



Current good manufacturing practice, hazard analysis and risk-based preventive controls for human food

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Reviewing the preventive controls standard (21 CFR 117)

Food Safety Modernization Act (FSMA)



Current good manufacturing practice, hazard analysis and risk-based preventive controls for human food



This standard requires that production or processing facilities have a written safety plan that includes a hazard analysis.

Establish preventive controls if any

21 CFR Part 117 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

- Subpart A – General Provisions
- Subpart B - Current Good Manufacturing Practice
- Subpart C – Hazard Analysis and Risk-Based Preventive Controls
- Subpart D – Modified Requirements
- Subpart E – Withdrawal of a Qualified Facility Exemption
- Subpart F – Requirements Applying to Records that Must Be Established and Maintained
- Subpart G – Supply-Chain Program



TO WHOM DO THE REQUIREMENTS OF PREVENTIVE CONTROLS FOR HUMAN FOOD APPLY?

- The requirements apply to you if **you manufacture, process, pack, or hold food for human consumption in the United States**, whether your facilities are domestic or foreign. **The requirements apply to you if you are required to register with the FDA** under section 415 of the Federal Food, Drug, and Cosmetic (FD&C) Act.
- Entities defined as **“FARMS”, retail food establishments and restaurants** are some of the entities that **are not subject to preventive control requirements** because they are not required to register.



Subpart A

General Provisions

Preventive Controls for Human Food (PCHF) Standard

- Hazard analysis and risk-based preventive controls.
- Current Good Manufacturing Practice (21CFR-110 changed to 21CFR-117)
- The standard, which went into effect in **September 2015**, **requires food facilities to have a food safety plan that includes a hazard analysis and risk-based preventive controls** to minimize or prevent identified hazards.



Compliance Dates for Facilities



Small businesses (a business with fewer than 500 full-time equivalent employees): two years – (September 18, 2017)



Very small businesses (less than \$1 million in food sales per year): three years (except certain registrations) - (September 17, 2018)



All Other Businesses (aka **Large Businesses**): One Year - (September 19, 2016)

Exemptions and Modified Requirements for the PCHF



Qualified facilities (very small companies)



Foods subject to low-acid canned food regulations (microbiological hazard only) (21 CFR 113)



Foods already subject to HACCP programs (juices 21 CFR 120 or shellfish 21 CFR 123)



Dietary Supplements – 21 CFR 111



Alcoholic beverages

PCHF Key Requirements for Businesses

Businesses that **manufacture, process, pack or hold food must draft a Food Safety Plan** that describes :



- Risk analysis
- Preventive controls
- Follow-up/monitoring procedures
- Corrective action procedures
- Verification procedures
- Supply Chain Program
- Recall plan

PCHF Key Business Requirements

Required

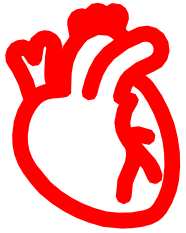


- Risk analysis
- Preventive controls (4 types)
- Follow-up/monitoring procedures
- Corrective action procedures
- Verification procedures
- Supply Chain Program
- Recall plan

Convenient

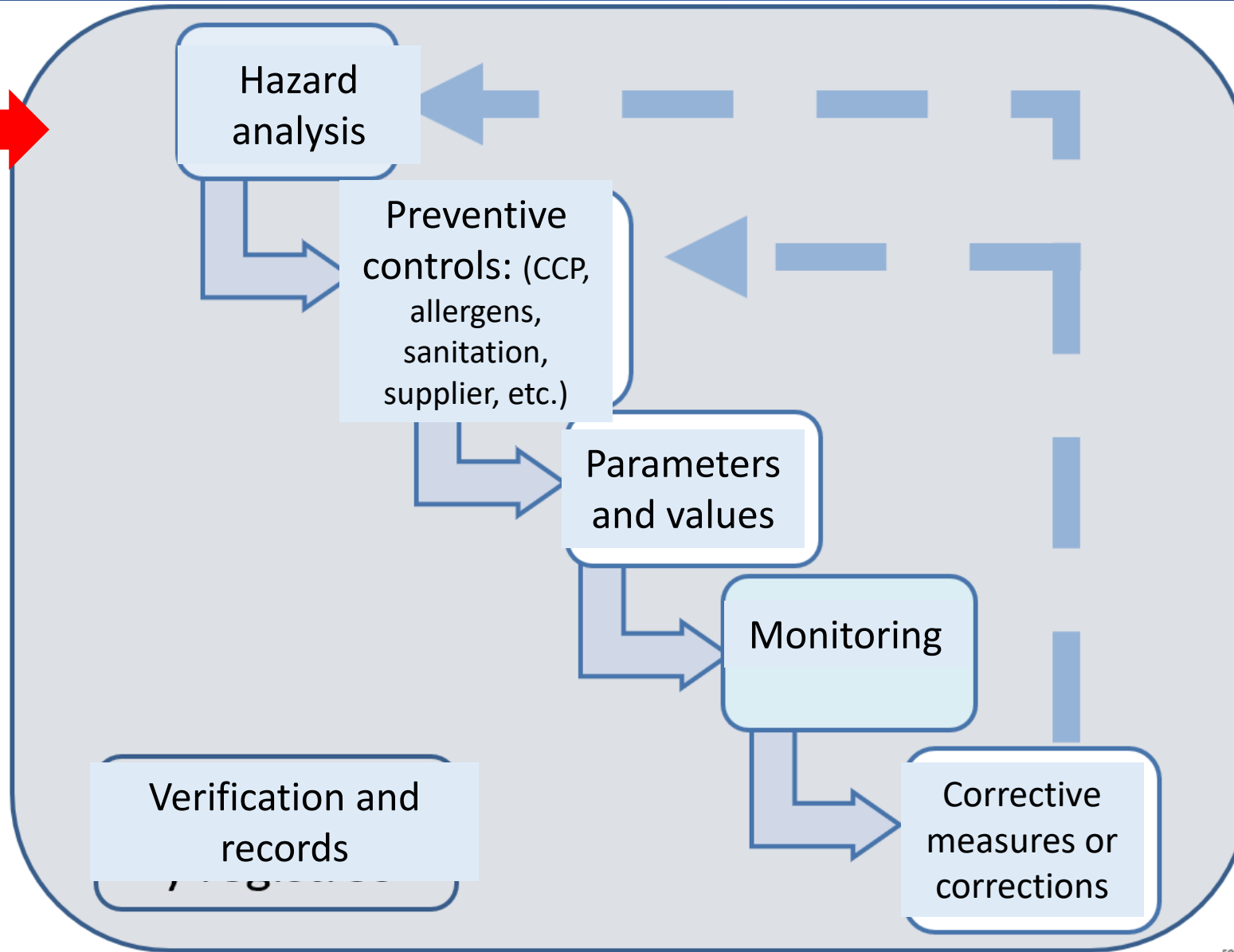


- Review of facility and Food Safety equipment
- Product description
- Process flowchart
- Process description
- Diagram of the facility



Consider hazards:

- Physical
- Chemical
- Biological
- Radiological



PCHF Key Business Requirements



4 Types of preventive controls

- Preventive Allergen Controls
- Preventive Process Controls
- Preventive Sanitation Controls
- Preventive Supply Chain Controls



Cross contact



Critical control points (CCP)



Cross contamination



Supplier controls hazard

Examples of questions for hazard analysis



- 1. Information on the description of the product, method of consumption and distribution.**
- 2. Plant experience on hazards and their probability of occurrence associated with finished products, including:**
 - Analysis of the finished product
 - Consumer complaints
- 3. Experiences of plant personnel about the conditions, functioning and design of the plant.**
- 4. Raw materials and ingredients used in the product:**
5. Hazards **such as allergens or pathogens known to be associated** with specific types of foods that may be introduced during the formulation or manufacturing of the product

Examples of questions for hazard analysis



Activities in each step of the manufacturing process:

1. Some processes introduce hazards:

- Metal to metal
- Glass containers
- Inadequate cooling allowing pathogen growth

2. Equipment used to manufacture the product is more difficult to clean than others or is more fragile

3. Types of packaging or packaging materials:

For example: Packaging with reduced oxygen can create environments that support the growth of *Clostridium botulinum* (*C. botulinum*) or migration of chemical substances through the packaging to the food.

Examples of some questions for hazard analysis



1. Sanitary practices:

- Inside the plant:
 - Cleaning of equipment and environment
 - Staff hygiene
 - Hard-to-clean equipment can harbor pathogens
 - Allergen cross contact

2. External information:

- Scientific Publications
- Using multiple allergens in different products increases the possibility of epidemiological studies (past safety outbreaks associated with ingredients or processes relevant to the product)
- Government or industry information
- Safety guide documents
- Historical data on similar products

What 's New in a Food Safety Plan?



Element	HACCP plan	Added to the food safety plan
Hazard Analysis	Biological, chemical, physical	Chemical hazards must include radiological hazards ; consider economically motivated hazards .
Preventive controls	CCP for processes	Process CCP + controls at other points that are not CCP
Parameters and values	Critical limits	Parameters and minimum/maximum values (= critical limits for process controls)
Monitoring	Required for CCPs	Required as applicable for other preventive controls
Corrective measures or corrections	Corrective measures	Corrective measures or corrections, as required by each case
Verification	For process controls	As applicable for all preventive controls. Verification of suppliers is required when the supplier controls a hazard.
Records	For process controls	As applicable for all preventive controls
Market recall plan	Not required in the plan	A hazard is identified that requires preventive controls

PCHF Key Requirements – for Staff

- Management must ensure that **all employees who manufacture, process, pack or hold food are qualified to perform assigned tasks.**



PCHF Key Requirements – for Staff

- Such employees must have the **necessary combination of education, training and/or experience to manufacture, process, pack or hold clean and safe food**. Individuals must be trained in the principles of hygiene and food safety, including the importance of employee health and hygiene as appropriate for the food, facility, and tasks assigned to the individual.



PCHF Key Requirements – for Staff

- *Records that document training required in the principles of hygiene and safety* must be established and maintained **(21 CFR 117.4(d))**.



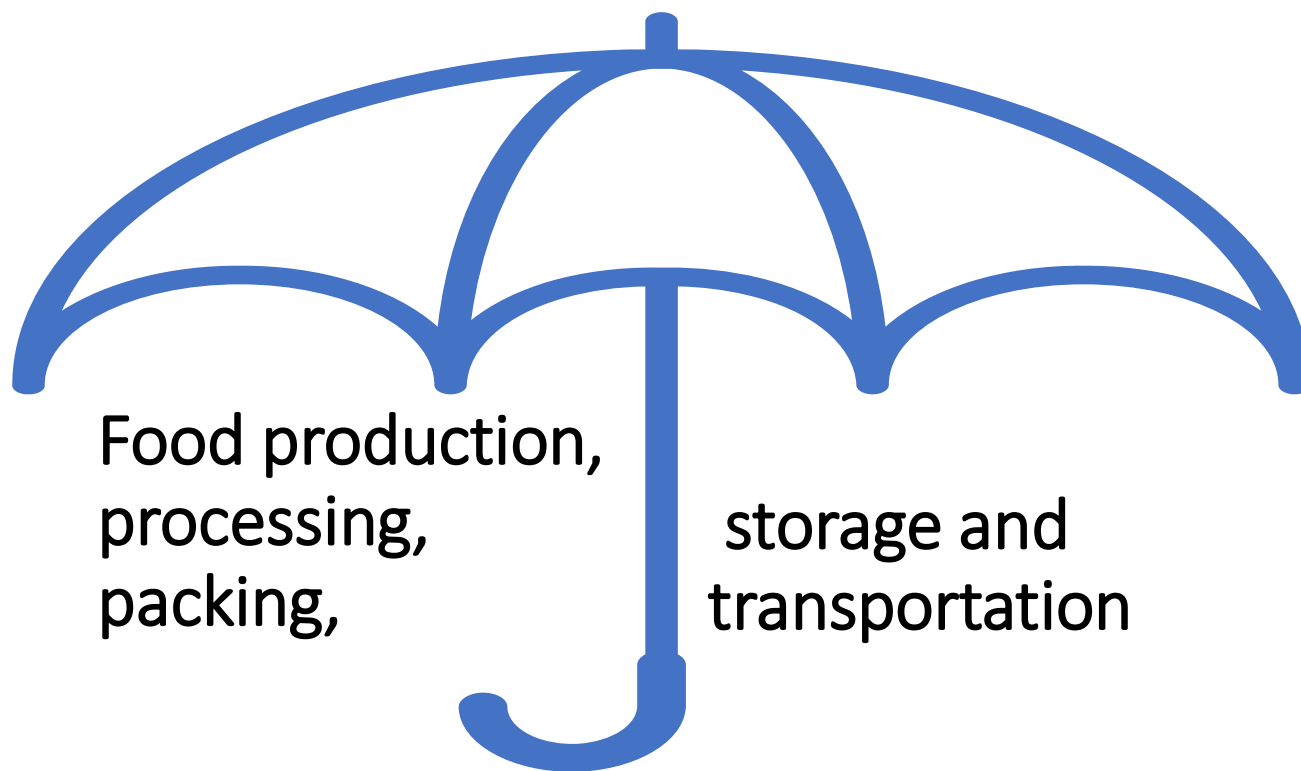
Qualified Facilities

Companies that earn on average less than \$1 million per year in food sales plus the value of unsold manufactured, processed, packed, or held human food.

- These qualified facilities are exempt from hazard analysis/preventive control requirements.
- Qualified facilities still have the following requirements:
 - They are subject to the cGMP of 21 CFR 117 (Subpart B)
 - [They are required to produce safe food.](#)



Federal Food, Drug, and Cosmetic Act includes the following provision in Section 402(a)(4): **a food is adulterated** “if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.” [21 United States Code § 342. Adulterated food.]



What has happened so far in the inspections carried out by FDA?

<https://datadashboard.fda.gov/ora/index.htm>

FDA Data Dashboard

Compliance Dashboards

[Inspections](#)

[Compliance Actions](#)

[Recalls](#)

[Imports Summary](#)

FSMA Data Search

Find firm compliance and enforcement information.

[Search Firm Information](#)

[LAAF Participants](#)



<https://datadashboard.fda.gov/ora/index.htm>

[Home](#) > [Compliance Dashboards](#) > Inspections


Inspections

NEW! Compliance Actions data is now available through

[FDA Dashboards - Inspections](#)

✕

Filters

 **Looking for something specific?**

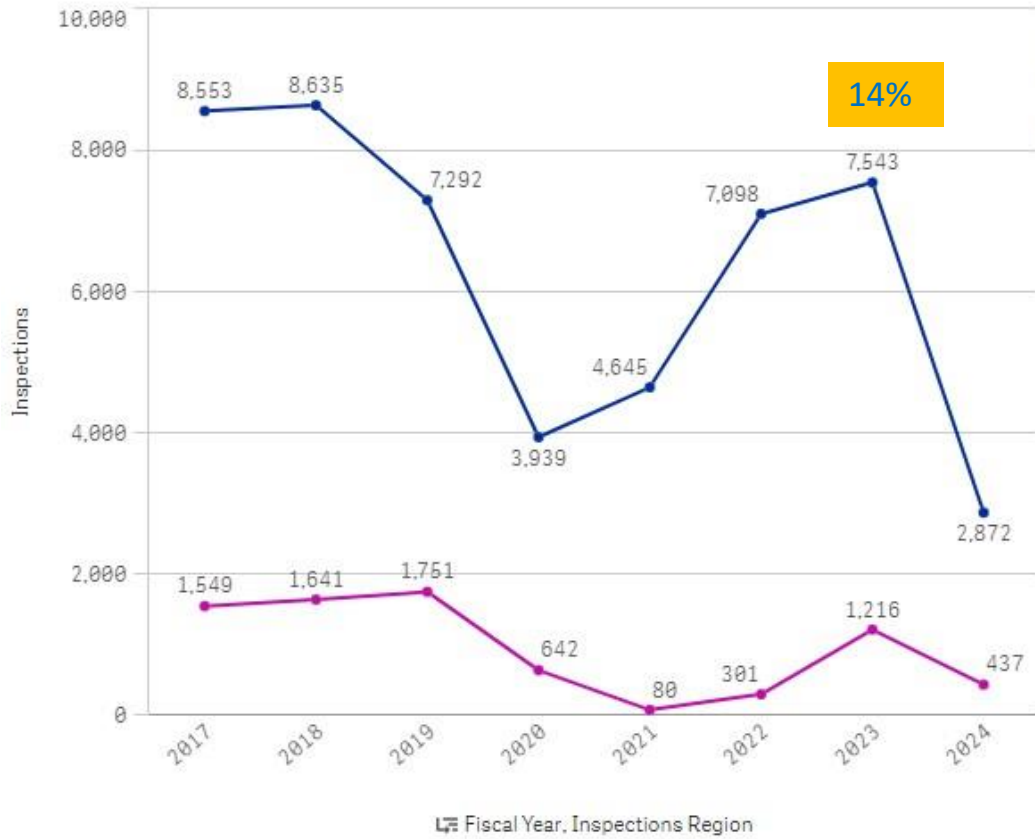
Narrow your data by clicking the filter options below or any of the data objects/visualizations on the dashboard page. Filters applied are displayed on the black selection bar.

[? Filter Help](#)

<input type="text" value="Fiscal Year"/>	<input type="text" value="Product Type"/>
<input type="text" value="Project Area"/>	<input type="text" value="Classification"/>
<input type="text" value="Posted Citations"/>	<input type="text" value="Region"/>
<input type="text" value="Country/Area"/>	<input type="text" value="State"/>
<input type="text" value="Legal Name"/>	<input type="text" value="Additional Details"/>

Foreign and Domestic Inspections

Fiscal Years: 8 of 16



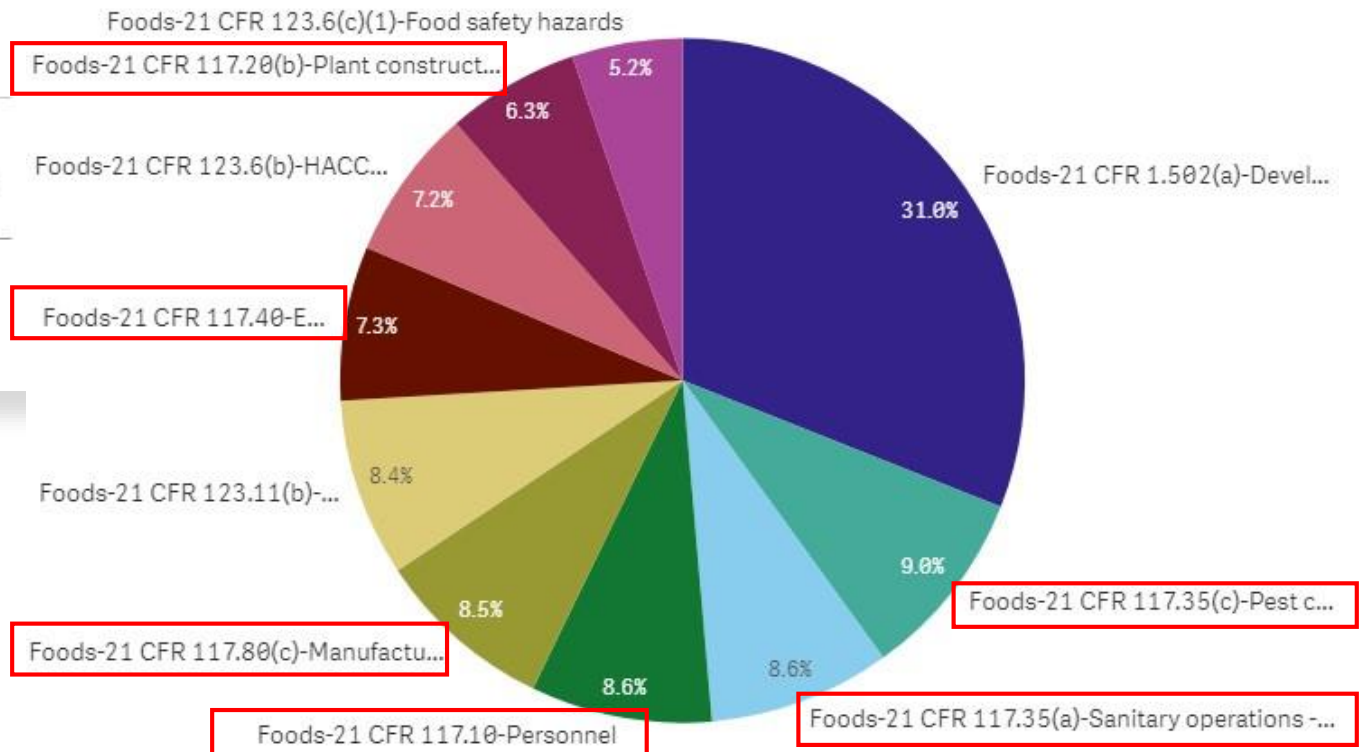
Inspections Region

- Domestic
- Foreign

Top 10 Citations

Fiscal Years: 8 of 16

40.3% - 21 CFR 117
31.0% - 21 CFR 1.502
20.8% - 21 CFR 123



<https://datadashboard.fda.gov/ora/index.htm>

1	Inspection ID	FEI Number	Legal Name	Inspection End D	Program Area	Act/CFR Number	Short Description	Long Description
2	1237144	1000497832	Coast-To-Coast Proc	04/29/2024	Foods	21 CFR 1.506(d)(1)(ii)	Verification activity - appropriate	You did not conduct an appropriate
3	1237224	3017300718	Sweet Laurel, LLC	04/29/2024	Foods	21 CFR 117.80(a)	Plant operations - Precautions	You did not take adequate precauti
4	1236987	3012509487	SANTIS PRODUCE LI	04/25/2024	Foods	21 CFR 1.505(c)(1)	Reevaluate - new information	You did not document that you pror
5	1236987	3012509487	SANTIS PRODUCE LI	04/25/2024	Foods	21 CFR 1.505(c)(2)	Reevaluate - document	You did not document that you took
6	1236846	3002406149	Nahlah Seaplus, Inc.	04/24/2024	Foods	21 CFR 123.6(b)	No HACCP plan	You do not have a written HACCP pl
7	1236846	3002406149	Nahlah Seaplus, Inc.	04/24/2024	Foods	21 CFR 123.12(a)(2)	Importer verification	You do not have or have not implem
8	1236770	3017696775	DESERT VALLEY DAT	04/23/2024	Foods	21 CFR 1.502(a)	Develop FSVP	You did not develop an FSVP.
9	1236611	3013602461	GOOD LIVING USA C	04/22/2024	Foods	21 CFR 1.512(b)(3)(i)	Very small importer assurances, si	As a very small importer, you did no
10	1236296	3004663784	Flavorpros, LLC	04/19/2024	Foods	21 CFR 117.37	Sanitary facilities and controls	Your plant did not have adequate sa
11	1236296	3004663784	Flavorpros, LLC	04/19/2024	Foods	21 CFR 117.40	Equipment and utensils - Design a	Your equipment and utensils were r
12	1236296	3004663784	Flavorpros, LLC	04/19/2024	Foods	21 CFR 120.11(a)(1)(iv)	Records - not signed and dated by	Your review of critical control point
13	1236296	3004663784	Flavorpros, LLC	04/19/2024	Foods	21 CFR 120.11(a)(2)	Calibration, testing - no records	You do not maintain records of calik
14	1236296	3004663784	Flavorpros, LLC	04/19/2024	Foods	21 CFR 120.12(c)	Records - signed/dated	Your written hazard analysis and wr
15	1236497	1000343584	Medina & Medina, I	04/19/2024	Foods	21 CFR 123.6(b)	HACCP plan implementation	You did not implement the monitori
16	1236497	1000343584	Medina & Medina, I	04/19/2024	Foods	21 CFR 123.8(a)(2)(ii)	Calibration - adequacy	Your process monitoring equipment
17	1236497	1000343584	Medina & Medina, I	04/19/2024	Foods	21 CFR 123.11(b)	Sanitation monitoring	You are not monitoring the sanitatic
18	1233670	3014161283	ST Tea, LLC/Good W	04/18/2024	Foods	21 CFR 1.502(a)	Develop FSVP	You did not develop an FSVP.
19	1236648	3009695118	Pretzel Pete, Inc.	04/18/2024	Foods	21 CFR 117.35(c)	Pest control	You did not exclude pests from your
20	1236181	3004698733	AVI Foodsystems Inc	04/17/2024	Foods	21 CFR 117.206(a)	Modified requirement: Temperatu	You did not implement adequate te
21	1230588	3008254576	Global CPG LLC	04/16/2024	Foods	21 CFR 1.502(a)	Develop FSVP	You did not develop an FSVP.

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observations related to **21**

CFR 117

- Subpart A – General Provisions
- Subpart B - Current Good Manufacturing Practice
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- Subpart G – Supply-Chain Program



- Subpart B

9142 - 67%

- Subpart C

3525 - 26%

- Subpart F

121 - 0.9%

- Subpart G

328 - 2.4%

Guidance to industry

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

- The Food Safety Preventive Controls Alliance (FSPCA) is a broad-based public-private alliance of industry, academia, and government stakeholders whose **mission is to support safe food production by developing a plan of basic studies, training and extension programs at the national level to help companies produce human and animal foods in compliance with preventive controls regulations.**



Participant Manual

FSPCA Lead Instructor (LI) Courses for 2024

- Dates in 2024 for FSPCA

Lead Instructor courses have been determined and registration will open soon.

- All Lead Instructor candidates will be notified once registration opens.

- Find full registration details on the FSPCA website using the links below.

- Click the Enroll tab on each web page.

FSPCA course	Course dates	Method of delivery
Lead Instructor course on preventive controls for animal foods	June 24-28	Virtual
Combined intentional adulteration vulnerability assessment course (IAVA)	For participants: August 6-7 For Lead instructors: August 13-14	Virtual
FSPCA Foreign Supplier Verification Program (FSVP) Lead Instructor Course	September 9-13	Virtual
FSPCA Preventive Controls for Human food – Lead Instructor Course version 2.0	October 7-11	Virtual




SUPPLEMENTAL SLIDES ON THE REQUIREMENTS FOR ADDITIONAL TRACEABILITY RECORDS FOR CERTAIN FOODS (21 CFR PART 1 Subpart S)

These slides summarize selected points that may be important to manufacturers of foods subject to the Preventive Controls for Human Food (PCHF) rule.



FSMA Food Traceability Rule (21 CFR Part 1 Subpart S)

- Final rule published: November 21, 2022
- Effective date: January 20, 2023
- Compliance date: January 20, 2026

A screenshot of the Federal Register page for the FSMA Food Traceability Rule. The page header includes the National Archives logo, the text 'FEDERAL REGISTER The Daily Journal of the United States Government', and the National Archives and Records Administration seal. A blue bar with a registered trademark symbol and the word 'Rule' is present. The main title is 'Requirements for Additional Traceability Records for Certain Foods'. At the bottom, it states 'A Rule by the Food and Drug Administration on 11/21/2022'.

Who must comply with the Food Traceability Rule?



-
- Persons who manufacture, process, pack or hold foods on the Food Traceability List (FTL).
 - Covers the entire food supply chain.
 - Includes both foreign and domestic facilities (in the United States).
 - Full or partial exemptions may apply.



Exemptions



-
- Certain small producers, for example, produce farms exempt from FSMA regulations.
 - Foods that receive certain types of processing.
 - Foods subject to a “kill” step, provided that certain records are kept.
 - A complete list of exemptions can be found at: § 1.1305 What foods and persons are exempt from this subpart?
 - A tool to identify exemptions can be found at <https://collaboration.fda.gov/tefcv13/> *



Components of the rule/key concepts



Food traceability list

- FDA used a hazard classification model to help identify foods subject to enhanced recordkeeping requirements.

Critical Tracking Event (CTE)

- Key points/steps along the supply chain where it is most important to collect traceability information.

<https://www.fda.gov/media/163132/download>

Key Data Elements (KDE)

- Data/information required for each CTE.



Standard components/key concepts



Traceability Plan (TP)

- Description of how and where you keep records, how you identify food in the FTL, how you assign traceability lot codes, and contact information for questions about your plan (and farm map for most producers).

Additional requirements

- Records must be provided to FDA within a 24-hour period (or within a reasonable timeframe accepted by the FDA) when requested.
- During an outbreak, FDA may request that records be provided in a sortable electronic spreadsheet.



Relevant Food Traceability List for Preventive Controls for Human Food (1)



- Cheese (made from pasteurized milk), fresh soft or soft unripened
Includes soft unripened/fresh soft cheeses. Examples include, but are not limited to, cottage, chevre, cream cheese, mascarpone, ricotta, queso blanco, queso fresco, queso de crema, and queso de puna. Does not include cheeses that are frozen or previously frozen, shelf stable at ambient temperature, or aseptically processed and packaged
- Cheese (made from pasteurized milk), soft ripened or semi-soft .
Includes soft ripened/semi-soft cheeses. Examples include, but are not limited to, brie, camembert, feta, mozzarella, taleggio, blue, brick, fontina, monterey jack, and muenster. Does not include cheeses that are frozen or previously frozen, shelf stable at ambient temperature, or aseptically processed and packaged.



Relevant Food Traceability List for Preventive Controls for Human Food (2)



- Cheese (made from unpasteurized milk), other than hard cheese. Includes all cheeses made with unpasteurized milk, other than hard cheeses. Does not include cheeses that are frozen or previously frozen, shelf stable at ambient temperature, or aseptically processed and packaged.



Relevant Food Traceability List for Preventive Controls for Human Food (3)



- **Nut and peanut butters**

Includes all types of tree nut and peanut butters. Includes all forms of nut butters, including shelf stable, refrigerated, frozen, and previously frozen products. Examples include, but are not limited to, almond, cashew, chestnut, coconut, hazelnut, peanut, pistachio, and walnut butters. Does not include soy or seed butters.



Relevant Food Traceability List for Preventive Controls for Human Food (4)



- **Leafy greens (fresh-cut)**

- Includes all types of fresh-cut leafy greens, including single and mixed greens.

- **Vegetables other than leafy greens (fresh-cut)**

- Includes all types of fresh-cut vegetables other than leafy greens.

- Vegetables listed in § 112.2(a)(1) are exempt from the requirements of the rule under § 1.1305(e).

- **Fruits (fresh-cut)**

- Includes all types of fresh-cut fruits.

- Fruits listed in § 112.2(a)(1) are exempt from the requirements of the rule under § 1.1305(e).



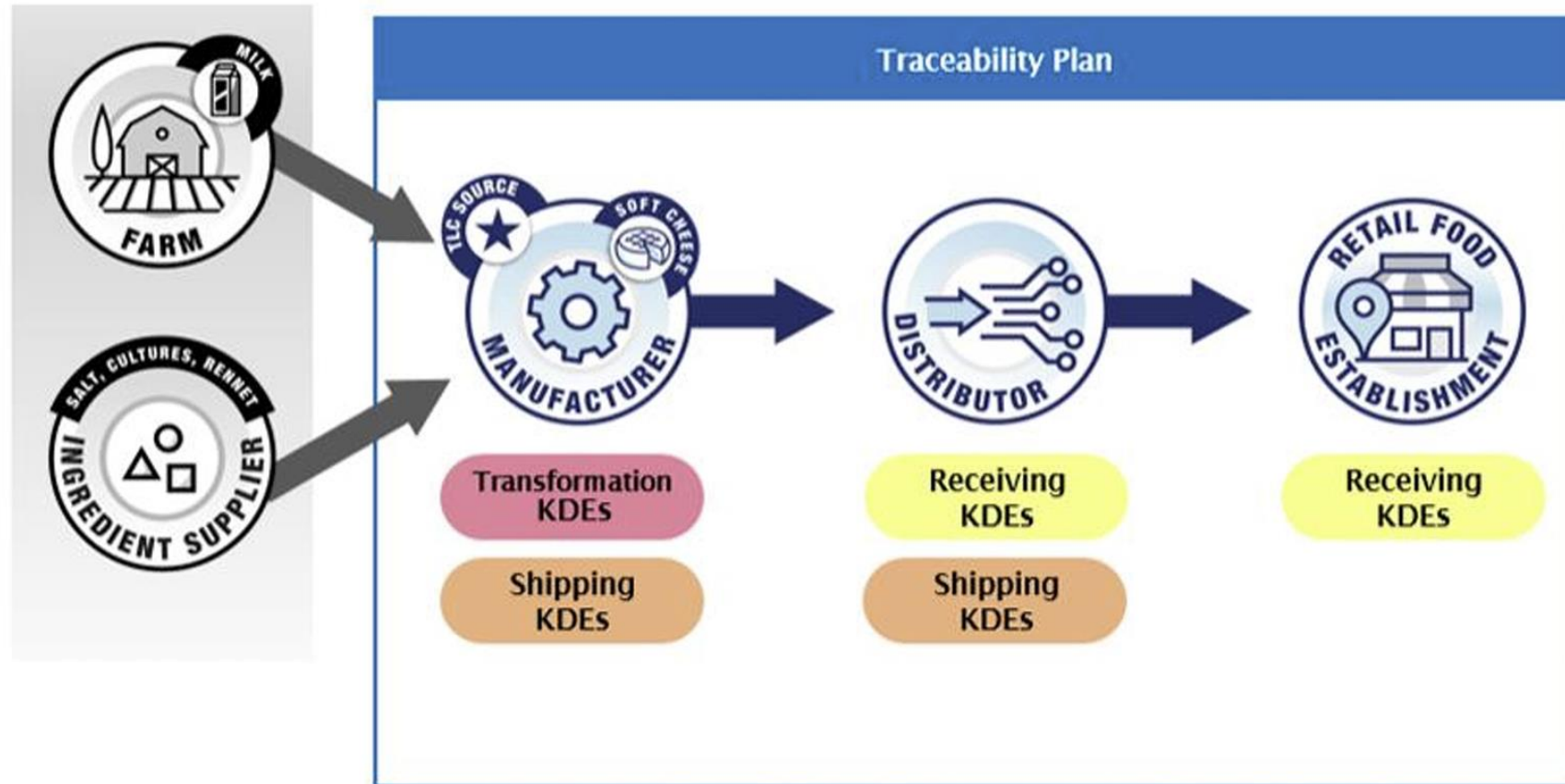
Relevant Food Traceability List for Preventive Controls for Human Food (5)



- Ready-to-eat deli salads (refrigerated)
 - Includes all types of refrigerated ready-to-eat deli salads, including ready-to-eat deli salads that are frozen at some point in the supply chain prior to retail.
 - Examples include, but are not limited to, egg salad, potato salad, pasta salad, and seafood salad.
 - Does not include meat salads.



Example* – Supply Chain, cheese



*Example credits - Slides: <https://www.fda.gov/media/163056/download>

* Example Credits - Transcript: <https://www.fda.gov/media/164486/download?attachmen>

Preventive Controls for
Human Food

Resources
available for
the industry



Guidance to industry



FOOD SAFETY PLAN BUILDER

- **FOOD SAFETY PLAN BUILDER**

The Food [Safety Plan Builder](#) (FSPB) is a free software application, developed by the FDA, that companies can download from the FDA website to guide them, step by step, through creating a food safety plan, as required by FSMA.

Guidance to Industry: guidance documents

- [Hazard Analysis and Risk-Based Preventive Controls for Human Food](#) *
- Environmental sampling
- Food allergen controls
- Process control validation
- Supply Chain Program
- [Small Entity Compliance Guide](#)
- [Classification of activities as harvesting, packing, holding or manufacturing/processing for farms and facilities](#)
- [Describing a hazard that needs control in documents accompanying the food, as required by Four rules implementing FSMA](#)
- [Control of *Listeria monocytogenes* in ready-to-eat foods - Draft guidance for industry](#)

All FSMA standards and guidance for the industry:

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm>



Guidance to industry

- **TECHNICAL ASSISTANCE NETWORK**

- The [Technical Assistance Network \(TAN\)](https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm) is a central source of information for questions related to FSMA rules, programs, and implementation strategies
<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>
- [FSMA TAN Common Questions](#)



Final Traceability Rule

Resources available for the industry

First Land-Based Receiver

Shipping

Receiving

Transformation

Traceability Plan

...e, process, pack, or hold foods on
...ir supply chain partners specific
...cking events (CTEs) in the food's
...e and efficient tracing and clearly
...h tracing.

...the rule varies depending on the type
...food, from harvesting or production
...ail or other point of service. Central
...nd sharing of traceability lot codes for
...ion identifying the foods as they move

of KDEs required for each CTE



Final Traceability Rule



FSMA Final Rule: Requirements for Additional Traceability Records for Certain Foods:

<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-standard-requirements-for-additional-traceability-records-for-certain>

- FDA Food Traceability List: <https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list>

- Webinars on FDA food traceability (in English): <https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/webinar-food-traceability-final-rule-12072022>

- Webinars on food traceability given by IICA in collaboration with FDA

[Produce Safety Rule: Regulation and Good Agricultural Practices | Inter-American Institute for Cooperation on Agriculture \(iica.int\)](#)

Final Traceability Rule

FDA Exemptions and Exclusions Tool:

<https://collaboration.fda.gov/tefcv13>

- Low-or no-cost food traceability challenge (in English):
<https://www.fda.gov/food/new-era-smarter-food-safety/meet-winners-fdas-low-or-no-cost-food-traceability-challenge>
- FDA Frequently Asked Questions (FAQs):
<https://www.fda.gov/food/food-safety-modernization-act/fsma/frequently-asked-questions-about-fsma-final-rule-requirements-for-traceability-records>
- Small entity compliance guide (in English):
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-requirements-additional-traceability-records-certain-foods-what-you>





When one teaches, two learn.

Robert A. Heinlein

Thank you for your
attention!!

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