

Seaweed Food Safety:

Comparing Compliance with Preventive Controls for Human Foods and Seafood HACCP

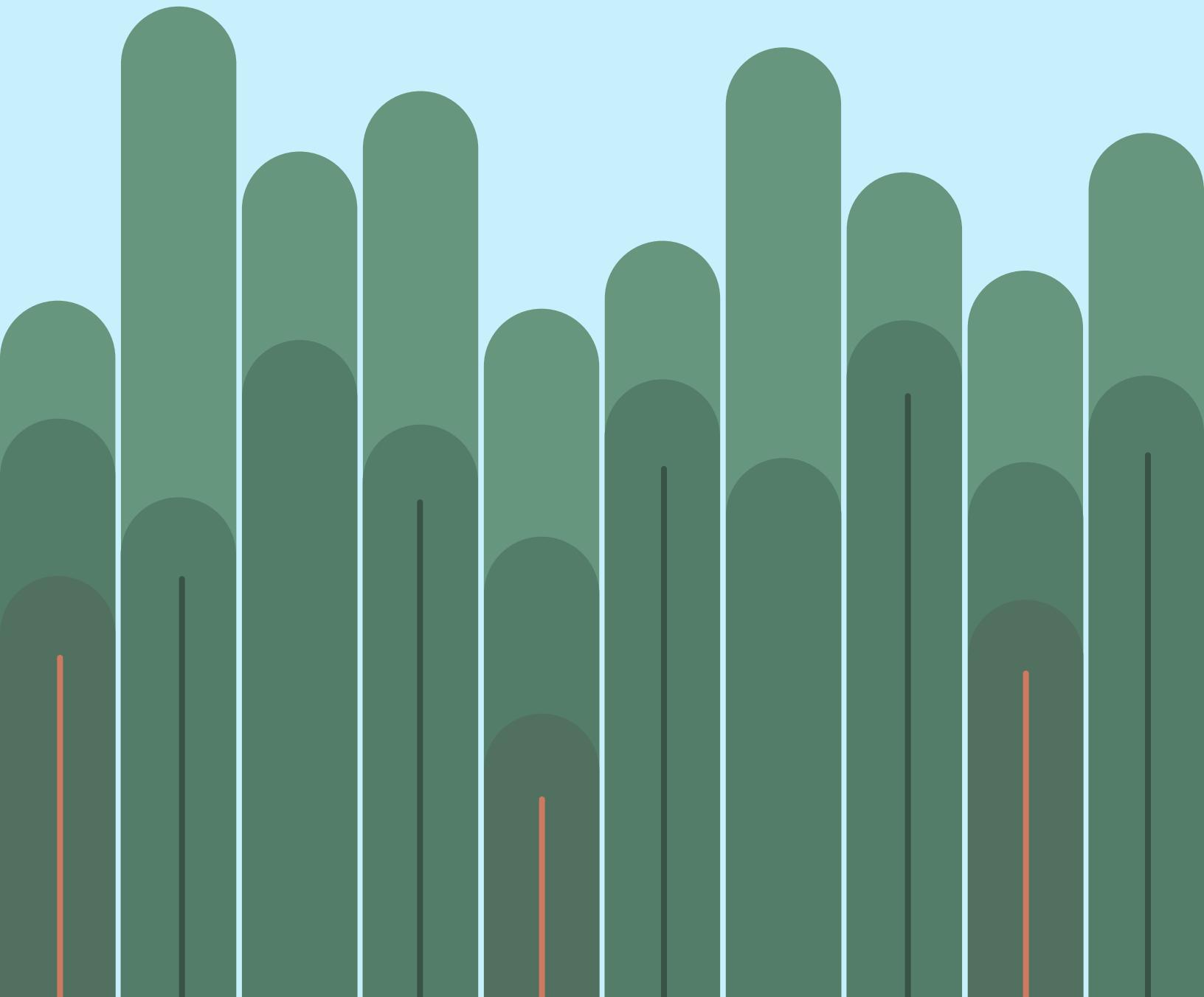


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Purpose of the Guide

With increased interest in seaweed production, there is a need for profitable markets for seaweed products. The food market is seen as one of the most profitable but there are many food safety regulations governing the processing and marketing of food products in the US to protect public health and prevent the occurrence of foodborne illness. While some resources already exist on the hazards associated with seaweed products (produced by Connecticut Sea Grant, Alaska Sea Grant, Food and Agricultural Organization of the United Nations and others), there is little guidance on the regulatory requirements for producing seaweed products in the US.

This guide was created to help the emerging seaweed industry understand the prevailing regulatory requirements surrounding the production of seaweeds as foods. There are currently two regulations that are being used to regulate seaweeds at either the federal or state level: the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (GMP/PCHF) regulation and the Seafood Hazard Analysis Critical Control Point regulation. This guide will help the reader understand the similarities and differences between the two regulations and help the reader understand how their operation might be regulated.

The guide was drafted by a core team including [Dr. Michael Ciaramella](#), New York Sea Grant, [Anoushka Concepcion](#), Connecticut Sea Grant, and [Catherine Janasie](#) and [Stephanie Otts](#), National Sea Grant Law Center. Members of the National Seaweed Hub's Regulations Work Group and the Seaweed Food Safety Training Workgroup (coordinated by New York Sea Grant), which include agencies, academics, industry, and non-profits, assisted with revisions and edits.

Instructions:

Orange text followed by ⓘ can be hovered-over to reveal the text's definition.

Blue-italicized text followed by ↪ are anchor links. When clicked, it will take you to the referenced location within this document.

Blue-underlined text are hyperlinks. To view: Right-Click (or Control-Click) on the hyperlink to open in a new browser tab.

Acknowledgments:

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Seaweed Food Safety Introduction

Federal and state agencies have a critical role in protecting public health and preventing foodborne illness by ensuring food is sourced, processed, and distributed in a way that reduces or eliminates potential foodborne illness. In the past decade there have been several documented cases of foodborne illness related to seaweed products (News Desk, [2016](#), [2021](#); Whitworth, [2019](#)). As the seaweed industry in the US experiences increased interest and growth as a new sustainable food source, agencies are looking closer at current food safety programs to determine where seaweed fits in to ensure it reaches the market as a safe and wholesome food. To date, federal and state agencies use guidance from the Preventive Controls for Human Foods (PCHF) regulation and Seafood Hazard Analysis Critical Control Point (HACCP) to ensure seaweed is safe for consumers.



The Food and Drug Administration (FDA), which develops and enforces federal food safety regulations, gets its regulatory authority from the Federal Food, Drug, and Cosmetic Act (FDCA), which prohibits food that is adulterated or misbranded from entering the US market. [Adulterated food](#) is any food produced under unsanitary conditions or contaminated with any foreign material (including dirt/debris, bacteria, hazardous chemicals, or physical objects) not naturally present in that product. Misbranded foods are those that are mislabeled or missing necessary information on a food label.

Federally, seaweed is recognized as a [raw agricultural commodity \(RAC\)](#), however, when processed it is subject to the Food Safety Modernization Act and the [Preventive Controls for Human Foods \(PCHF\)](#) regulation. A complicating factor is that most facilities/operations processing seaweed are [very small businesses](#) ⓘ and are exempt from the preventive control requirements of the regulation (Subparts C and G). Currently there is no federal oversight of farm level seaweed production and harvest.

Seaweed processors often turn to state agencies to determine the requirements for processing and marketing foods in their state. On the state level, the regulatory framework surrounding seaweed processing and marketing varies. Seaweed is a new industry in many states and agencies are unfamiliar with it as a product. Some states have followed the lead of the federal government and adopted the PCHF regulation. Other states consider seaweed as a seafood, and have turned to the Seafood HACCP regulation to regulate food safety. While the Seafood HACCP regulation is a preventive food safety system and very similar to PCHF, the language and terminology utilized and requirements vary slightly. *This guide is meant to help operations understand what is expected of them as a seaweed processor and how to merge a HACCP plan into a PCHF food safety plan as a facility/operation expands and no longer qualifies for the PCHF exemptions. State level regulatory oversight of seaweed farming and harvest practices varies by state and will not be directly addressed in this guide.*

Definitions and Acronyms

The following terms are used throughout the document. Definitions and acronyms are provided below for clarity.

Definitions

- An **Operation** is a generic term used throughout the document to describe seaweed businesses. It is not a term used in the applicable regulations. A seaweed operation could be a “Farm,” “Facility,” “Mixed-Type Facility,” or “Qualified Facility” under federal regulations.
- **Manufacturing/Processing** includes making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients.
 - *Example: cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity, freezing, labeling, packaging, trimming, blanching, or washing.*
- A **Raw Agricultural Commodity (RAC)** is any food in its raw or natural state.
 - *Example: fresh, dried/dehydrated (when done by the “Farm”) seaweed.*
- A **Farm** is defined as an operation that grows and harvests crops, raises animals (including seafood), or a combination of these activities.
- A **Facility** is any establishment, structure, or structures under one ownership at one general physical location (unless a mobile facility), that manufactures/processes, packs, or holds food for consumption in the United States.
- A **Mixed-Type facility** is defined as a facility that conducts activities associated with both a farm and manufacturer/processor.
 - *Example: a seaweed farmer that also cuts, blanches, and packages products for commercial sale.*
- A **Very Small Business** is a business averaging less than \$1,000,000 per year for the past 3 years 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).
- A **Qualified Facility** is a facility that is *either* a very small business *or* one in which the average annual monetary value of all food sold during the last 3 years was less than \$500,000 and sales to qualified end-users exceeds sales to others. *See page 6 for criteria ↓.*
 - *Example: An operation processing and selling products (including non-seaweed products) valued at less than \$1 million per year for the past 3 years (i.e., a very small business).*

Acronyms

- FDA – Food and Drug Administration
- FDCA – Federal Food, Drug, and Cosmetic Act
- FSMA – Food Safety Modernization Act
- RAC – Raw Agricultural Commodity
- PC – Preventive Control
- PCHF – Preventive Controls for Human Foods
- HACCP – Hazard Analysis Critical Control Point
- CCP – Critical Control Point
- PCQI – Preventive Controls Qualified Individual
- FSVP – Foreign Supplier Verification Program



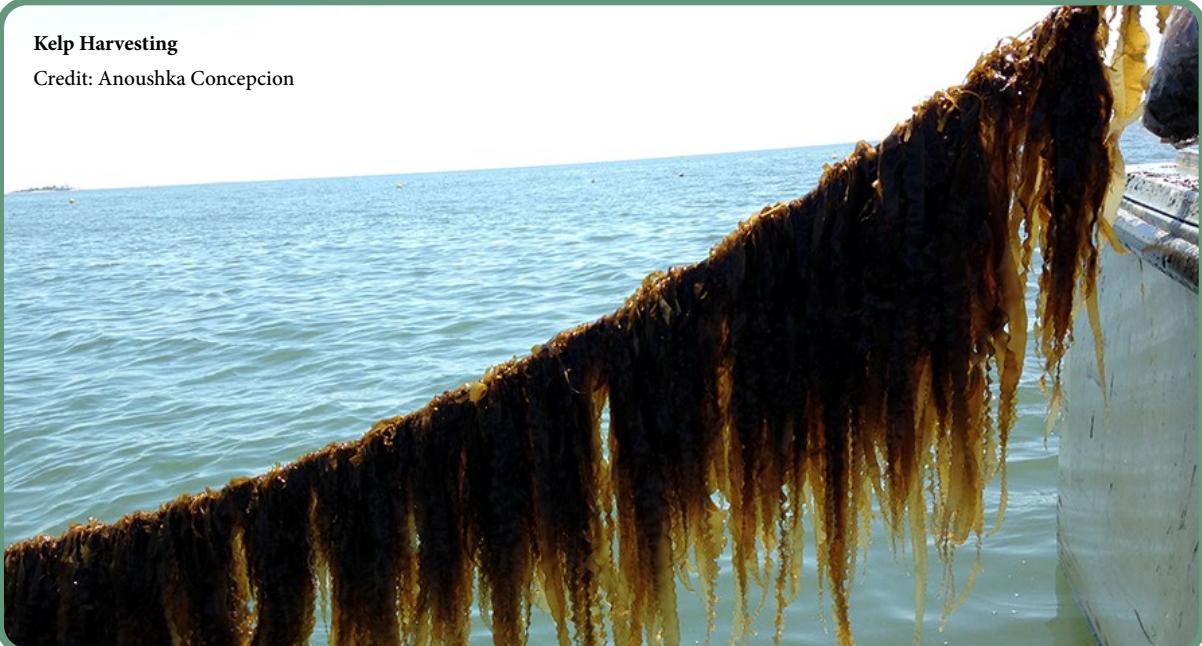
Food Safety Modernization Act Umbrella: Preventive Controls for Human Foods Regulation

| Preventive Controls for Human Foods (PCHF) Regulation (Access Here) | | | | | | | |
|---|--|--|---|---|--|---|---|
| Subparts | A | B | C | D | E | F | G |
| General Provisions | Current Good Manufacturing Practices | Hazard Analysis and Risk-Based Preventive Controls | Modified Requirements (<i>for qualified facilities</i>) | Withdrawal of a Qualified Facility Exemption | Requirements Applying to Records that Must be Established and Maintained | Supply-Chain Program | |
| Description | Provides an overview of the regulation, definitions of terms used, exemptions and training requirements. | Outlines general best practices for ensuring facilities/operations operate in a sanitary manner. | Covers the requirements of the food safety plan required to prevent or eliminate significant food safety hazards. | Modified requirements that must be met by qualified facilities since they are exempt from Subparts C and G. | Outlines instances where facilities/operations may lose their qualified facility status and the process for withdrawal of this status. | Covers general recordkeeping requirements | Outlines the required supply chain program for any preventive controls identified as necessary for products/ingredients being received. |

Qualified Facilities ① are exempt from subparts C and G but still subject to subparts A, B, D, E, and F. These subparts cover the Good Manufacturing Practices, which are required of all food facilities/operations and outline the modified requirements and record requirements still necessary for qualified facilities. A facility that meets the definition of qualified facility must submit a form to the FDA attesting to its status as a qualified facility. [See page 7 for more information about qualified facilities ↓.](#)

Kelp Harvesting

Credit: Anoushka Concepcion



Exempt Facilities/Operations and Farms

Seaweed operations are not subject to [the PCHF requirements](#) of the PCHF regulation if they meet the definition of a **Farm** ① or a **Qualified Facility** ①. The Farm exemption is based on the type of product the seaweed operation is producing. The Qualified Facility exemption is based on the monetary value of seaweed products sold by the operation. In the following section of the guide the exemptions for Farms and Qualified Facilities will be explained.

| | | |
|-----------------------------|---|---|
| Farms | Exempt based on the <i>type</i> of seaweed product produced. | Not subject to FSMA. |
| Qualified Facilities | Exempt if a very small business or based on the monetary value (< \$500,000/year for 3 years) of products sold. | Subject to FSMA, but exempt from certain PCHF requirements. |

Exemption #1: Farms

FSMA's requirements only apply to Facilities. Farms are not subject to the PCHF requirements in the PCHF regulation. How do we know if a seaweed operation is a Farm?

A **Farm** is defined as an operation that grows and harvests crops, raises animals (including seafood), or a combination of these activities. In addition, a Farm can also be an operation that packs or holds a **raw agricultural commodity** ①. Generally, an operation does not qualify as a Farm if it engages in manufacturing or processing activities.

Note: Since seaweed is a raw agricultural commodity, seaweed operations that are only producing raw seaweed fit within the definition of a Farm and are exempt from FSMA.

However, there are a few manufacturing/processing activities that an operation can engage in without losing its classification as a Farm. These activities include drying or dehydrating a raw agricultural commodity to create a distinct product, and packaging and labeling that product. However, no other manufacturing or processing activity may occur, such as slicing the raw agricultural commodity.

Example: *A Farm that dries seaweed, a raw agricultural commodity, would remain within the definition of a Farm as long as they are also not cutting or producing a value-added product (i.e. salsa).*

Farms do not need to register with the FDA or comply with PCHF. However, Farms must ensure they are not misbranding or [adulterating](#) their seaweed products in compliance with the [FDCA prohibition on misbranded or adulterated food](#).

Farms are subject to state regulation and must comply with any requirements or regulations that the state may implement. For instance, some states require seaweed operations that meet the definition of a Farm to prepare Seaweed HACCP plans.

If a seaweed operation produces both a raw agricultural commodity AND other seaweed products that fit under the definition of processed foods (i.e. cutting, canning, cooking, blanching, freezing or milling), it will meet the definition of a **Mixed-Type Facility** ①.

Note: Activities within the definition of a Farm conducted by a Mixed-Type Facility are not subject to the requirements of the PCHF regulation. However, these seaweed operations must register with the FDA and comply with PCHF for their processed food activities, but may be exempt from certain PCHF requirements if they meet the requirements of a Qualified Facility.

Exemption #2: Qualified Facility

Since the majority of seaweed operations in the United States are very small businesses, most meet the definition of a Qualified Facility. There are two ways to meet the definition of a **Qualified Facility** ①.

Option #1: Be a “very small business” - a business that grossed less than \$1 million a year for the previous three years in its sales of human food, including food it held for a fee.

Example 1: XYZ Seaweed Company has never sold more than \$800,000 worth of product per year thus qualifies as a very small business and is a Qualified Facility.

Example 2: Sea Food, Co. sells \$1 million worth of raw kelp, and \$200,000 worth of processed seaweed patties. Sea Food, Co. is NOT a Qualified Facility.

Example 3: Food From the Sea Inc. sells \$1.5 million worth of shellfish and \$200,000 worth of processed seaweed patties. Food from the Sea Inc. is NOT a Qualified Facility.

Option #2: This option is based on direct sales to consumers and other “qualified end users,” which includes restaurants and retail food establishments in the same state or within 275 miles that sell food directly to consumers. To meet this requirement, the value of the food sold to consumers and other qualified end users in the previous three years must be greater than the value of the food sold to other purchasers and less than \$500,000 per year.

Example: XYZ Seaweed Company sells \$400,000 worth of its blanched kelp to restaurants in town. This is a Qualified Facility because all their products are being sold to a qualified end user (restaurant within 275 miles) and less than \$500,000.

The table below lists the compliance requirements for different types of seaweed operations under the regulations: Farms, Facilities, Qualified Facilities, and Mixed-Type Facilities. Where “Yes” indicates that the entity must comply and “No” indicates that compliance is not required.

| Operation Type | Registration | Subpart A General Provisions | Subpart B Current Good Manufacturing Practices | Subpart C Hazard Analysis/PC | Subpart D Modified Requirements (for qualified facilities) | Subpart E Withdrawal of a Qualified Facility Exemption | Subpart F Records | Subpart G Supply-Chain Program |
|---------------------|--------------|------------------------------|--|---|--|--|-------------------|----------------------------------|
| Farm | No | No | No | No | No | No | No | No |
| Facility | Yes | Yes | Yes | Yes | No | No | Yes | Yes |
| Qualified Facility | Yes | Yes | Yes | No | Yes | Yes, if losing Qualified Facility status | Yes | No |
| Mixed-Type Facility | Yes | Yes | Yes | Yes, unless a Qualified Facility, then follow Subpart D | Yes, if a Qualified Facility | Yes, if losing Qualified Facility status | Yes | Yes, unless a Qualified Facility |

Food Safety in Practice - Preventive Controls for Human Foods and Seafood HACCP

Modern food safety regulations, like the PCHF and Seafood HACCP Regulations, focus on preventive food safety programs that are designed to identify significant hazards and implement controls to prevent those hazards from occurring. These are known as preventive controls, which reduce the risk of foodborne illness, outbreaks and product recalls. While the basic premise and components are similar, the language or terminology used can sometimes vary between regulations governing food safety programs. This chart will explore the PCHF and Seafood HACCP regulation to highlight the similarities and slight differences between the two. If you are not already familiar with these two regulations you can follow the links to learn more about the [PCHF regulation](#) and [Seafood HACCP regulations](#).



The text in green highlights the differences between the two programs. Note that these requirements reflect federal requirements with regard to these food safety programs, some states may implement and enforce additional requirements.

| Element | <u>PCHF (21 CFR Part 117 Subpart C)</u> | <u>Seafood HACCP (21 CFR Part 123)</u> |
|-------------------------|--|---|
| Food Safety Plan | <p>The Preventive Controls for Human Foods (PCHF) regulation requires that all processors subject to the regulation develop “Food Safety Plans” to prevent potential hazards that are identified as significant, if any.</p> | <p>The Seafood HACCP regulation requires that all processors subject to the regulation develop “HACCP Plans” to prevent potential hazards that are identified as significant, if any.</p> |
| Note: | | <p><i>Both programs require preventive food safety plans be developed and implemented. The PCHF regulation requires a Food Safety Plan that includes written process, sanitation, and allergen controls (as applicable), while Seafood HACCP requires a HACCP Plan that outlines written process controls.</i></p> |
| Hazard Analysis | <p>A hazard analysis must be conducted, and documented (written), to identify known or reasonably foreseeable (potential) hazards to determine if preventive controls are required. Hazards which require preventive controls are considered significant. A hazard analysis must address the following:</p> <ul style="list-style-type: none"> • Biological Hazards • Chemical Hazards <ul style="list-style-type: none"> ◦ Radiological Hazards • Physical Hazards <p>This should include naturally occurring hazards, unintentionally introduced hazards, and hazards intentionally introduced for economic gain.</p> | <p>A hazard analysis must be conducted to identify any hazards that are reasonably likely to occur (significant) and to identify preventive measures that can be applied. The hazard analysis must address the following hazards for the product and the process:</p> <ul style="list-style-type: none"> • Biological Hazards • Chemical Hazards • Physical Hazards |
| Note: | | <p><i>Both programs require a hazard analysis be conducted to identify significant hazards that warrant controls, however, only PCHF requires that the analysis be written. PCHF also specifically references potential radiological hazards in addition to the biological, chemical, and physical hazards. While not explicitly mentioned in the Seafood HACCP regulation, operations should consider identifying and controlling all potential hazards that are significant in their product or processes. A big difference between PCHF and HACCP is the terminology used. Under PCHF potential hazards are called “known or reasonably foreseeable.” Significant hazards in the HACCP system are typically referred to as “reasonably likely to occur” and in the PCHF regulation as “hazards requiring preventive controls.”</i></p> |

| Element | PCHF (21 CFR Part 117 Subpart C) | Seafood HACCP (21 CFR Part 123) |
|---------------------|--|--|
| Preventive Controls | <p>Must have and implement controls for significant hazards (those requiring preventive controls) including:</p> <ul style="list-style-type: none"> • Process controls <ul style="list-style-type: none"> ◦ Implemented at points in the process identified as critical control points or CCPs • Sanitation controls • Food allergen controls • Supply-chain controls • Other controls, if identified | <p>Must have and implement controls for significant hazards (reasonably likely to occur) including:</p> <ul style="list-style-type: none"> • Process controls <ul style="list-style-type: none"> ◦ Implemented at points in the process identified as critical control points or CCPs |
| Note: | | <i>Both programs require controls to be developed and implemented to prevent any significant hazards identified. While Seafood HACCP only requires process controls, PCHF specifically calls out many other preventive control categories that must be addressed.</i> |
| Process Controls | Parameters and maximum or minimum values must be identified for each of the process controls identified as necessary to control a significant hazard. Parameters and values can include observations or maximum/minimum values for certain parameters (i.e., temperature, time, acidity, absence/presence of ice, etc.). | Critical limits must be identified for each of the process controls identified as necessary to control a significant hazard. Critical limits are observations or maximum/minimum values for certain parameters (i.e., temperature, time, acidity, absence/presence of ice, etc.). |
| Note: | | <i>The requirements for this are nearly identical in the two programs but the language/terms used are different. The parameter and minimum/maximum values mentioned in PCHF are equivalent to the critical limits discussed in Seafood HACCP.</i> |
| Monitoring | Preventive controls for all process, sanitation and allergen controls identified as necessary to prevent a significant hazard must be monitored to ensure the selected control parameters are being met. | All critical limits at each CCP identified for process controls must be monitored to ensure they are being met. |
| Note: | | <i>Both programs require monitoring of the controls that are put in place to prevent significant hazards identified through the hazard analysis. Since PCHF requires more than just process controls be addressed, there will likely be more monitoring associated with a PCHF food safety plan than a Seafood HACCP plan.</i> |

| Element | PCHF (21 CFR Part 117 Subpart C) | Seafood HACCP (21 CFR Part 123) |
|---|--|---|
| Corrective Actions and Corrections | <p>PCHF requires that corrective actions be taken if a preventive control is not properly implemented. A corrective action must be documented (written) and address the safety/ status of the product and how the process was corrected to prevent future deficiencies.</p> <p>Corrections are implemented to address deficiencies in the sanitation or allergen control programs and do not need to comply with the predetermined corrective action requirements if action is taken in a timely manner to identify and correct conditions and practices.</p> <p>Corrections can also be taken to address minor and isolated problems within a facility that do not impact product safety.</p> | <p>Seafood HACCP requires that corrective actions be taken whenever there is a deviation from a critical limit identified in an operation's HACCP plan. The corrective actions must address both the product and process. While predetermined written corrective actions are not required, if a corrective action becomes necessary and they are not predetermined, the corrective action procedures outlined in the regulation must be followed.</p> |
| Note: | | <p><i>The requirements are similar for each program, however, seafood HACCP does not require the corrective action to be predetermined and written in the HACCP Plan, while PCHF allows for corrections. Corrections are related to the sanitation and allergen controls and do not always warrant documentation or records. Consult with your regulators to determine when documentation of corrections is necessary.</i></p> |
| Verification Activities | <p>The PCHF regulation specifically requires, when necessary/relevant:</p> <ul style="list-style-type: none"> Preventive controls be scientifically validated to ensure they are adequate to control the hazard. Calibration of process monitoring equipment. Periodic product testing for pathogens or other hazards. Environmental monitoring for environmental pathogens when a ready-to-eat food is exposed to the environment prior to packaging. Monitoring and corrective action record review within seven days. All others within a reasonable time. Food Safety plan re-analysis at least every three years OR whenever there is a change in the facility/operation or process; a new potential hazard to consider; or the occurrence of a food safety issue. | <p>The Seafood HACCP regulation specifically requires, when necessary/relevant:</p> <ul style="list-style-type: none"> Review of consumer complaints that relate to a food safety hazard to determine if adjustments need to be made at a CCP or reveal the existence of an unidentified CCP. Calibration of process monitoring equipment. Periodic product testing for pathogens or other hazards. Monitoring and corrective action record review within seven days. All others within a reasonable time. HACCP plan reassessment at least once a year and whenever changes occur in the product or process. |
| Note: | | <p><i>While the verification activities are very similar, the PCHF regulation more explicitly outlines specific practices that might be necessary for verification of an effective food safety plan. While not specifically addressed under the Seafood HACCP regulation some practices, like validation studies and environmental monitoring, may still be necessary to effectively control and prevent potential hazards in some products.</i></p> |

| Element | PCHF (21 CFR Part 117 Subpart C) | Seafood HACCP (21 CFR Part 123) |
|--------------------|--|--|
| Records | <p>The PCHF regulation requires that records be maintained of all preventive controls in place. This includes process controls, allergen controls, sanitation controls, and supply chain controls. All records must be maintained for 2 years.</p> | <p>The Seafood HACCP regulation requires that records be maintained of all preventive process controls in place. Records must be maintained for 1 year for refrigerated products and 2 years for frozen, preserved, or shelf-stable products.</p> |
| Note: | | <p><i>Both programs require records be kept of all required preventive controls but PCHF specifically requires more broad controls be included in the food safety plan, not just the process controls, which are the only ones required in a HACCP plan. The PCHF regulation requires all records be retained for two years while HACCP allows records for fresh products to be discarded after 1 year.</i></p> |
| Recall Plan | <p>Whenever a hazard is identified as needing preventive control(s), a recall plan must be in place to ensure the food can be quickly removed from commerce if the control(s) fail.</p> | <p>The Seafood HACCP regulation does not require a written recall plan be developed as part of the HACCP plan.</p> |
| Note: | | <p><i>A major difference between these two programs is that the PCHF regulation requires a written recall plan whenever a hazard is identified that requires a preventive control. The Seafood HACCP plan does not require a recall plan.</i></p> |
| Training | <p>The development of a PCHF food safety plan, validation, re-analysis and record review must be performed by a trained or experienced individual called a Preventive Controls Qualified Individual (PCQI).</p> | <p>The development of a seafood HACCP plan, reassessment, and record review must be performed by an individual with relevant experience or trained in the principles of HACCP.</p> |
| Note: | | <p><i>Both programs required a trained or experienced individual to develop, re-assess/analyze, and review records of the plans. The individual can either complete a standardized training or meet the requirement with adequate on the job experience. Whether regulated under Seafood HACCP or PCHF all personnel within a facility must be trained to do the jobs they are assigned. This does not need to be a formal outside training but training records must be maintained as per 21 CFR Subpart A Part 117.4:</i></p> <p>PCHF - https://www.ifsh.iit.edu/fspca HACCP - https://www.afdo.org/training/sha</p> |

| Element | PCHF (21 CFR Part 117 Subpart C) | Seafood HACCP (21 CFR Part 123) |
|--|--|---|
| Importing | <p>Those importing foods (Importers) subject to the PCHF regulation must be in compliance with the importer verification requirements outlined in subpart G of the regulation (CFR part 117 subpart G) or the foreign supplier verification program (FSVP, 21 CFR Part 1, subpart L) regulation. These regulations require US importers to verify their foreign suppliers follow food safety standards equivalent to the standards established by the FDA.</p> | <p>Those importing seafoods are subject to the Seafood HACCP regulation importer verification requirements outlined in CFR part 123.12. This part of the regulation requires US importers to verify their foreign suppliers follow food safety standards equivalent to the standards established by the FDA.</p> |
| Note: | | <p><i>While both regulations require importers to verify the food entering US commerce is in compliance with current US food safety standards, the verification programs required by each regulation vary slightly. The importer verification (21 CFR 117 subpart G) and foreign supplier verification (FSVP 21 CFR 1 Subpart L) programs require importers to conduct a hazard analysis, identify significant hazards and evaluate whether or not the foreign supplier is controlling those hazards, along with additional requirements. Seafood HACCP (21 CFR 123.12) requires importers to identify and implement written verification procedures, and take affirmative steps, which are outlined in the regulation.</i></p> |
| Current Good Manufacturing Practices (cGMP) | <p>The PCHF regulation requires all wholesale food producers to be in compliance with the current Good Manufacturing Practices (cGMPs) in subpart B of the regulation regardless of exempt status.</p> | <p>The Seafood HACCP regulation requires all wholesale seafood producers to be in compliance with the cGMPs.</p> |
| Note: | | <p><i>Regardless of exempt status and which regulation you are operating under at the state level, all processors are expected to follow the cGMP's in subpart B of Title 21 CFR Part 117.</i></p> |
| Sanitation Practices | <p>The PCHF regulation requires that any hazards with sanitation preventive controls identified in the hazard analysis (i.e. to prevent/control environmental pathogen contamination or allergen cross-contact) are controlled through a written sanitation and/or allergen control plan as part of the facility's/ operation's food safety plan.</p> | <p>The Seafood HACCP regulation does not require, but allows, sanitation preventive controls for hazards such as contamination with environmental pathogens and allergen cross-contact to be included in a HACCP plan. They can be controlled separately through a facility's/operation's sanitation control program, which does not have to be written. The regulation does require seafood processors to monitor 8 key sanitation practices derived from the cGMPs and keep records of this monitoring.</p> |
| Note: | | <p><i>The PCHF regulation requires that if a hazard needs a sanitation preventive control to control it, the processor must have and implement written sanitation procedures as part of their food safety plan. The Seafood HACCP regulation does not require sanitation preventive controls be written into their HACCP plan, however it does require processors to monitor 8 key areas of sanitation (derived from the cGMPs) and maintain records of that monitoring.</i></p> |

| Element | PCHF (21 CFR Part 117 Subpart C) | Seafood HACCP (21 CFR Part 123) |
|---------------------|---|--|
| Supply-Chain | <p>The PCHF regulation 21 CFR Part 117 Subpart G, requires food processors to have and implement supply-chain controls for identified hazards that requires a preventive control. These controls require the processor to obtain supporting documentation from their supplier to demonstrate the supplier properly managed the identified hazard.</p> | <p>The Seafood HACCP regulation does not require facilities/operations to develop supply-chain programs specifically, but does require that all hazards, including those that can occur before, during, and after harvest/transport outside of the facility/operation be assessed and controlled when significant.</p> |
| Note: | | <p><i>While the Seafood HACCP regulation does not specifically require supply-chain programs be developed, facilities/operations are required to identify significant hazards that could occur outside of the facility/operation during transit to the facility/operation. Thus, even though a specific supply-chain program is not required, seafood processors are responsible for ensuring that significant hazards are controlled while product(s) are in transit to their facilities. The PCHF regulation has more strict requirements for how a supply-chain program is run.</i></p> |



Transitioning from HACCP to PCHF

For those operating under a HACCP system on the state level, or selecting to operate under the HACCP system as a qualified facility, it is important to understand what that means if one no longer meets the exemption requirements of a qualified facility, and is then subject to the full extent of the PCHF regulation. Qualified facilities must [submit an annual attestation](#) that a facility/operation meets the requirements of a qualified facility by July 1st of each year. If a facility/operation no longer meets the criteria of a qualified facility, they will have until December 31st of that calendar year to comply with the full extent of the PCHF regulation. Those transitioning from a HACCP based system to the PCHF system will need to:

| ✓ | HACCP to PCHF Transition Checklist |
|---|---|
| | Familiarize yourself with the PCHF regulation and its requirements. |
| | To meet the requirements of being a preventive control qualified individual some staff will need training on how to effectively develop, maintain, and implement a risk based preventive controls food safety plan in accordance with the PCHF regulation. For those who do not already have relevant experience in developing and implementing food safety plans, they should take a training that is at least equivalent to the Food Safety Preventive Controls Alliance (FSPCA) course . <i>Note: The Seafood HACCP training does not satisfy the PCHF training requirements.</i> |
| | Ensure you have a written hazard analysis that outlines process, sanitation, allergen and other hazards (significant) that require a preventive control. |
| | Ensure you have and implement written preventive control programs for those hazards identified as requiring a preventive control, including process, sanitation, allergen, supply-chain and other programs as necessary. Note that if you have a Seafood HACCP plan, it can be used as a “Process Control Plan” under the Food Safety Plan. |
| | Ensure that process, sanitation, allergen, supply-chain and other necessary preventive control programs are written and include procedures, as applicable, for monitoring (except for supply-chain), corrective action, verification, validation (process controls only) and records. <i>Note: Pre-determined corrective actions are required in PCHF food safety plans.</i> |
| | Become familiar with the preventive control program requirements and verification and validation activities to ensure they meet the requirements of the PCHF regulation, which could warrant additional testing or environmental monitoring for ready-to-eat foods that could be exposed to environmental pathogens prior to packaging. |
| | Make sure you have a written recall plan if you identified any hazards that require a preventive control. |
| | Retrain all personnel to ensure they are familiar with the updated food safety plan and any new expectations for ensuring compliance, including when to conduct and document corrections for sanitation and allergen control program deficiencies. Records for trainings should be maintained as required by 21 CFR 117 Subpart C. |
| | Adjust record retention practices to ensure all records are maintained for 2 years. |
| | Confirm your food safety plan contains all required elements including a hazard analysis, any preventive control programs necessary and a recall plan if a hazard has been identified as needing a preventive control. |

This checklist was created with the best available knowledge at the time of publication and may not be represent the needs of all facilities. Be sure to review federal and state regulations and work with your agencies to ensure all requirements are met.