter.

Farm:

> (1) Primary production farm. A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term "farm" includes operations that, in addition to these activities:
>
> (i) Pack or hold raw agricultural commodities;
>
> (ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; and
>
> (iii) Manufacture/process food, provided that:
>
> (A) All food used in such activities is consumed on that farm or another farm under the same management; or
>
> (B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

(1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(2) Secondary activities farm. A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(ii) and (iii) of this definition.

FDA: The Food and Drug Administration.

Food: (1) Articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article, and includes raw materials and ingredients.

Food allergen: Major food allergens defined in section 201(qq) of the FFDCA, i.e., milk, eggs, fish (e.g., bass, flounder, cod), crustacean shellfish (e.g. crab, lobster, shrimp), tree nuts (e.g., almonds, walnuts, pecans), peanuts, wheat, soybeans, and any ingredient that contains protein derived from one or more of them.

Food-contact surfaces: Surfaces that contact human food, and surfaces from which drainage − or other means of transfer − onto the food, or onto surfaces where food contact ordinarily occurs during the normal course of operations. *Food-contact surfaces* include utensils and food-contact surfaces of equipment.

Full-time equivalent employee: Represents the number of employees of a business entity for the purpose of determining whether the business qualifies for the small business exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours × 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

Harvesting: Activities on farms and farm mixed-type facilities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the FFDCA. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves, and washing raw agricultural commodities grown on a farm.

Hazard: Any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

Hazard requiring a preventive control : A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components, and to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

Holding: Storage of food, and activities performed incidental to storage of a food, e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity − such as drying/dehydrating hay or alfalfa. Holding also includes activities performed as a practical necessity for the distribution of that food, such as blending of the same raw agricultural commodity and breaking down pallets, but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the FFDCA. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Known or reasonably foreseeable hazard: A biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food.

Lot: The food produced during a period of time and identified by an establishment's specific code.

Manufacturing/processing: Making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms: Yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites, including species that are pathogens. The term "undesirable microorganisms" includes those microorganisms that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Mixed-type facility: An establishment that engages in activities that are exempt from registration under section 415 of the FFDCA as well as activities that require the establishment to be registered. An example is a "farm mixed-type facility," an establishment that is a farm, but also conducts activities outside the farm definition that require it to be registered.

Monitor: To conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Packing: Placing food into a container other than packaging[4] the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen: A microorganism of public health significance.

PCHF: The Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Regulation (21 CFR Part 117)

Pest: Any objectionable animals or insects including birds, rodents, flies, and larvae.

Plant: The building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

[4] Packaging means placing food into a container that directly contacts the food and that the consumer receives

Preventive controls: Those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Preventive controls qualified individual: A qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Qualified auditor: A person who is a qualified individual as defined in this part and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required by § 117.180(c)(2). Examples of potential qualified auditors include:

(1) A government employee including a foreign government employee[5],; and

(2) An audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter[6].

Qualified end-user: With respect to a food, it means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227 of this chapter) that:

(1) Is located;

(i) In the same State or the same Indian reservation as the qualified facility that sold the food to such restaurant or establishment; or

(ii) Not more than 275 miles from such facility; and

(2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

Qualified facility: a facility that is a very small business: (when including the sales by all its subsidiaries or affiliates, if it has any; or of the entity of which the facility itself is a subsidiary or affiliate, if it is either); OR a facility to which both of the following conditions apply:

[5] For example, a government inspector

[6] See 21 CFR part 1, subpart M, Accreditation of Third-Party Certification Bodies to conduct Food Safety Audits and to Issue Certifications"

(1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at the facility that is sold directly to qualified end-users (as defined above) exceeded the average annual monetary value of the food sold by the facility to all other purchasers; and

(2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

Qualified individual: A person who has the education, training, or experience (or a combination of these) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

Quality control operation: A planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.

Raw agricultural commodity: means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

Ready-to-eat food (RTE food): Any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

Receiving facility: A facility that is subject to subpart C, Hazard Analysis and Risk-Based Preventive Controls, and subpart G, Supply-Chain Program, and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

Restaurant: A facility that prepares and sells food directly to consumers for immediate consumption. “Restaurant” does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers. Entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens are restaurants

Retail food establishment: An establishment that sells food products directly to consumers as its primary function. A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell food, including food that it manufactures/processes, packs, or holds, from that establishment directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term “consumers” does not include businesses. A “retail food establishment” includes grocery stores, convenience stores, and vending machine locations.

Rework: Clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions, or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

Safe-moisture level: A level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, processing, packing, and holding. The safe moisture level for a food is related to its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a w will not support the growth of undesirable microorganisms.

Sanitize: To adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Significantly minimize: To reduce to an acceptable level, including to eliminate.

Small business: For purposes of this rule, a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees.

Subsidiary: Any company which is owned or controlled directly or indirectly by another company.

Supplier: The establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature.

Supply-chain-applied control: A preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.

Unexposed packaged food: Packaged food that is not exposed to the environment.

Validation: Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Very small business: For purposes of this rule, a business (including any subsidiaries and affiliates) averaging less than $1,000,000, adjusted for inflation, per year, during the 3-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 (e.g., held for a fee).

Water activity (a_w): A measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

You: For purposes of this rule, the owner, operator, or agent in charge of a facility.