Seaweed Food Safety Guidance

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A Note to Users

This document was developed by a team of food safety experts from across the United States. It provides recommended **guidelines** for food safety practices aimed at minimizing biological, chemical, and physical hazards associated with production, storage, handling, processing, and transportation of seaweed intended for human consumption.

Please note that **this is not a regulatory document**. The authors do not assume responsibility for ensuring regulatory compliance or legal protection. Adherence to the recommendations provided does not guarantee compliance with local, state, or federal laws and regulations. It is the sole responsibility of the user to determine the applicability of these guidelines to their specific operations and to ensure that their procedures meet all current regulatory requirements.

While this guide offers examples and general guidance on how various hazards may be controlled, it is not exhaustive. Users can develop their own control methods based on scientific literature, in-house research, or historical experience. Compliance with the recommendations in this document is not required, and users may choose alternative approaches that are appropriate for their operations and meet applicable regulatory standards.

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Dr. Michael Ciaramella is the Seafood Safety and Technology Specialist with New York Sea Grant and Cornell Cooperative Extension, a position he has held since 2015. He earned his Bachelor of Science in Biology from Rider University, Master of Science in Aquatic Health Sciences from the University of Prince Edward Island, and Ph.D. in Food Science and Technology from Mississippi State University. Dr. Ciaramella provides technical expertise in seafood and seaweed safety, working with industry, regulators, and food professionals to support safe production and processing practices. He manages components of a national seafood safety training program, facilitates statewide cross-sector collaboration, and develops science-based resources to advance domestic seaweed production and food safety.

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Dr. Jennifer Perry specializes in microbial food safety and processing, with research focused on identifying sources of contamination and developing intervention strategies to reduce spoilage and foodborne illness. Her work includes evaluating non-thermal technologies, biocontrol methods, and fermentation processes to enhance food safety. Dr. Perry has contributed to advancing understanding of microbial risks in seaweed and other raw foods, supporting the development of science-based safety practices for emerging food sectors.

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Dr. Amanda Shore is a microbiologist specializing in marine systems and microbial ecology. Her research explores host-pathogen interactions, microbial community dynamics, and environmental stressors in aquatic ecosystems. With a background in marine microbiology and coral disease ecology, Dr. Shore brings valuable expertise to understanding microbial risks and safety considerations in seaweed production and processing. Dr. Shore holds a Bachelor of Science in Microbiology from the University of Florida and a Ph.D. in Microbiology with a specialization in Marine Biology from the University of Hawai'i at Manoa.

Anoushka Concepcion

Anoushka Concepcion served as an Associate Extension Educator with Connecticut Sea Grant and UConn's Department of Extension, where she led programming to support marine aquaculture stakeholders, including the emerging seaweed industry. Her work focused on developing guidance for seaweed safety, facilitating industry-regulator collaboration, and addressing human health hazards in seaweed production and processing. She also led the National Seaweed Hub and contributed to global initiatives like the Global Seaweed Coalition. Anoushka holds a Bachelor of Science degree in Marine Biology from UNC Wilmington, and a Master of Science degree from the University of Rhode Island.

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Dr. Indu Upadhyaya is a food safety extension specialist with expertise in microbiology, poultry health, and produce safety. She leads outreach and applied research programs at the University of Connecticut, focusing on HACCP training, biosecurity, and product safety. With a background in veterinary science and a Ph.D. in Animal Science (Food Microbiology concentration) from UConn, Dr. Upadhyaya contributes to national efforts to improve food safety practices, including emerging sectors like seaweed production.

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Zachary Gordon is an aquaculture extension educator with Connecticut Sea Grant, specializing in seaweed aquaculture. Since joining the program in 2021, he has led initiatives to support the growth and safety of the seaweed industry, including organizing the annual seaweed aquaculture meeting, serving as a Seafood HACCP trainer, and managing the seaweed mobile laboratory. Zachary holds a Bachelor of Arts in Environmental Science from Skidmore College and a Professional Science Master's in Ocean Food Systems from the University of New England.

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Dr. Brian Himelbloom is a retired seafood microbiologist with over three decades of experience in food safety research and education. He earned a Master of Science in Food Science from Louisiana State University, a Ph.D. in Food Science (Microbiology minor) from North Carolina State University, a post doctorate in the Department of Microbiology at the University of Massachusetts Amherst, and a faculty sabbatical in the Department of Seafood Research at the Technical University of Denmark, in Lyngby. At the University of Alaska Fairbanks' Kodiak Seafood and Marine Science Center (1987-2017), he focused on microbial contamination, spoilage prevention, pathogen control, and seafood quality assurance. In 2014, he earned the Certified Food Scientist (C.F.S.) credential and has maintained it. For the past ten years and currently, he is one of two Alaska food processing authorities. His work supported Alaska's seafood industry through applied research, HACCP training, and outreach, and he continues to contribute to mariculture initiatives including seaweed safety. Last November, he began service on the Seafood Technical Committee for the Alaska Seafood Marketing Institute.

Seaweed Food Safety Guidance Reviewers

We extend our sincere gratitude to everyone who took the time to review and provide thoughtful feedback on the seaweed food safety guidance document. Your expertise, insights, and careful attention to detail were instrumental in refining this extensive resource. Your contributions have helped ensure that the guidance is both scientifically sound and practically useful for stakeholders across the seaweed industry. Thank you for your commitment to advancing food safety and supporting the development of this important work.

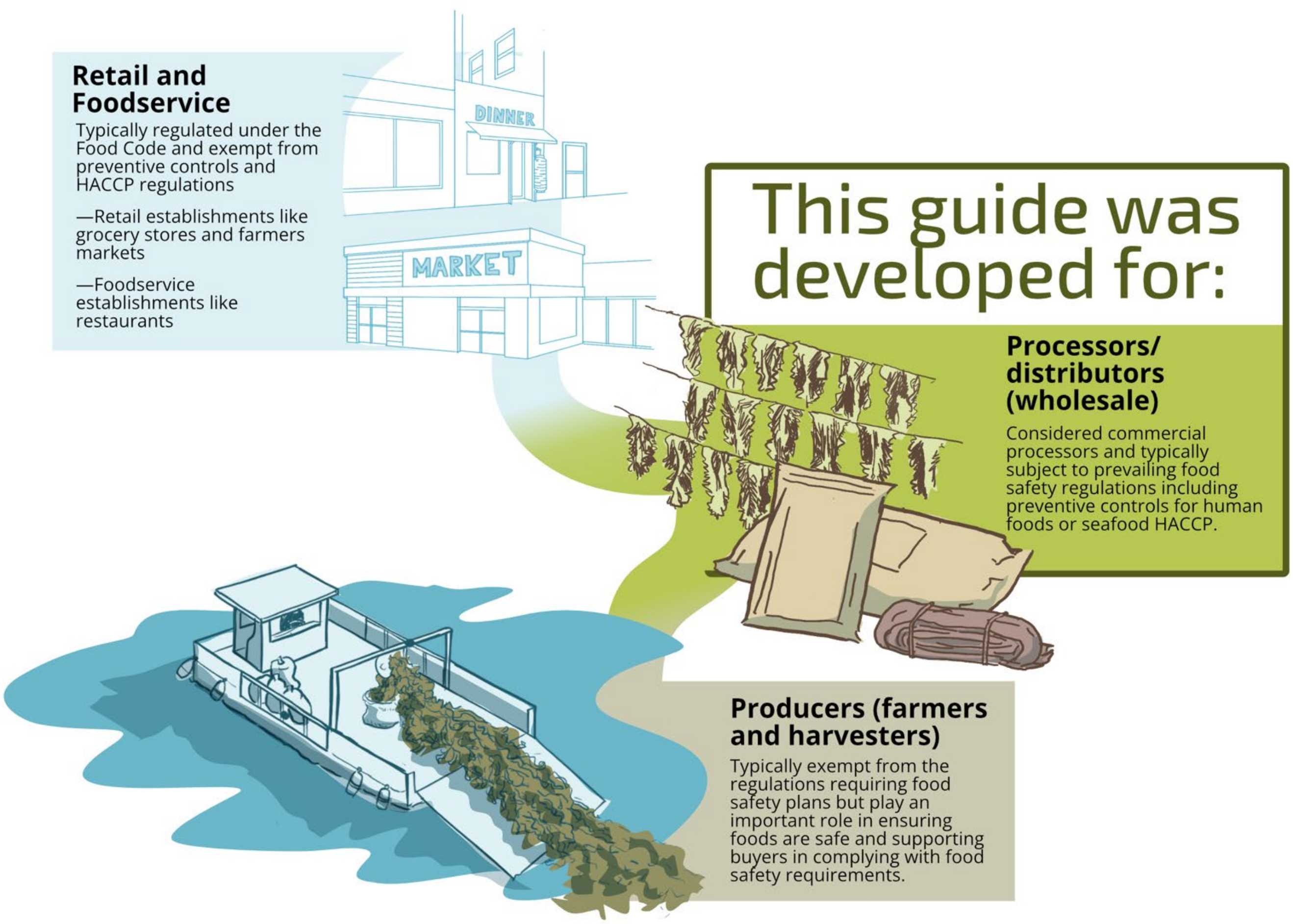
Dr. Carrie Byron, Eugene Evans, Dr. Evelyn Watts, Samantha Garwin, Kim Hoffmann, Melissa Good, Nicole Richard, Virginia Ng, Dr. Katheryn Parraga-Estrada, Dr. Brianna Shaughnessy, and *Steve Eddy*

We also extend our sincere gratitude to the editors who generously contributed their expertise to this work but preferred to remain unnamed.

Guide Purpose

Individuals involved in the sale of seaweed should familiarize themselves with the potential hazards linked to seaweed and seaweed products. This ensures they can identify risks that may impact their products and implement adequate practices and controls to mitigate these hazards effectively.

This guide serves as a resource for individuals involved in seaweed processing, particularly those who are responsible for developing and implementing preventive controls for food safety or HACCP plans. It is intended primarily for processors engaged in wholesale sale and distribution, who must comply with current food safety regulations, including preventive controls for human foods and seafood HACCP.



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Chapter 1 Introduction and Background

Macroalgae, commonly referred to as seaweeds, are a group of photosynthetic organisms found in marine and freshwater ecosystems. They are diverse in species and applications, ranging from human food and animal feed uses to non-food applications like biofuel, fertilizer, pharmaceutical products, cosmetics, and more. Seaweeds are classified into three major groups: brown, red, and green seaweeds. Most seaweed species contain a blade—or grouping of blades—that resembles leaves, a stipe that resembles a plant stem, and a holdfast that attaches the seaweed to the water bottom, or another hard surface underwater (Figure 1-1). Brown (e.g., kelp, wakame, kombu) and red (e.g., Irish moss, dulse, nori) species of seaweed account for the majority of global seaweed production. In 2019, they accounted for 47.3% and 52.6% of worldwide production, respectively, while green species (e.g., sea lettuce) accounted for about 0.05% (Cai et al., 2021).

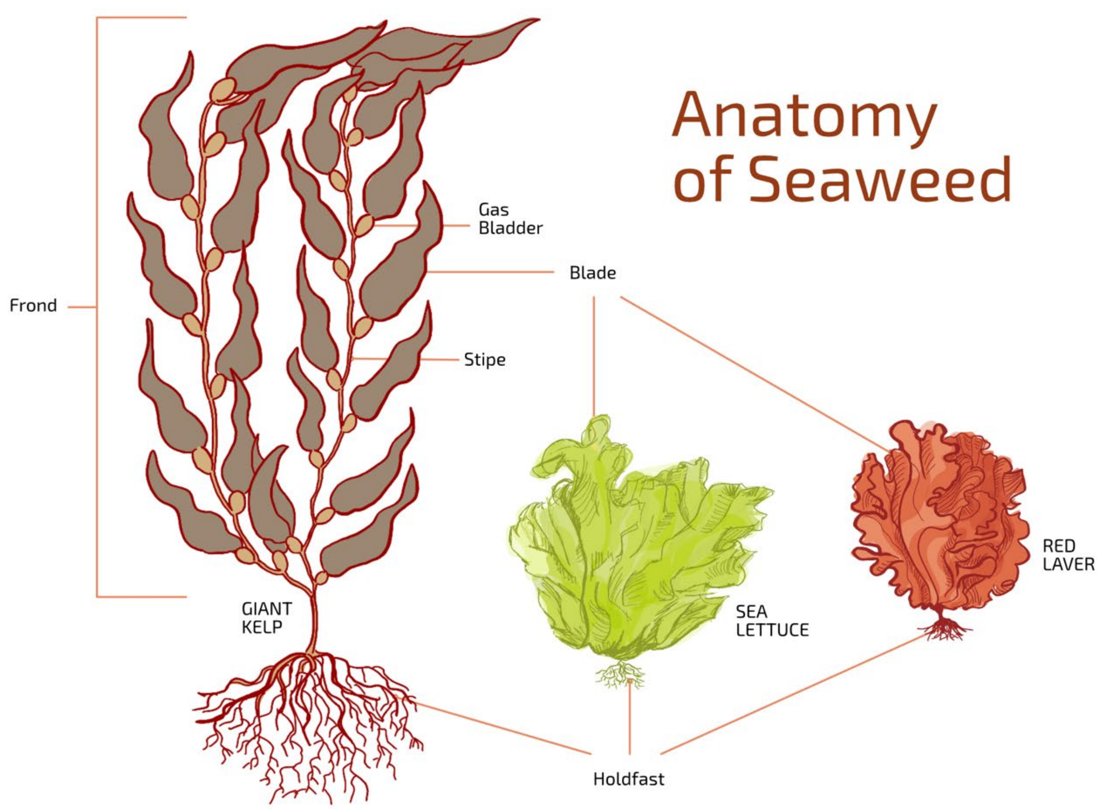

Figure 1-1: Anatomy of Seaweed

Seaweeds have long been a staple food in many Asian countries and are used in a variety of dishes such as sushi, salads, and dried snacks. Seaweeds provide a wide range of nutritional and health benefits. Many seaweeds are marketed as a “superfood” because they contain dietary fiber, omega-3 fatty acids, protein, essential amino acids, antioxidants, calcium, iodine, magnesium, and vitamins A, B, C, and E (Fleurence, 1999; Fujiwara-Arasaki et al., 1984; MacArtain et al., 2007; Monteiro et al., 2022; Rajapakse & Kim, 2011). Because of these health benefits, there are growing efforts to add more seaweed to American diets. This has led to more seaweed-based products in stores, new seaweed dishes on restaurant menus, and cookbooks focused on seaweed. The rising demand is driven by more consumer awareness of seaweed’s nutritional benefits, its environmental sustainability, and how versatile it is as a culinary ingredient. This guide was developed to inform the production of seaweed-based food products that are safe for human consumption.

Like all foods, seaweed products may carry food safety risks. But because seaweeds do not fit the defined food categories of seafood or produce, there are no consistent guidelines or standards for evaluating and controlling potential food safety hazards in seaweeds. As more U.S. consumers seek out seaweed and seaweed products, experts have raised concerns about the potential adverse health impacts and risks associated with excessive and prolonged consumption (Huang et al., 2025). Given the growing demand for seaweeds in the U.S. and the expansion of domestic seaweed aquaculture (farming), it is important to create clear national guidance. This will help identify and mitigate significant—either “reasonably likely to occur” (HACCP) or “hazard requiring a preventive control” (PCHF)—seaweed food safety hazards to ensure continued growth and access to a highly nutritious food commodity in U.S. markets.

The United States imports about 95% of the seaweed it consumes (Piconi et al., 2020). While detailed data on U.S. seaweed consumption and demand is limited, the broader commercial seaweed market can provide insights. In 2023, the entire North American commercial seaweed market—including edible and non-edible seaweeds; domestic and imported—valued approximately $2.15 billion. It is projected to grow to approximately $4.30 billion by 2032 (NACS, 2025). Globally, the market for edible seaweeds is also growing—from approximately $16 billion in 2023 to a projected $29 billion by 2032 (Gupta, 2025).

As seaweed-based foods gain popularity in North America, market demand is expected to continue rising. In the U.S., seaweed has traditionally been harvested from the wild, but this sector has remained relatively small compared to global production. With increasing demand, wild harvesting alone is no longer sufficient to meet market needs sustainably (Hanisak, 1998). As a result, seaweed farming is expanding rapidly. Currently, 99.8% of global seaweed aquaculture occurs in China, Korea, Indonesia, and Japan (FAO, 2021). Domestically, seaweed is now one of the fastest-growing aquaculture sectors.

Seaweed farming in the U.S. has seen substantial growth in recent years. In Alaska, production increased from 19,590 pounds in 2017 to 155,732 pounds in 2024, with a peak harvest of

872,288 pounds in 2022 (Alaska Department of Fish & Game, 2024). Maine has also experienced rapid expansion, growing from 53,500 pounds in 2018 to over 1.3 million pounds harvested by the state's largest producer in 2024 (Global Seafood Alliance, 2024). In Connecticut, where seaweed farming began in 2012, production increased tenfold by 2024 (Getchis et al., 2024). Other states—including Washington, Oregon, Rhode Island, and New York—are also developing seaweed farming industries, contributing to the sector's national growth.

Seaweed Food Uses

Seaweeds are used in many different industries , including food and medicine (pharmaceuticals) (Kim & Wijesekara, 2010; Ngo & Kim, 2013), cosmetics (Khan et al., 2022; McHugh, 2003; Pangestuti & Kim, 2011), bioenergy (Kraan, 2010), biodegradable materials (Morone et al., 2020), agriculture (Ali et al., 2021; Craigie, 2011; Rathore et al., 2009), wastewater treatment (Chung et al., 2011; Fourest & Volesky, 1997), and more. While these applications are important, this guide focuses on seaweeds used in food products or for human consumption.

It is also important to understand that seaweed can come in many marketable forms. It can be sold fresh, dried, or processed into a wide range of value-added products and ingredients. Below are some of the most common ways seaweeds are processed and used in food products. This list is not complete, and food safety risks can vary greatly depending on the seaweed species, how it's processed, and end use.

- **Fresh Raw:** Many seaweeds can be consumed straight from the water without processing. This is desirable for direct sale to high-end restaurants and consumers. Fresh seaweed is commonly consumed raw and unprocessed, and used in a variety of dishes (e.g., seaweed salads).
- **Dried:** Drying seaweed increases its shelf life for easier transport and storage (Santhoshkumar et al., 2023). There are many uses for dried seaweed including seasoning mixes, soup stocks, nutritional additives, or direct consumption (e.g., seaweed snacks). Seaweeds are commonly dried with and without pretreatment (e.g., soaking, blanching, etc.).
    - *Air dried:* Some seaweeds are dried at ambient or lower temperatures in the sun or in greenhouses to preserve nutrients and flavor.
    - *Mechanically dried:* Some seaweeds are dried in various types of ovens, freeze dryers, or dehydrators to better control temperature, time, and consistency in the drying process.
- **Blanched:** Blanching involves boiling seaweed in water or exposing it to steam for a short period of time before rapidly cooling. Blanching can stabilize the seaweed for

longer shelf life, especially when paired with other preservation methods (e.g., freezing or drying). It can also give some seaweeds a more vibrant color, reduce strong flavors, and reduce unwanted components (Akomea-Frempong et al., 2021).

- **Fermented, Canned, and Pickled:** Fermenting, canning, or pickling seaweed with other ingredients is a common practice with some species. These processes break down polysaccharides and proteins to make them more digestible, create novel flavors, and create shelf stable products (Maiorano et al., 2022; Pérez-Lloréns, 2019). Fermenting seaweed has also been investigated as a non-dairy based probiotic, and to help reduce heavy metals content in seaweed (Akomea-Frempong et al., 2021).
- **Frozen:** Freezing can be used as a stabilization step either before or after processing to help extend product shelf life. Freezing has been shown to preserve taste, texture, and nutritional value more effectively than other stabilization methods (Choi et al., 2012).
- **Extracts:** Components of seaweeds can be added to foods, pharmaceuticals and biomaterials as a thickening agent or source of nutrients. One common example is Carrageenan, which is used in a wide range of food and non-food products (e.g., ice cream, sauces, plant-based milks, processed meats, toothpaste, cosmetics, and more). In 2021 the U.S. imported approximately 11,000 tons of Carrageenan valued at $115 Million (Zhang et al., 2023).

Current Regulatory Guidelines for Potential Food Safety Hazards in Seaweed

This section provides a brief overview of existing regulatory guidelines for seaweed harvest and processing:

International Guidelines: Food and Agriculture Organization (FAO) and World Health Organization (WHO)

The Food and Agriculture Organization (FAO) and World Health Organization (WHO) released a *Report of the Expert Meeting on Food Safety for Seaweed* (FAO & WHO, 2022), which offers international recommendations for managing hazards in seaweed production. These include monitoring for microbial, physical, and chemical hazards.

However, the international community lacks consensus on the regulatory framework for seaweeds related to certain food safety concerns. For instance, maximum allowable levels for heavy metals and iodine in seaweed food products vary widely—or are not determined—in different countries and for different product types (FAO & WHO, 2022; Huang et al., 2025).

U.S. Federal Regulatory Framework

In the United States, seaweeds intended for human consumption are regulated by the U.S. Food and Drug Administration (FDA) under the following Acts:

1. **The Federal Food, Drug, and Cosmetic Act (FDCA)** prohibits the sale of adulterated or misbranded food. Adulterated foods are any foods that are contaminated, unsafe, or produced under unsanitary conditions.
2. **The Food Safety Modernization Act (FSMA)**, specifically the Preventive Controls for Human Food Rule (PCHF), which applies to domestic and foreign facilities that manufacture, process, pack, or hold human food, including seaweed for food use.

Seaweeds are not considered fish or fishery products and therefore are not federally regulated under the Seafood Hazard Analysis and Critical Control Points (HACCP) regulation (21 CFR Part 123). Seaweeds are also not considered "produce" as defined in the Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption (Produce Safety Rule, 21 CFR Part 112). Instead, unprocessed seaweeds are federally classified as a raw agricultural commodity (RAC) in their unprocessed whole form.

- **Unprocessed seaweed (RAC)** must comply with the general provisions of the FDCA.
- **Processed seaweed** falls under the *Preventative Controls for Human Food Rule (PCHF)*, unless a full or partial exemption applies. Regulatory requirements vary based on the size and type of establishment, the processing activities conducted, and the location of these activities.

More details on the current federal regulations related to seaweed are described in Chapter 2 of this guidance.

Some State-Specific Initiatives

Several states have developed their own approaches to seaweed regulation:

- **Alaska:** Seaweed farming and harvest activities are jointly managed by the Department of Fish and Game and the Department of Natural Resources. Harvested seaweed is regulated as a raw agricultural commodity (RAC) under Alaska's general food safety code.

- **Connecticut:** The Connecticut Department of Agriculture initiated a state-specific HACCP approach to identify and manage hazards associated with seaweed cultivation and processing in 2020 and updated the guidance in 2025 (Connecticut Department of Agriculture, 2025). These guidelines are limited to Connecticut, only apply to seaweed as a RAC, and do not address interstate seaweed trade or producers operating in other coastal states.

- **Hawaiʻi:** Wild seaweed harvesting is permitted by the Hawaii State Department of Land and Natural Resources. Aquaculture is regulated through the Animal Industry Division of the State Government, while the Food and Drug Branch of the Hawaii Department of Health oversees seaweed sales. No additional permits are required to sell.

- **Maine:** Seaweed is regulated by the Department of Marine Resources as seafood during cultivation and up to the point of harvest. After harvest, oversight shifts to the Maine Department of Agriculture, Conservation and Forestry, which regulates post-harvest handling, processing, distribution, and sale under produce regulations.

- **New York:** In New York, seaweeds for wholesale production are regulated by the NY State Department of Agriculture and Markets (NYS AGM). Facilities must follow GMPs (21 CFR 117 Subpart B; 1 NYCRR Subpart 261) and comply with the Preventive Controls for Human Food Rule (21 CFR Part 117). If exempt, NYS AGM recommends a HACCP plan to manage food safety hazards. Seaweed sold at restaurants or foodservice establishments is regulated by local health departments under the Food Code.

- **Other States:** States with burgeoning seaweed industries either have varied regulatory approaches or no formal seaweed-specific regulations in place.

Need for a Seaweed Food Safety Guide

Developing a Seaweed Food Safety Guide is important to support regulators, producers, processors, and retailers, in assessing and mitigating food safety risks associated with seaweed products in the U.S. market. A guide would help to build and maintain consumer confidence by promoting safe handling and processing practices.

As the seaweed aquaculture industry continues to expand in the U.S., it presents exciting opportunities for sustainable food production and economic growth. To fully realize this potential, a comprehensive hazard guidance document is needed to provide a clear framework for assessing hazards, ensuring product safety, and supporting compliance with existing food safety regulations.

Building on current guidelines and resources available in the U.S. and internationally, this guidance has been developed to support the seaweed industry—particularly seaweed marketed for human consumption. States that are developing or expanding their seaweed cultivation and processing sectors can tailor the document to reflect their unique species, environmental conditions, and regulatory frameworks. Serving as a flexible model, this guidance can promote consistency in evaluating and mitigating food safety hazards across regional and national markets—advancing growth and safeguarding consumer health.

How to Use the Guide

This guide follows the format of the FDA's *Fish and Fishery Products Hazards and Controls Guidance* and incorporates elements of *Preventive Controls for Human Foods (PCHF)*. It includes guidance on all species of seaweeds and seaweed products produced and consumed in the U.S. and all potential hazards related to those species and processes. Please note, guidance applies to the species and processes that you, the reader, are working with. The chapter outline below provides basic information on how to use the guide.

Chapter Outline

Chapters 2–3

These chapters provide preliminary information on current federal regulations related to seaweed food safety and general requirements for food processors to produce food safely that all seaweed processors should be familiar with.

Chapter 4

This chapter covers all potential food safety hazards that have been associated with edible seaweeds and seaweed products based on historical occurrence and scientific literature available at the time of publication. The tables within are divided into species related hazards and process related hazards. To determine the hazards that may be applicable to your operation, you must locate your species in Table 4-1 and the processes you plan to implement in Table 4-2. Any box with a check mark means that this is a potential hazard for your operation. Producers are responsible for determining whether that hazard is significant for their operation based on production practices, geography, species, etc. (see chapters 5–15).

Chapters 5–15

These chapters each cover a specific hazard identified in Chapter 4. Following the format of the FDA's *Fish and Fishery Products Hazards and Controls Guide*, a separate chapter (Chapter 12) is dedicated to Botulism. The chapters include an introduction to the hazard, guidance on how to determine if the hazard is significant for your operation, and what control strategies can be implemented to mitigate the hazard. If controls are warranted, the processor can select one or more controls from the options listed in the chapter and apply it to their operation.

Chapter 16

This chapter provides a summary of the guide as a whole and describes the current knowledge gaps. Research in these areas could inform more targeted and efficient food safety guidance.

Appendices A–F

These appendices give supplemental reference tables for specific hazards that may be helpful to readers in assessing risk.

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Chapter 2 Seaweed Regulations and General Guidance

Introduction

As mentioned in Chapter 1, seaweed has many uses. However, this chapter focuses solely on the regulation of seaweed as a human food on the federal level. Federal laws and regulations have specific definitions for certain terms that may differ from general understanding of these terms. These specific definitions will be noted and placed in **bold** in the chapter. A full list of federal definitions will be provided at the end of the chapter.

How the U.S. Food & Drug Administration (FDA) regulates seaweed as a human food source depends on whether the seaweed is in its raw, natural form or is a *processed food*. Specifically, the FDA considers seaweed to be a **raw agricultural commodity**, defined by federal law as "any food in its raw or natural state." (refer to USFDA regulation 21 U.S.C. § 321(r) for more information). Seaweed in its natural state is regulated under the Food, Drug, and Cosmetic Act (FDCA), which means for federally regulatory purposes only uncooked, unprocessed seaweed is considered "raw." While the FDCA or FDA regulations do not define what raw means, the FDCA does define what a *processed food* is. For example, dried or dehydrated seaweed is not considered raw, regardless of how the seaweed is dried or dehydrated.[1] Rather, dried or dehydrated seaweed falls under the definition of a *processed food*:

> "…any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling." 21 U.S.C. § 321(gg).

The FDA regulates processed seaweed under the following rules: FDCA, Food Safety Modernization Act (FSMA), and Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR Part 117 or PCHF Rule). This chapter will focus on the food safety requirements for raw, dried or dehydrated, and processed seaweed under the FDCA, FSMA, and 21 CFR Part 117.

As you read, please keep the following points in mind:

- Currently, there is very little federal guidance specific to seaweed when it comes to food safety regulations. The FDA has not issued any seaweed-specific guidance. However, they do classify seaweed as a **raw agricultural commodity**, which means that once seaweed is processed—such as dried, cut, or packaged—it becomes subject to the

[1] While "raw food" diets may consider dried seaweed that is dried below a certain temperature to be a "raw food", for federal regulatory purposes, dried seaweed is a processed food.

requirements of 21 CFR Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food. Because of this, this chapter will explain the key requirements under the FDCA, FSMA, and 21 CFR Part 117. However, it is still unclear exactly how the FDA will apply some of these regulations specifically to seaweed products.

- The FDA has indicated in correspondence with the authors that in the context of 21 CFR Part 117, there is no distinction between dried seaweed and dehydrated seaweed. However, *state regulators* may treat these types of seaweed differently. This underscores the importance of seaweed operations working with their applicable state regulators to understand any additional state requirements that go beyond how the FDA regulates seaweed under federal law.
- Under FDA regulations, raw seaweed is not subject to the requirements of 21 CFR Part 117. Similarly, farms that *dry or dehydrate* their own seaweed are also not subject to Part 117. This exemption is tied to how the FDA defines a "farm" under 21 CFR Part 117, which will be explained in more detail later in this chapter. Although dried or dehydrated seaweed meets the definition of a processed food, if the drying or dehydration is done by the farm itself, the product remains exempt from Part 117. However, both raw and farm-dried seaweed are still regulated under federal law, as they must comply with the requirements of the FDCA. If the drying or dehydration is performed by a *facility* other than the farm, the seaweed is considered subject to 21 CFR Part 117.
- Smaller seaweed operations that meet the FDA's definition of a "qualified facility" are subject to less strict requirements under 21 CFR Part 117. This chapter will explain what qualifies a business as a *qualified facility* and outline the specific reduced requirements later on.

States may choose to apply additional food safety rules to seaweed, particularly for products that are not covered by 21 CFR Part 117. For example, some states may require businesses that produce only raw seaweed to follow Seafood HACCP requirements. This highlights the importance of working closely with state regulators to ensure that seaweed operations understand and comply with both state and federal requirements. While this chapter will mention certain state-specific rules, these examples are not intended to cover all possible state regulations.

Finally, this chapter is not meant to serve as a detailed explanation of all the requirements under 21 CFR Part 117. For a more in-depth understanding of these regulations, readers should refer to other resources, such as the FDA's *Draft Guidance for Industry: Hazard Analysis and*

Risk-Based Preventive Controls for Human Food and the Preventive Controls Food Safety Alliance (FSPCA).

Food Safety Overview

As with all agricultural commodities, edible seaweed carries certain food safety risks that need to be managed. Federal and State agencies draft and enforce regulations to ensure this is done. In the United States, the FDA regulates the safety of raw, dried or dehydrated, and processed seaweed under the FDCA, FSMA, and 21 CFR Part 117.

Food, Drug, & Cosmetic Act (FD&C Act)

All seaweed intended for human consumption is regulated under the Food, Drug, & Cosmetic Act. This law prohibits the sale of food that is considered *adulterated* meaning it could be harmful or unsafe. Under the FD&C, food can be considered adulterated in several situations, such as:

- If it contains poisonous or deleterious (harmful) substances that could injure or make people sick, however, a food is not considered adulterated if the potentially harmful substance is not added to the food, and the amount is present at levels that are not generally harmful to health.
- If it contains unsafe substances, including added poisonous or deleterious (harmful) substances, pesticide chemical residues, unsafe food additives, and unapproved animal drugs.
- If the food is made from or contains rotten, decomposed, or otherwise spoiled material.
- If it is prepared, packed, or held in conditions that could lead to contamination or make it unsafe to eat.
- If it is held in a container that could make the food harmful. These rules apply to all seaweed sold as food in the U.S.

Food is also considered adulterated if it is transported in a way that does not comply with the regulations for sanitary transportation practices, which can be found at 21 CFR § 1.900-1.934. This standard could be important when considering the transportation of seaweed from the farm to a farmers market, restaurant, or a processor. For example, a processor may require a grower or wild harvester to use clean vehicles when transporting seaweed to drying areas, to keep the seaweed covered during transport, and follow other practices that help prevent contamination of the seaweed.

Food Safety Modernization Act (FSMA)

Congress passed FSMA in 2011 to improve how food safety is managed in the United States. The law is structured to prevent food safety issues before they occur, instead of reacting to problems after the fact. Under FSMA, the FDA has a greater responsibility to oversee food safety including a legal requirement to focus on prevention, mandatory inspections and testing, and stronger authority to respond to food safety risks. Since FSMA became law, the FDA has created seven major rules to implement and enforce the Act, including 21 CFR Part 117.

As explained earlier, the FDA considers seaweed a raw agricultural commodity—and not a seafood or a plant.[2] This determination means that under FSMA, a seaweed operation *could* be classified as a food facility. If so, they would need to register with the FDA and follow the regulations under 21 CFR Part 117.

Under FSMA, operations that manufacture, process, pack, or hold food for human or animal consumption in the United States are required to register as a food facility with the FDA.[3] According to 21 CFR Part 117, a *facility* is defined as "a domestic facility or foreign facility that is required to register" under FDCA Section 415.[4] The FDA's facility registration rules provide more details on what qualifies as a *facility:*

> "…any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. *The private residence of an individual is not a facility*…."[5]

Certain operations are exempt from the facility registration process, including farms (discussed more fully below), retail food establishments, and restaurants.

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[2] Email on file with author. The FDCA defines a raw agricultural commodity as "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." 21 U.S.C. § 321(r).
[3] 21 U.S.C. § 350d.
[4] 21 C.F.R. § 117.3.
[5] *Id.* § 1.227. (emphasis added).

21 CFR Part 117: Current Good Manufacturing Practices, Hazard Analysis, and Risk-Based Preventative Controls for Human Food Rule

The FDA regulates seaweed under 21 CFR Part 117. The rule can be considered in two parts: requirements for Current Good Manufacturing Practices (GMPs) and requirements for Hazard Analysis/Preventive Controls (PC).

Good Manufacturing Practices (GMPs) are basic standards that help ensure clean and sanitary conditions required in food production are maintained. GMPs are designed to protect food safety by defining controls for employee hygiene, how food facilities, grounds, and equipment are built and maintained, how the facility is cleaned, and how food is handled and processed during production.[6] The FDA first created these standards in 1969[7], which were updated in 2015 after FSMA was passed. More details about GMPs are provided in Chapter 3.

Under 21 CFR Part 117, a *facility* must conduct and write a hazard analysis. This is a careful review of potential food safety risks in their operation. If any of the potential hazards are known or reasonably foreseeable in the facility's product or processes, the facility must then develop and implement PC—specific steps to reduce or eliminate those risks. Unless the operation qualifies as a "qualified facility" (explained below), every facility must have a written hazard analysis and food safety plan that includes the preventive measures it uses to manage the hazards identified. These documents must be made available to the FDA if requested either verbally or in writing. A trained individual, known as a **Preventive Controls Qualified Individual (PCQI)**, must prepare or oversee the preparation of the food safety plan.[8]

However, smaller seaweed operations in the United States may meet the definition of a *qualified facility*, which means they are subject to modified requirements under 21 CFR Part 117. A *qualified facility* still needs to have food safety management strategies in place, but they do not need to have these strategies written down in the same formal way as larger facilities. What counts as a *qualified facility*, and the specific modified requirements of 21 CFR Part 117 are explained later in the sections on *processed food*.

Classifying Seaweed Under 21 CFR Part 117

How the FDA regulates seaweed under 21 CFR Part 117 depends on both the type of seaweed being produced and the size of the business, based on total seaweed sales. In general, 21 CFR Part 117 does not apply to:

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[6] *Current Good Manufacturing Practices C(GMPs) for Food and Dietary Supplements,* U.S. Food & Drug Admin. (Jan. 31, 2020).
[7] FDA, Current Good Manufacturing Practices (CGMPs) for Food and Dietary Supplements.
[8] *Id.* § 117.3.

1. Seaweed sold as a raw agricultural commodity; or
2. Seaweed processed, packed, or held through certain exempt activities done directly on the farm.

Seaweed operations that fall below certain sale thresholds may qualify as *qualified facilities* and follow modified requirements. The specific requirements for raw, dried or dehydrated, and processed seaweed are explained in the sections below.

Raw Seaweed: Growers and Harvesters

The FDA considers whole, intact seaweed as a **raw agricultural commodity (RAC).** Growers and harvesters of RACs may meet the definition of a farm under 21 CFR 1.227. If the operation qualifies as a farm, it does NOT need to register with FDA and is exempt from 21 CFR Part 117. However, certain activities that might seem like processing (e.g., drying), can still be allowed under the farm definition[9], depending on how and where the activity is done.

To determine whether this exemption applies, the operation must first determine if it meets the definition of a farm. The *farm definition* includes two types of farms: "primary production" farms and "secondary activities" farms.

1. Primary Production Farms: Are farms under one management that focus on growing and harvesting crops (e.g., seaweed). All parts of the farm need to be in the same general location, but the location does not need to be contiguous[10] (connected or directly next to each other).

2. Secondary Activities Farms: If an operation that is not part of the primary production farm location but is used to harvest, pack, or hold raw agricultural commodities like seaweed. To qualify as a secondary production farm, the operation must be linked to the primary production farm that either:

    a. Grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm; or
    b. It must jointly own a majority of the secondary activities farm itself.[11]

Even if a seaweed operation qualifies as a farm and is exempt from 21 CFR Part 117, it's important to remember that **all seaweed businesses**—whether growing, harvesting, transporting, or processing—are still legally responsible for ensuring their products are safe. All

[9] 21 C.F.R. § 1.227.
[10] *Id.*
[11] *Id.*

seaweed sold across state lines must comply with the FDCA, including rules that prevent adulterated (unsafe or contaminated) food from being sold.

Seaweed Dried or Dehydrated on the Farm

It is important to understand that farms may conduct limited manufacturing/processing activities and still be considered a farm under FDA rules. Some examples of these activities include:

- Drying
- Dehydrating
- Labeling
- Packaging
- Trimming
- Washing
- Waxing

If a farm dries or dehydrates its own seaweed, it is still considered a *farm* and remains *exempt from FSMA facility requirements*. This means the farm does not need to register as a food facility with the FDA and does *not* have to follow 21 CFR Part 117.

The FDA has also clarified that **drying and dehydrating** are treated the same under the regulations. There is no rule requiring these activities to take place within a certain timeframe after harvest for the farm exemption to apply. As long as the farm itself performs the drying or dehydrating, it remains covered by the *farm definition* and stays exempt from the facility regulations.[12]

There are a few key points to keep in mind:

- This exemption only applies if the farm conducts no other manufacturing/processing activities besides the ones listed above.
- If *drying or dehydrating is done by someone other than the farm*—for example, by a separate business or facility—that seaweed is considered *processed food*. In that case, the operation performing the drying or dehydration must register with the FDA as a food facility and follow FSMA requirements, including 21 CFR Part 117.
- As with raw seaweed, farms that grow, harvest, introduce, deliver, or process seaweed products in interstate (across state lines) commerce are still responsible for ensuring their products are safe and meet the requirements of the FDCA. This includes ensuring that their seaweed is not adulterated or unsafe for consumers.

[12] Email correspondence with Emanuel Hignutt, on file with the author.

Facilities and Mixed-Type Facilities: Seaweed Processed Outside the Farm (Including Seaweed Not Dried or Dehydrated by the Farm)

An operation that receives seaweed from growers and processes or manufactures it into another product is generally considered a *facility*. In this case, the operation would likely need to register with the FDA and comply with 21 CFR Part 117.

Some operations both grow or harvest seaweed and process it. These are typically classified as either a *facility* or a *mixed-type facility*, depending on the activities performed, and are also subject to 21 CFR Part 117.

Examples of processing activities that can trigger FDA facility requirements include, but are not limited to:

- Baking
- Boiling
- Canning
- Cooking
- Cooling
- Cutting
- Evaporating
- Extracting Juice
- Formulating
- Grinding
- Homogenizing
- Irradiating
- Milling
- Mixing
- Pasteurizing
- Peeling
- Rendering

Mixed-type facilities are operations that perform a combination of activities, some that fall under the *farm definition* (which are exempt from registration) and others that do *require registration* as a facility. For example, a *farm mixed-type facility* is a farm that also conducts certain processing or manufacturing steps not covered under the farm exemption, requiring the operation to register with the FDA as a facility.

Qualified Facilities

Some seaweed operations in the United States may qualify for modified requirements under 21 CFR Part 117 if they are classified as qualified facilities.

There are two main ways a seaweed operation can be considered a qualified facility:

1. Very Small Business: If the operation has made less than $1 million per year (adjusted for inflation) in total sales of human food over the past three years, including any food it stores for others for a fee, it qualifies as a very small business.

2. Sales to Local Customers: An operation can also qualify if it sells mostly directly to consumers or local businesses, such as restaurants or retail stores. These businesses, known as "qualified end users," must be located either in the same state or within 275 miles of the seaweed operation. To meet this second option, two conditions must be met:
    a. The value of food sold directly to consumers and qualified end users over the past three years must be greater than the value of food sold to other buyers.
    b. Total food sales to these local customers must be less than $500,000 per year during that time.

If either of these conditions is met, the seaweed operation may be eligible for the modified requirements for qualified facilities, which are explained in later sections of this guide.

Here are some simple examples to help explain how a seaweed business could qualify for modified requirements as a qualified facility under 21 CFR Part 117:

Option #1: A Very Small Business

A business qualifies as a "*very small business"* if it made less than $1 million per year (adjusted for inflation) from sales of human food over the past three years. This total includes any food the business stored for others for a fee.

- **Example 1:** *XYZ* Seaweed Company has never sold more than $800,000 worth of product per year. This means it qualifies as a very small business and is considered a Qualified Facility.

- **Example 2:** Sea Food, Co. sells $1 million worth of raw kelp and $200,000 worth of processed seaweed patties per year. Since total sales are above $1 million, 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 per year. Since total food sales are over $1 million, Food from the Sea Inc. is NOT a Qualified Facility.

Option #2: Local Sales to Qualified End Users

A business can also qualify if it sells mainly to consumers, restaurants, or retail stores in the *same state or within 275 miles*. To qualify:

- The value of food sold to these local buyers over the past three years must be *greater than* the value sold to other buyers.
- Annual sales to these local customers must also be *less than $500,000***.**

- Example: XYZ Seaweed Company sells $400,000 worth of its blanched kelp to restaurants in their town (within 275 miles). Since all sales are local and total sales are under $500,000, this business qualifies as a *qualified facility*.

For additional guidance on the requirements of 21 CFR Part 117 and qualified facilities, see *Seaweed Food Safety: Comparing Compliance with Preventive Controls for Human Foods and Seafood HACCP* (PDF).

Table 2-1: *Summary of compliance requirements for different types of seaweed operations. In the table, "**Yes**" means the operation must comply with the regulation, and "**No**" means it is exempt.*

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

State Regulations

Individual states have the option to set their own food safety requirements for seaweed production within their borders.

- **Alaska:** Seaweed sold in its whole form is classified as a raw agricultural commodity. Unlike some other states, Alaska has chosen not to apply the Seafood HACCP rules to seaweed. In fact, Alaska state regulators revised their regulations to remove aquatic plants, including seaweed, from the state's definition of "fish and fishery products." As a result, seaweed products in Alaska are regulated under the state's general food safety code. Other states, like Washington, follow a similar approach.[13]
- **Connecticut:** State regulators require seaweed growers to follow the Seafood Hazard Analysis Critical Control Point (Seafood HACCP) regulation. Issued by the FDA in 1995, these regulations require processors of fish and seafood products to develop and implement a HACCP food safety plan.[14]
- **Maine:** Seaweed is treated as seafood during cultivation and up until the point of harvest. The Maine Department of Marine Resources approves the cultivation of kelp for human consumption in waters that meet the same water quality standards used for shellfish farming—classified as Approved or Conditionally Approved for shellfish. This approach controls water quality at the source by identifying suitable growing areas and monitoring for bacterial contaminants. However, once harvested, seaweed is no longer regulated as seafood. Post-harvest handling, processing, distribution, and sale of seaweed are managed under produce regulations, overseen by the Maine Department of Agriculture, Conservation and Forestry.
- **New York:** Adopted 21 CFR Part 117 as its standard but recommends that businesses exempt from full requirements—such as qualified facilities—still use HACCP plans as a best practice.
- **Other States:** Some states (e.g., Massachusetts) are still determining how to regulate seaweed. Currently, *Saccharina latissima* (sugar kelp) in Massachusetts is treated as a seasonal, raw, fresh product. There are no seaweed processing facilities in the state at this time. According to the Massachusetts Department of Public Health and Division of

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[13] See 18 AAC 31.
[14] Seafood HACCP: Final Rule (PDF) - 60 FR 65096 - December 18, 1995

Marine Fisheries, *Saccharina latissima* must be sold directly to a licensed wholesale seafood dealer.[15]

These examples highlight the fragmented and evolving nature of seaweed regulation across the United States. With no uniform national standard, seaweed farmers and processors must work closely with state regulators to understand and comply with all applicable state and federal rules.

Definitions

Code of Federal Regulations (CFR): The Code of Federal Regulations (CFR) is the official legal print publication containing the codification of the general and permanent rules published in the Federal Register by the departments and agencies of the Federal Government. The Electronic Code of Federal Regulations (eCFR) is a continuously updated online version of the CFR and can be accessed at https://www.ecfr.gov/. It is not an official legal edition of the CFR.

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." 21 U.S.C. § 321(f).

Holding/Storing: **"**Storage of food and also includes 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))." 21 C.F.R. § 1.227.

- "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 it does not include activities that transform a raw agricultural commodity into a processed food…." 21 C.F.R. § 1.227.
- "Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks." 21 C.F.R. § 1.227.

Manufacturing/Processing: "Making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients." 21 C.F.R. § 1.227.

[15] Sea Grant Seaweed Hub State of the States, available at https://seaweedhub.org/symposium/.

- Examples 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." 21 C.F.R. § 1.227.
- "For farms or farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding." 21 C.F.R. § 1.227.

Packaging (when used as a verb): "Placing food into a container that directly contacts the food and that the consumer receives." 21 C.F.R. § 1.227.

Packing: "Placing food into a container other than packaging 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))." 21 C.F.R. § 1.227.

- It "does not include activities that transform a raw agricultural commodity…into a processed food…" 21 C.F.R. § 1.227.

Preventive Controls Qualified Individual (PCQI): "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." 21 C.F.R. § 117.3.

Processed Food: "Any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling." 21 U.S.C. 321(gg).

Qualified Individual (QI): "A person who has the education, training, or experience (or a combination thereof) 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." 21 C.F.R. § 117.3.

Raw Agricultural Commodity (RAC): "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." 21 U.S.C § 321(r).

References

21 C.F.R. § 1.227.

21 C.F.R. Part 117, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Rule.

Ciaramella, Concepcion, Janasie & Otts. Seaweed Food Safety: Comparing Compliance with Preventive Controls for Human Foods and Seafood HACCP. 2023.

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Chapter 3 Prerequisite Programs

Introduction

All food producers must implement general prerequisite programs (certain foundational safety practices) as part of a robust food safety system. These core programs include current Good Manufacturing Practices (GMPs)—standards for how facilities are maintained and how work is done—and Sanitation Control Procedures (SCPs), which outline how equipment, workspaces, and personnel should operate to reduce food safety risks. These practices apply broadly across all types of food production, not just to specific products like seaweed. While GMPs and SCPs are standard for all producers, additional programs may be needed depending on the specific operations and processes involved.

Good Manufacturing Practices (GMP)

Current GMP regulations can be found in Title 21 Part 117 Subpart B of the Code of Federal Regulations and serve as a core prerequisite program that applies to all businesses that process, pack, or hold food for human consumption in the United States. They set the minimum standards facilities must meet to ensure food is produced safely and is fit for consumption. These regulations cover essential aspects such as methods, equipment, facilities, and controls used in food processing. A brief overview of each requirement is provided below:

21 CFR 117.10 Personnel

All personnel must be in good health and maintain good hygiene when working with food for human consumption to limit the potential for contamination. Personnel should be properly trained and supervised to ensure their health and hygiene do not compromise food safety.

21 CFR 117.20 Plants and Grounds

The grounds surrounding a food facility must be adequately maintained and in good condition to limit the potential for contamination. The plant (facility) must be constructed and designed to support its intended operations and allow for effective maintenance and sanitary operations to limit the potential for contamination.

21 CFR 117.35 Sanitary Operations

All food facilities must maintain certain sanitary operations when food production, packaging, and storage are taking place. These include:

- **General Maintenance:** Buildings, fixtures and other physical areas within a facility must be kept clean, sanitary, and in good repair.
- **Substances Used in Cleaning and Sanitizing:** Cleaning and sanitizing agents must be appropriate for the manner in which they are being used. Toxic compounds must be properly labeled and stored away from food and food production areas to limit the risk of contaminating the food and food-contact surfaces. Your suppliers and food safety professionals can assist you in determining what cleaning and sanitizing products are appropriate for your operation.
- **Pest Control:** Effective pest control methods should be implemented to ensure pests are excluded from all areas of a food facility.
- **Sanitation of Food-Contact Surfaces:** Any surface within a facility that comes in contact with food (food-contact surface) must be cleaned as frequently as necessary to protect foods from microbial and chemical contamination and allergen cross-contact. How often cleaning and sanitizing needs to happen will vary from operation to operation. The factors that will influence this frequency include: equipment design and complexity, potential for contamination, historical data and results of past inspections, number of personnel who have had contact with these surfaces, frequency of use, and types of foods being processed, etc.
- **Sanitation of Non-Food-Contact Surfaces:** Any surface within a facility that does not come in direct contact with food (non-food-contact surface) must be cleaned as frequently as necessary to protect foods, food-contact surfaces, and food packaging from microbial and chemical contamination and allergen cross-contact.
- **Storage and Handling of Cleaned Equipment:** All clean and sanitized equipment and utensils must be stored in a manner that protects them from contamination.

21 CFR 117.37 Sanitary Facilities and Controls

All food facilities must have water that is safe and suitable for each of its intended uses, such as for cleaning equipment, processing food, or handwashing—along with proper plumbing, sewage disposal, toilet facilities, hand washing stations and waste disposal.

21 CFR 117.40 Equipment and Utensils

Equipment and utensils in a facility should be designed and built for their intended purpose and in a way that makes them easy to maintain and clean, helping to prevent contamination. This includes having smooth seams and surfaces without cracks or crevices where dirt or bacteria can collect.

21 CFR 117.80 General Processes and Controls

General Processes and Controls within any food facility must be implemented to control hazards associated with:

- **Raw Materials and Other Ingredients:** All ingredients must be unadulterated (safe) and suitable for processing into food and stored in a way that minimizes deterioration and protects against microbial and chemical contamination and allergen cross-contact.
- **Manufacturing Operations:** All manufacturing, processing, packing, and storage activities within a facility must be carried out in ways that prevent or minimize the risk of microbial and chemical contamination and allergen cross-contact. This can include using physical and chemical controls such as temperature, pH, salinity, as well as thorough cleaning and sanitation practices.

21 CFR 117.93 Warehousing and Distribution

Warehousing—storing food and its packaging before it is sold or distributed—and distribution practices should be designed and managed in a way that ensures foods are protected from contamination and deterioration of the food and its packaging.

21 CFR 117.95 Holding and Distribution of Human Food By-Products for Use as Animal Food

Food waste intended for use as animal feed must be stored and handled in ways that prevent contamination, such as keeping it covered or protected and maintaining appropriate temperature controls.

21 CFR 117.110 Action Defect Level

Food manufacturers, processors, packers, and handlers are required to follow protocols that minimize natural or unavoidable "defects" in food. For seaweed, these defects may include the presence of fouling organisms and mold. The FDA's *Defect Action Levels Handbook* provides information on acceptable limits for defects in various foods; however, no defect action levels have been published for seaweed or seaweed products. Until such levels are established, any potential defects in seaweed will be evaluated on a case-by-case basis.

Sanitation Control Procedures (SCP)

Sanitation is an important component of any Food Safety program. SCP are a compilation of all sanitary practices within a facility including the sanitation standard operating procedures (SSOPs). SSOPs are specific procedures or instructions for maintaining sanitary facilities, equipment, and practices within a facility.

SSOPs should clearly describe the appropriate procedures for cleaning, sanitizing, and maintaining facilities and equipment. Effective SSOPs should include:

- The sanitation procedures, including how to clean and sanitize equipment and work areas, control pests, and maintain the building and grounds.
- When and how often procedures should be conducted.
- The individual(s) responsible for conducting and/or monitoring sanitation activities.
- The monitoring procedures that are in place to verify that the sanitation controls implemented are effective.
- Description of the actions or corrections that will be taken when a sanitation problem is identified. This should also specify how any product that may have been contaminated or otherwise affected will be handled.
- Identify the records that will be kept to document monitoring activities and any corrections made.

Note to users: The way sanitation control procedures fit into a facility's overall food safety program will depend on the regulations that apply to that facility. Qualified facilities that are exempt from having a Preventive Controls for Human Food (PCHF) food safety plan, as well as facilities in states that regulate seaweed under Seafood HACCP, will generally follow HACCP requirements. Facilities that are not considered qualified facilities are regulated under the Preventive Controls for Human Food rule. The following two sections outline how these different regulatory frameworks affect sanitation-related compliance requirements.

Sanitation and Hazard Analysis and Critical Control Points (HACCP)

The GMPs outlined above address sanitation and the maintenance of sanitary conditions within a facility. Under the Seafood HACCP regulation 21 CFR 123, eight key sanitation areas—drawn from the GMPs—are written directly into the regulation. Facilities must monitor each of these areas and keep records of that monitoring, to ensure compliance with these sanitation requirements. If operating under a HACCP system, it is important to address all eight key sanitation areas and maintain the required records for each. Sanitation practices are considered prerequisite programs and therefore do not need to be included in the facility's HACCP plan.

The 8 key areas of sanitation include:

1. Safety of water
2. Condition and cleanliness of food contact surfaces
3. Prevention of cross-contamination
4. Maintenance of hand washing, hand sanitizing, and toilet facilities

5. Protection from adulterants
6. Labeling, storage and use of toxic compounds
7. Employee health
8. Exclusion of pests

Sanitation and Preventive Controls for Human Foods (PCHF)

Under the Preventive Controls for Human Food Rule (21 CFR Part 117 Subpart C), sanitation procedures are generally part of current Good Manufacturing Practices (GMP) and serve as prerequisite programs. However, in some cases, a hazard analysis may identify post-process contamination risks—such as cross-contact or cross-contamination from the processing environment—that require a specific Sanitation Preventive Control.

This situation often arises when a product is exposed to the environment after a kill step (e.g., thermal processing) but before it is packaged. In these cases, standard GMP sanitation procedures must be elevated to the level of a Preventive Control. This elevation requires the development of written procedures, as well as documented monitoring, corrective actions, and verification activities.

It is also recommended that facilities implement an environmental monitoring program to assess the effectiveness of the Sanitation Preventive Control. While GMP sanitation practices are not required to be documented under the PCHF rule, a Sanitation Preventive Control must be written and included in the facility's Food Safety Plan.

Sanitation Preventive Controls are especially important for ready-to-eat (RTE) foods that will not be cooked before consumption, such as seaweed salad or vegetable maki rolls.

Other Prerequisite Programs

While GMPs and SCPs are the most common prerequisite programs for most food producers, there can be a variety of other regulations and prerequisite programs that should or must be in place to ensure you have an effective food safety system. Some additional regulations and programs to consider are listed below. This list is not exhaustive, and it is important to work with state and federal regulatory agencies and subject matter experts to ensure you are building an effective food safety system.

1. Preventive controls for animal food
    a. If selling or diverting seaweed or seaweed by-products for animal food production.
2. Mitigation for intentional adulteration (21 CFR Part 121)
3. Sanitary transportation of human and animal food (21 CFR Part 1 Subpart O)
4. Employee Training and Training Records (21 CFR 117 Subpart A 117.4)

5. Food allergen Labeling and Consumer Protection Act of 2004
6. Food Labeling and Nutrition (21 CFR Part 101)
7. Country of Origin Labeling (Title 7 CFR Part 60)
8. Local/Overseas Requirements/Regulations
    a. State Specific requirements
    b. Country/International requirements
        i. For Example, the Codex Alimentarius International Food Standards

Chapter 4 Seaweed Food Safety Hazards and Definitions

This chapter discusses the potential hazards of edible seaweeds and seaweed products, drawing on historical data and the scientific literature available at the time of publication. The tables in this chapter can be used to help identify potential hazards that may be associated with specific seaweed species and products. While the hazards listed are considered potential, it is the processor's responsibility to evaluate their own products and processes to determine which hazards are significant—either "reasonably likely to occur" (HACCP) or "hazard requiring a preventive control" (PCHF)—and require controls. While the tables include a variety of edible species from around the world, it is likely not inclusive. If a species is not listed in Table 4-1, processors should identify a similar or closely related species as a reference point. In general, the list below provides potential food safety hazards often associated with each of the three main categories of seaweed:

- **Brown seaweed potential species-related hazards:** Pathogens in the harvest area, environmental chemicals, iodine, and natural toxins
- **Red seaweed potential species-related hazards:** Pathogens in the harvest area, environmental chemicals, and natural toxins
- **Green seaweed potential species-related hazards:** Pathogens in the harvest area, environmental chemicals, and natural toxins

The end of this chapter provides definitions for various terms that may be used throughout the guide or when discussing the processing of seaweeds and seaweed products. These definitions are for reference within this document and are not intended to serve as official definitions accepted by all agencies or organizations.

Seaweed Food Safety Hazards Tables

Tables 4-1 to 4-3 list potential hazards associated with specific seaweed species. To use the tables, start by finding the species by common name. Species are organized into 3 categories—brown (Table 4-1), green (Table 4-2), and red (Table 4-3)—and listed alphabetically. Verify the scientific name, then read across the row. A check mark in any hazard column indicates that the species may potentially be associated with that hazard. Superscripts link to additional details provided in the footnotes for each table.

Currently, all species within each seaweed category (brown, green, or red) share the same set of potential hazards. However, the hazards differ among the three categories. The detailed tables below show which species were assessed during development and can be updated in the future if new species-specific data becomes available.

Table 4-1: *Species-related seaweed hazards for edible brown seaweeds known to be used for human consumption.*

Common Name/ Scientific Name	Scientific Name	Pathogens[1] in Harvest Area Chapter 5	Parasites[2] in Harvest Area Chapter 6	Environmental Chemicals Chapter 7	Iodine Chapter 8	Natural Toxins Chapter 9
Arame	*Eisenia bicyclis*	✓		✓	✓	✓
Bell-Bladed Sargassum	*Sargassum turbinarioides*	✓		✓	✓	✓
Bladderwrack	*Fucus vesiculosus*	✓		✓	✓	✓
Bull Kelp	*Nereocystis luetkeana*	✓		✓	✓	✓
Channeled Wrack	*Pelvetia canaliculata*	✓		✓	✓	✓
Cochayuyo	*Durvillaea antarctica*	✓		✓	✓	✓
Cystoseira barbata	*Cystoseira barbata*	✓		✓	✓	✓
Forkweed	*Dictyota dichotoma*	✓		✓	✓	✓
Hijiki	*Sargassum fusiforme*	✓		✓	✓	✓
Jania capillacea	*Jania capillacea*	✓		✓	✓	✓
Japanese Wireweed	*Sargassum muticum*	✓		✓	✓	✓
Kappaphycus	*Kappaphycus*	✓		✓	✓	✓
Kombu	*Saccharina japonica*	✓		✓	✓	✓
Mozuku	*Cladosiphon okamuranus*	✓		✓	✓	✓
Mozuku	*Nemacystus decipiens*	✓		✓	✓	✓
Oarweed	*Laminaria digitata*	✓		✓	✓	✓
Ocean Ribbons	*Lessionopsis littoralis*	✓		✓	✓	✓
Peacock's Tail	*Padina pavonica*	✓		✓	✓	✓
Ribbon Kelp	*Alaria marginata*	✓		✓	✓	✓
Rockweed	*Ascophyllum nodosum*	✓		✓	✓	✓
Rockweed	*Fucus distichus*	✓		✓	✓	✓
Sea Fern Weed	*Halopteris filicina*	✓		✓	✓	✓

[1] Not considered a significant hazard if the seaweed will be processed with a method that will kill potential microbial pathogens prior to consumption.
[2] No data to support parasitic hazards in seaweeds to date.

Common Name/ Scientific Name	Scientific Name	Pathogens[1] in Harvest Area Chapter 5	Parasites[2] in Harvest Area Chapter 6	Environmental Chemicals Chapter 7	Iodine Chapter 8	Natural Toxins Chapter 9
Sea Flax Weed	*Halopteris scoparia*	✓		✓	✓	✓
Sea Palm	*Postelsia palmaeformis*	✓		✓	✓	✓
Seaweed Spaghetti	*Himanthalia elongata*	✓		✓	✓	✓
Serrated Wrack	*Fucus serratus*	✓		✓	✓	✓
Spiral Wrack	*Fucus spiralis*	✓		✓	✓	✓
Sugar Kelp	*Saccharina latissima*	✓		✓	✓	✓
Tangle	*Laminaria hyperboria*	✓		✓	✓	✓
Wakame	*Undaria pinnatifida*	✓		✓	✓	✓
Winged Kelp	*Alaria esculenta*	✓		✓	✓	✓

Table 4-2: *Species-related seaweed hazards for edible green seaweeds known to be used for human consumption.*

Common Name/ Scientific Name	Scientific Name	Pathogens[1] in Harvest Area Chapter 5	Parasites[2] in Harvest Area Chapter 6	Environmental Chemicals Chapter 7	Iodine Chapter 8	Natural Toxins Chapter 9
Boodlea coacta	*Boodlea coacta*	✓		✓		✓
Flax Brick Weed	*Chaetomorpha linum*	✓		✓		✓
Green Feather Algae	*Caulerpa sertularioides*	✓		✓		✓
Gutweed	*Ulva intestinalis*	✓		✓		✓
Latok	*Caulerpa lentillifera*	✓		✓		✓
Maesaengi	*Capsosiphon fulvescens*	✓		✓		✓
Rooting Green Thread Weed	*Rhizoclonium riparium*	✓		✓		✓
Sea Grape	*Caulerpa spp.*	✓		✓		✓
Sea Grape	*Caulerpa racemosa*	✓		✓		✓
Sea Lettuce	*Ulva* species	✓		✓		✓
Sea Lettuce	*Ulva lactuca*	✓		✓		✓
Slender Sea Lettuce	*Ulva linza (Ulva fasciata)*	✓		✓		✓
Stiff Sea Lettuce	*Ulva rigida*	✓		✓		✓
Ulva prolifera	*Ulva prolifera*	✓		✓		✓

[1] Not considered a significant hazard if the seaweed will be processed with a method that will kill potential microbial pathogens prior to consumption.
[2] No data to support parasitic hazards in seaweeds to date.

Table 4-3: *Species-related seaweed hazards for edible red seaweeds known to be used for human consumption.*

Common Name/ Scientific Name	Scientific Name	Pathogens[1] in Harvest Area Chapter 5	Parasites[2] in Harvest Area Chapter 6	Environmental Chemicals Chapter 7	Iodine Chapter 8	Natural Toxins Chapter 9
Alsidium corallinum	*Alsidium corallinum*	✓		✓		✓
Amphiroas	*Amphiroas*	✓		✓		✓
Centroceras clavulatum	*Centroceras clavulatum*	✓		✓		✓
Chondria armata	*Chondria armata*	✓		✓		✓
Coelothrix irregularis	*Coelothrix irregularis*	✓		✓		✓
Dulse	*Palmaria palmata (Rhodymenia palmata)*	✓		✓		✓
Dulse	*Palmaria mollis (Devaleraea mollis)*	✓		✓		✓
***Gelidium* spp.**	*Gelidium* spp.	✓		✓		✓
Gracilaria	*Gracilaria tikvahiae*	✓		✓		✓
Gracilaria	*Gracilaria edulis*	✓		✓		✓
Gracilaria	*Gracilaria verrucosa (Gracilariopsis longissima)*	✓		✓		✓
Gracilaria	*Gracilaria chorda*	✓		✓		✓
Gracilaria	*Gracilaria coronopifolia*	✓		✓		✓
Gracilaria	*Gracilaria corticata*	✓		✓		✓
Gracilaria	*Gracilaria lemaneiformis*	✓		✓		✓
Gracilaria	*Gracilaria lichenoides*	✓		✓		✓
Gracilaria	*Gracilaria tenistipitata*	✓		✓		✓
Gracilaria	*Gracilaria vermiculophylla*	✓		✓		✓
Green Sacol	*Kappaphycus striatus*	✓		✓		✓
Gulman	*Gracilariopsis heteroclada*	✓		✓		✓

[1] Not considered a significant hazard if the seaweed will be processed with a method that will kill potential microbial pathogens prior to consumption.
[2] No data to support parasitic hazards in seaweeds to date.

Common Name/ Scientific Name	Scientific Name	Pathogens[1] in Harvest Area Chapter 5	Parasites[2] in Harvest Area Chapter 6	Environmental Chemicals Chapter 7	Iodine Chapter 8	Natural Toxins Chapter 9
Guso	*Euchema cottonii*	✓		✓		✓
Irish Moss	*Chondrus crispus*	✓		✓		✓
Kaijinso/Makura	*Digenea simplex*	✓		✓		✓
Limu Manauea	*Gracilaria coronopifolia*	✓		✓		✓
Nori/Laver	*Erythroglossum laciniatum*	✓		✓		✓
Nori/Laver	*Pyropia spp.*	✓		✓		✓
Nori/Laver	*Porphyra spp.*	✓		✓		✓
Nori/Laver	*Porphyra yezoensis*	✓		✓		✓
Ogo	*Refer to Gracilaria*	✓		✓		✓
Peyssonnelia squamaria	*Peyssonnelia squamaria*	✓		✓		✓
Sarcodiotheca gaudichaudii	*Sarcodiotheca gaudichaudii*	✓		✓		✓
Sea Birds Nest	*Eucheuma cottoni*	✓		✓		✓
Sea Moss	*Eucheuma spinosum*	✓		✓		✓
Spiny Red Seaweed	*Acanthophora specifera*	✓		✓		✓
Wrack Siphon Weed	*Vertebrata lanosa*	✓		✓		✓

Process-Related Hazards

Process-related hazards are those that occur or are introduced during processing. The type of hazard can vary depending on the processing methods, final product type, and the type of packaging used. Table 4-4 lists potential process-related hazards associated with various seaweed processing methods.

To use Table 4-4, locate the finished product type in the first column, then read across the row to identify any potential hazards for corresponding packaging types. A check mark (✓) indicates the presence of a potential hazard, and blank box (☐) indicates none. "**ROP**" stands for Reduced Oxygen Packaging and "**Other**" stands for Oxygen-Permeable Packaging (Air Packed). Footnotes refer to additional details about specific hazards.

Table 4-4: Process-Related Seaweed Hazards

Finished Product	Pathogen Growth Due to Temperature Abuse Chapter 10	Pathogen Contamination Chapter 11	Growth of *Clostridium botulinum* and Toxin Formation Chapter 12	Pathogen Survival Through Cooking/ Pasteurization Chapter 13	Allergens and Food Intolerance Substances Chapter 14[1]	Physical Hazards (metal, glass, plastic) Chapter 15[2]
Raw Seaweed	✓ ROP ✓ Other	✓ ROP ✓ Other	✓ ROP ☐ Other	☐ ROP ☐ Other	✓ ROP ✓ Other	✓ ROP ✓ Other
Dried Whole[3] (<0.85 a_W)	☐ ROP ☐ Other	✓ ROP ✓ Other	☐ ROP ☐ Other	☐ ROP ☐ Other	✓ ROP ✓ Other	✓ ROP ✓ Other

[1] Seaweed with heavy fouling and high concentrations of crustaceans may contain the allergenic crustacean protein tropomyosin. Each facility is responsible for assessing this risk based on the presence of crustaceans in their product.
[2] This hazard may apply depending on processing practices and prerequisite programs in place.
[3] Additional concern: *Staphylococcus aureus* is a common pathogen and can grow in dried products, if concerned with *Staphylococcus aureus* growth, target a water activity (a_W) of 0.83 or below.

Finished Product	Pathogen Growth Due to Temperature Abuse Chapter 10	Pathogen Contamination Chapter 11	Growth of *Clostridium botulinum* and Toxin Formation Chapter 12	Pathogen Survival Through Cooking/ Pasteurization Chapter 13	Allergens and Food Intolerance Substances Chapter 14[1]	Physical Hazards (metal, glass, plastic) Chapter 15[2]
Dried Milled[3] (<0.85 a_W)	☐ ROP ☐ Other	✓ ROP ✓ Other	☐ ROP ☐ Other	☐ ROP ☐ Other	✓ ROP ✓ Other	✓ ROP ✓ Other
Fermented/Acidified/Salted/ Brined/Pickled (not cooked/Pasteurized)	✓ ROP ✓ Other	✓ ROP ✓ Other	✓ ROP ☐ Other	☐ ROP ☐ Other	✓ ROP ✓ Other	✓ ROP ✓ Other
Low Acid Canned Food	✓ ROP ✓ Other	✓ ROP ✓ Other	✓ ROP ☐ Other	☐ ROP ☐ Other	✓ ROP ✓ Other	✓ ROP ✓ Other
Partially Cooked (blanched)	✓ ROP ✓ Other	✓ ROP ✓ Other	✓ ROP ☐ Other	☐ ROP ☐ Other	✓ ROP ✓ Other	✓ ROP ✓ Other
Pasteurized	✓ ROP ✓ Other	✓ ROP[4] ✓ Other[4]	✓ ROP ☐ Other	✓ ROP ✓ Other	✓ ROP ✓ Other	✓ ROP ✓ Other
Fully Cooked Prepared Food	✓ ROP ✓ Other	✓ ROP[4] ✓ Other[4]	✓ ROP ☐ Other	✓ ROP ✓ Other	✓ ROP ✓ Other	✓ ROP ✓ Other
Prepared from Ready-to-Eat Seaweed Product (salads, dips, spreads, dressings)	✓ ROP ✓ Other	✓ ROP ✓ Other	✓ ROP ☐ Other	☐ ROP ☐ Other	✓ ROP ✓ Other	✓ ROP ✓ Other

[4] This hazard is applicable after the product undergoes a sufficient kill step (cooking and pasteurization) and before the product is packaged.

Definitions

Acidified Food: A product with a pH of 4.6 or less accomplished by adding acid, which is a form of pickling. Acidified shelf stable products are also regulated under 21 CFR 114 (Acidified Foods Regulations).

Action Level: A threshold established by regulatory bodies, such as the U.S. Food and Drug Administration (FDA), indicating the maximum concentration of a contaminant (e.g., arsenic, cadmium, lead, or mercury) in food or feed. If a contaminant in a product exceeds this level, regulatory action may be taken, such as removing the product from the market or issuing a recall. Action levels are not legally binding but serve as guidelines for industry compliance.

Blanching: Submersion of foods in boiling water or exposure to steam for a short period of time before rapidly cooling. Blanching is commonly done to fix color and stop enzymatic activity.

Brining: To treat with or steep in a brine, which is, most commonly, a strong solution of salt and water (wet brine). Other ingredients, like sugar, herbs/spices, and vinegar can also be added to enhance flavor.

Drying (Dehydrating): The natural (sun or air drying) or mechanical (dehydrator, oven, freeze drying, etc.) removal of water from a food or food product to reduce the water available for microbial growth (Aw). A commonly used method of food preservation.

Fermentation: A process commonly used to preserve and/or enhance foods, which involves the chemical breakdown of molecules such as sugars by bacteria into acids. This rapidly reduces the pH of the product and is another form of pickling.

Low Acid Canned Food (LACF): Any canned food with a pH greater than 4.6 and a water activity (aW) above 0.85.

Parasites: An organism living in or on another (host) and relying on the host for survival, typically at the host's expense.

Pasteurization: A process (commonly heat) applied to foods to reduce the population of a target pathogen to a safe level.

Pathogens: Microorganisms that cause disease.

Pickling: The process of preserving food by reducing its pH either by natural fermentation or acidification with vinegar.

Primary Processor: A processor sourcing and receiving raw materials directly from the farmer or harvester.

Raw Agricultural Commodity (RAC): [*regulatory term*] 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.

Raw Food: [*industry term*] Any food that has not been processed, cooked or heat treated.

Ready-to-Eat (RTE): Foods being sold with the intention of being consumed without any further processing or preparation.

Recommended Daily Intake (RDI): The average daily level of nutrient intake sufficient to meet the requirements of nearly all healthy individuals in a specific age and gender group. RDIs are set by health authorities and are used as a reference for dietary guidelines, labeling, and ensuring nutritional adequacy.

Reduced Oxygen Packages (ROP): Food packaging method that results in reduced or no presence of oxygen (mechanical vacuum, steam flush, hot fill, modified atmosphere packaging (MAP), controlled atmosphere packaging, hermetically sealed, or packed in oil).

Salting: Adding salt to foods to preserve or enhance the food, sometimes referred to as dry brining.

Secondary Processor: A processor sourcing and receiving product from another processor and NOT directly from the farmer or harvester.

Serving Size: The standard portion typically consumed in one sitting, defined by regulatory agencies or nutritional guidelines. Serving sizes can vary based on the type of food product (e.g., dried, fresh, or processed) and cultural or dietary norms. For instance, the serving size might be specified as a weight (e.g., 5 grams of dried seaweed) or a volume (e.g., 1 cup of rehydrated seaweed).

Tolerable Level: The maximum amount of a substance, such as a heavy metal or toxin, that can be consumed daily over a lifetime without posing a significant health risk. This level is typically expressed in terms of a dose relative to body weight (e.g., micrograms per kilogram of body weight per day). It is established by health organizations such as the World Health Organization (WHO) or the European Food Safety Authority (EFSA) based on scientific risk assessments.

Water Activity (a_W): A measure of free or available water in a food, which is different from total water in a food, which is referred to as moisture content. Available water is used by microorganisms for growth; by limiting available water, one reduces a_W, which reduces the risk of pathogen growth and spoilage of foods.

Abbreviations

Table 4-5: Abbreviations Used in This Guide.

Abbreviation	Meaning
ASP	Amnesic Shellfish Poisoning
aw	Water Activity
CAGR	Compound Annual Growth Rate
CCP	Critical Control Point
EFSA	European Food Safety Authority
DIL	Derived Intervention Levels
EHEC	Enterohemorrhagic *E. coli*
FALCPA	Food and Allergen Labeling and Consumer Protection Act of 2004
FFDCA	Federal Food, Drug, and Cosmetics Act
FASTER	Food Allergy Safety, Treatment, Education, and Research Act
FSMA	Food Safety Modernization Act
GMP	Good Manufacturing Practices
GRAS	Generally Recognized as Safe
HACCP	Hazard Analysis Critical Control Point
IMTA	Integrated Multitrophic Aquaculture Systems
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LCF	Low Acid Canned Food
MAP	Modified Atmosphere Packaging
NORM	Naturally Occurring Radioactive Material
PC	Preventive Controls
PCBs	Polychlorinated Biphenyls
PCHF	Preventive Controls for Human Foods
PCQI	Preventive Controls Qualified Individual
POP	Persistent Organic Pollutants
PBDEs	Polybrominated Diphenyl Ethers
PRI	Populations Reference Intake

Abbreviation	Meaning
RAC	Raw Agricultural Commodity
RDI	Recommended Daily Intake
RH	Relative Humidity
ROP	Reduced Oxygen Packages
RTE	Ready-to-Eat (foods)
SCP	Sanitary Control Procedures
SSOPs	Sanitation Standard Operating Procedures
STEC	Shigatoxigenic *E. coli*
SPM	Suspended Particulate Matter
TTI	Time-Temperature Indicator
WHO	World Health Organization

Chapter 5 Pathogens in the Harvest Area

General Background: Understanding the Potential Hazard

Pathogens—including bacteria, fungi, and viruses—are potential hazards for all food products and cause millions of illnesses each year in the U.S. (Scallan et al., 2011). While only a small number of bacterial- and viral-related foodborne illness outbreaks have been linked to seaweeds (Table 5-1), most foodborne illnesses are never reported. This underscores the importance of understanding the sources of pathogen contamination and implementing validated control measures (Scallan et al., 2011). This chapter provides an overview of major foodborne pathogens, summarizes available data on pathogen presence in raw seaweeds, and outlines key considerations for controlling these hazards. The information applies to both wild-harvested and farm-raised seaweed. Because the source of seaweed—whether farmed or wild—can influence the type and extent of microbial hazards, processors must evaluate and manage risks based on the specific conditions in which the seaweed was harvested or cultivated.

Table 5-1: *Outbreaks of foodborne illness associated with seaweed consumption.*

Location	Year	Pathogen	Seaweed / Product	Number of Cases	Reference
South Korea	2015	Norovirus	Sea Lettuce / Seaweed Salad	9	Park et al., 2015
Japan	2017	Norovirus	Laver / Dried Seaweed	1100	Kusumi et al., 2017; Somura et al., 2017
Norway	2019	Norovirus	Wakame / Seaweed Salad	>100	Whitworth et al., 2019
Hawaii	2016	*Salmonella*	Limu (Ogo) / Raw Seaweed	15	Nichols, 2017
Japan	2021	Enteroaggressive *E. coli*	Seaweed Salad	1	Kashima et al., 1999
Japan	1999	Enteroaggressive *E. coli*	Wakame / Pickled Seaweed	4	Hamada et al., 1999
California	1997	*Vibrio cholerae*	Ogo / Raw Seaweed	1	Vugia et al., 1997

Microorganisms—including potential human pathogens—present in the water column can attach to the surfaces of seaweeds (Barberi et al, 2020; Geoke et al., 2010; Kreissig et al., 2023). As a result, pathogens present in the harvest area may pose a biological hazard when seaweed is intended to be consumed raw without any additional steps to control or eliminate them. Understanding the potential microbial hazards in the growing or harvest areas is essential both to prevent foodborne illness and to support the validation and implementation of processing steps that can eliminate or reduce these hazards to safe levels.

Biological Hazards in Freshly Harvested Seaweeds

Certain harmful microorganisms have been found on freshly harvested seaweeds. These include types of bacteria such as Shiga toxin-producing *Escherichia coli* (STEC), *Salmonella enterica*, various *Vibrio* species, and endospore-forming bacteria like *Bacillus cereus* (see Appendix A, Table A-1). In addition to bacteria, Norovirus has also been detected on freshly harvested seaweed. Heat-tolerant fungi, including some yeasts and molds, are rarely found on seaweed (Gupta et al., 2010; Moore et al., 2002; Pan-utai et al., 2023), and no human illnesses linked to fungal infections from eating raw seaweed have been reported (Benedict et al., 2016).

Some bacteria, especially *Vibrio* species, naturally live in ocean environments and may be present in seaweed simply due to the conditions at the harvest site. In contrast, other bacteria and viruses are usually linked to contamination from sewage or wastewater near where the seaweed is collected. For this reason, the cleanliness and safety of the water where seaweed is harvested are critically important to reduce the risk of these biological hazards. This topic is discussed in more detail in a later section.

Other well-known foodborne pathogens—such as *Clostridium botulinum*, *Staphylococcus aureus*, *Listeria monocytogenes*, and Hepatitis A virus—are not commonly found on raw seaweed. However, they can become a concern if seaweed is contaminated during processing or manufacturing. These types of risks will be covered in Chapter 11.

Vibrio

Vibrio as a Naturally Occurring Hazard

Vibrio bacteria are naturally found in coastal waters and are commonly detected on seaweeds (Hollants et al., 2013). These bacteria have been isolated from seaweeds collected in various ocean regions and across both wild and farmed (aquaculture) settings (see Appendix A, Table A-1). Of particular concern are certain species of Vibrio that can cause illness in humans, including *Vibrio cholerae*, *Vibrio parahaemolyticus*, *Vibrio vulnificus*, and *Vibrio alginolyticus*. However, not all strains of these species are harmful. Testing for potentially harmful (pathogenic) strains typically involves screening for the presence of specific toxin genes.

The levels of pathogenic *Vibrio* in seawater tend to increase as water temperatures rise (Haley et al., 2012; Mahmud et al., 2007; Mahmud et al., 2008). As a result, the time of year when seaweed is harvested can influence the risk posed by these bacteria. Warmer months may present a higher risk. Additionally, long-term ocean warming driven by climate change is contributing to the spread of pathogenic *Vibrio* into new areas, including regions farther from the equator (Vezzulli et al., 2013). These environmental changes have been linked to an overall rise in *Vibrio*-related infections from seafood consumption (Baker-Austin et al., 2013; Martinez-Urtaza et al., 2010).

Vibrio cholerae is the bacterium responsible for causing cholera, an illness that can lead to severe, watery diarrhea, often described as mucus-filled. While *Vibrio cholerae* has the potential to cause serious disease, only one outbreak of cholera has ever been linked to the consumption of raw seaweed (Vugia et al., 1997).

Laboratory studies have shown that *Vibrio cholerae* can attach to a wide range of seaweed species (Hood & Winter, 1997; Islam et al., 1988), and it has been found on wild seaweeds such as *Ascophyllum nodosum*, *Gracilaria corticata*, *Sargassum turbinarioides*, and *Ulva lactuca* (see Appendix A, Table A-1). Although the overall risk of cholera from seaweed consumption appears to be low, the ability of this pathogen to adhere to seaweed surfaces highlights the importance of monitoring harvest area water quality and handling practices.

***Vibrio parahaemolyticu*s** is a bacterial species known to cause gastroenteritis, an illness characterized by symptoms such as vomiting and diarrhea. Most foodborne outbreaks and individual cases linked to this bacterium have been associated with the consumption of raw or undercooked seafood, particularly crabs, shrimp, scallops, oysters, and clams (Su & Liu, 2007).

Among the *Vibrio* species, *Vibrio parahaemolyticus* is one of the most frequently detected on seaweeds. It has been found on a wide range of species, including *Caulerpa lentillifera*, *Gracilaria vermiculophylla*, *Gracilariopsis heteroclada*, *Kappaphycus striatus*, *Laminaria* species, *Porphyra* species., *Saccharina latissima*, *Sargassum* species, *Ulva lactuca*, *Ulva reticulata*, and unidentified species of *Fucus* and *Ulva* (see Appendix A, Table A-1).

There is ongoing scientific debate about whether *Vibrio parahaemolyticus* can establish itself as a long-term resident on seaweed surfaces. While some laboratory studies have shown that the number of bacteria decreases significantly after being exposed to seaweed (Pang et al., 2006; Liu & Pang, 2010), other studies have found *Vibrio parahaemolyticus* remains present on seaweed across multiple seasons—or even year-round—and often in higher concentrations than in the surrounding seawater. This suggests that, under certain conditions, seaweed may serve as a stable habitat for the bacterium (Barberi et al., 2020; Mahmud et al., 2006; Mahmud et al., 2007).

Vibrio vulnificus is a bacterium that can cause serious and sometimes life-threatening infections in humans. These include gastroenteritis (inflammation of the stomach and intestines), bloodstream infections (septicemia), necrotizing fasciitis (a severe soft tissue infection sometimes referred to as "flesh-eating disease"), and bone infections (osteomyelitis). A notable example of the health risks posed by *Vibrio vulnificus* occurred in 2005 following Hurricane Katrina, when floodwaters led to dozens of *Vibrio*-related illnesses, including five deaths—most of which were attributed to *Vibrio vulnificus* (CDC, 2005).

Vibrio vulnificus is commonly found in coastal waters, where it may live freely in the water column or be associated with plankton, fish, and shellfish such as oysters, clams, mussels, and scallops (Oliver et al., 2006). While no human infections have been directly linked to the consumption of seaweed, the bacterium has been found in high numbers on several seaweed species, including *Fucus* species, *Gracilaria vermiculophylla*, *Laminaria* species, *Porphyra* species and *Undaria* species (see Appendix A, Table A-1).

Like *Vibrio parahaemolyticus*, *Vibrio vulnificus* shows a strong seasonal pattern, with higher levels detected during warmer months. This seasonal trend suggests that seaweed harvested in warmer water temperatures may carry a greater risk of contamination with this pathogen (Mahmud et al., 2008).

Vibrio alginolyticus is a marine bacterium that can cause infections in humans, primarily by entering through cuts or wounds in the skin. While it most commonly leads to soft tissue infections, it can also cause gastrointestinal illness when ingested (Mustapha et al., 2013; Reilly et al., 2011).

This species is frequently found in seawater and is considered one of the most abundant potentially harmful Vibrio species in marine environments (Ortigosa et al., 1989). It has also been detected on a variety of seaweed species, including *Alaria esculenta*, *Caulerpa racemosa*, *Gracilariopsis heteroclada*, *Kappaphycus striatus*, *Saccharina latissima*, *Sargassum vulgare*, *Sargassum* species, and *Ulva reticulata* (see Appendix A, Table A-1). Although infections from *Vibrio alginolyticus* are relatively rare, its widespread presence in seawater and on seaweed highlights the importance of proper handling and hygiene during harvest and processing to reduce potential risks.

Coliform Bacteria

Coliform bacteria are a group within the Enterobacteriaceae family, many of which originate in the intestines of warm-blooded animals, including humans. Because of this, testing for coliform bacteria in water is commonly used to assess whether a water source has been contaminated by sewage or other forms of wastewater.

There are several types of coliform indicators used in water testing:

- **Total Coliforms:** A broad group of bacteria commonly found in the environment, including soil, water, and vegetation. While some may originate from fecal sources, many are harmless and not directly associated with human or animal waste.

- **Fecal (Thermo-tolerant) Coliforms**: A subset of total coliforms that are more specifically linked to fecal contamination. These bacteria can grow at higher temperatures and are more likely to indicate the presence of waste from warm-blooded animals.

- **Generic *Escherichia coli* (*E. coli*):** A specific type of fecal coliform that is strongly associated with fecal matter. Its presence is considered a more accurate indicator of recent fecal contamination and potential health risks.

In most cases, water samples are first tested for total coliforms. If they are detected, further testing is usually done to determine whether fecal coliforms and/or *E. coli* are also present. Fecal coliforms are often preferred for water quality assessments because total coliforms may include harmless environmental bacteria, which could overestimate the actual health risk.

Coliform bacteria have been detected in a variety of raw seaweeds, including *Alaria esculenta*, *Fucus* species, *Porphyra yezoensis*, and *Saccharina latissima*, as well as in seaweed that has washed up on beaches (see Appendix A, Table A-1). Research suggests that the presence of coliforms on seaweed is more closely linked to the proximity of sewage pollution sources rather than to any specific seaweed species (Kreisseg et al., 2023).

E. coli is a large and diverse group of bacteria. While most strains of *E. coli* are harmless and naturally found in the intestines of humans and animals, some strains (pathotypes) of *E. coli* can cause diarrhea, while others may lead to urinary tract infections, respiratory illnesses, pneumonia, and other health conditions. As with other coliform bacteria, *E. coli* has been detected on raw seaweed. Seaweed species where it has been found include *Fucus spiralis*, other *Fucus* species, *Macrocystis pyrifera*, *Saccharina latissima*, *Sargassum muticum*, *Ulva pinnatifida*, *Ulva reticulata*, and other *Ulva* species (see Appendix A, Table A-1). However, other studies have reported little or no detection of *E. coli* on raw seaweed (Blikra et al., 2019; Lytou et al., 2021; Moreira-Leite et al., 2023; Skonberg et al., 2021; Swinscoe et al., 2020).

Where *E. coli* has been detected, researchers have consistently noted that contamination appears linked to nearby sources of pollution, such as wastewater discharges or stormwater runoff (Barberi et al., 2020; Kreissig et al., 2023). This reinforces the importance of monitoring water quality at harvest sites to minimize microbial risks.

Toxin-producing strains of *E. coli* pose the greatest concern for food safety. Some of these strains can cause severe diarrhea, while others can lead to bloody diarrhea and potentially serious complications such as kidney damage. These illnesses may require hospitalization. One outbreak of toxin-producing Enteroaggregative *E. coli* was linked to a seaweed salad product in Japan in 2020. However, investigators were unable to determine whether contamination occurred during seaweed harvesting or later during processing (Kashima et al., 2021).

Shiga toxin-producing *E. coli* (STEC) has also been detected on seaweed. In one study, Saccharina latissima samples tested positive for STEC at multiple harvest sites and during several collection periods within a single harvest season (Barberi et al., 2020; see Appendix A, Table A-1). These findings highlight the need for careful monitoring of both harvest water quality and post-harvest handling practices to reduce the risk of contamination with toxin-producing *E. coli*.

Other Enterobacteriaceae bacteria, including species in the genera *Enterobacter*, *Klebsiella*, *Proteus*, and *Citrobacter*, are known to cause foodborne illnesses and have been found in various seafood products (Sanjit Singh et al., 2017). Some of these bacteria, such as *Enterobacter cloacae* and *Klebsiella oxytoca*, have been detected on raw seaweed samples in several studies (Ezhilarasi et al., 2023; Gupta et al., 2010; Kreissig et al., 2023; see Appendix A, Table A-1). However, there have been no documented outbreaks of illness linked to these pathogens in raw seaweed, and current evidence does not consider them to pose a serious health risk in seaweed intended for raw consumption (Banach et al., 2020; Cavallo et al., 2021; Løvdal et al., 2021).

Salmonella

Salmonella enterica is a bacterium that can cause serious illness (and even death), especially in young children, older adults, and individuals with weakened immune systems. It is the leading cause of hospitalizations and deaths from gastroenteritis in the U.S. Because *Salmonella enterica* is commonly found in other raw seafood products, it should be considered as a potential hazard in raw seaweeds as well (Banach et al., 2020; Cavallo et al., 2021; Lovdal et al., 2021). However, most studies that have tested raw seaweed for *Salmonella enterica* have not detected its presence (Akomea-Frempong et al., 2021; Akomea-Frempong et al., 2022; Banach et al., 2024; Lytou et al., 2021; Moreira-Leite et al., 2023; Oliveira et al., 2024; Skonberg et al., 2021; Son et al., 2014; Sorensen et al., 2023). Despite this, outbreaks have occurred.

In 2016, fourteen cases of salmonellosis in Hawaiʻi were linked to the consumption of raw seaweed sold by a farm that lacked adequate bathroom and handwashing facilities (Nichols et al., 2017). Additionally, *Salmonella enterica* was detected in 83% of *Saccharina latissima* samples collected near a wastewater treatment outflow, indicating that environmental contamination can pose a significant risk (Barberi et al., 2020; see Appendix A, Table A-1). These findings underscore the importance of maintaining good hygiene practices and ensuring harvest waters are free from wastewater contamination.

Listeria

Listeria monocytogenes is a bacterium that causes listeriosis, an illness that includes symptoms such as fever, muscle aches, and diarrhea. In pregnant women, listeriosis is particularly dangerous, as it can result in miscarriage, premature birth, or severe infection in newborns. People with weakened immune systems and adults aged 65 and older are also at increased risk of serious complications, including brain infections (encephalitis). Most studies that have tested raw seaweed for Listeria monocytogenes have not detected the pathogen (Akomea-Frempong et al., 2021; Akomea-Frempong et al., 2022; Blikra et al., 2019; Lytou et al., 2021; Moreira-Leite et al., 2023; Skonberg et al., 2021; Son et al., 2014). However, one study reported the presence of Listeria monocytogenes in a Sargassum species (Beleneva et al., 2011).

Listeria monocytogenes has also been attributed to several cases of listeriosis in marine animals, including dolphins, seals, and sea turtles (Bailey et al., 2024; Di Renzo et al., 2022; Grattarola et al., 2016; Rubini et al., 2023; Sevellec et al., 2020). It is known to survive in marine environments for extended periods—up to three weeks in some studies (Bremer et al., 1998). These findings suggest that while the risk appears low, *Listeria monocytogenes* should still be considered a potential hazard, particularly if seaweed is harvested from areas where environmental or animal contamination may occur.

Spore-Forming Bacteria

The **Bacillus** genus includes over 140 species, most of which grow under oxygen-rich (aerobic) conditions (Logan et al., 2012). All *Bacillus* species are capable of forming endospores, structures that allow them to survive harsh environmental conditions (Kramer et al., 1989). While many *Bacillus* species are not harmful to humans, certain strains—particularly *Bacillus cereus*—are associated with foodborne illnesses due to their production of heat-stable toxins (Kramer et al., 1989; Lovdal et al., 2021). Some *Bacillus* species naturally colonize seaweed surfaces (Hollants et al., 2013), and aerobic spore-forming bacteria (often indicative of *Bacillus*) have been readily detected on raw seaweeds (Blikra et al., 2019; Lytou et al., 2021).

Specifically, regarding *Bacillus cereus*, several studies have not found it on raw seaweed samples (Banach et al., 2024; Blikra et al., 2019; Kim et al., 2006; Son et al., 2014; Lytou et al., 2021), while others have reported positive detections (Indraningrat et al., 2023; Lytou et al., 2021; Wiese et al., 2009). Certain seaweed species may be more prone to contamination. For example, Bacillus cereus was detected on *Saccharina latissima* (sugar kelp) but not on *Alaria esculenta* (winged kelp) grown at the same aquaculture site (Lytou et al., 2021).

Other potentially pathogenic *Bacillus* species, such as *Bacillus licheniformis* and *Bacillus pumilus*, have also been identified on raw seaweeds (Blikra et al., 2019; Wiese et al., 2009). Although these are often considered environmental contaminants introduced during handling or processing, their natural occurrence in marine environments and detection on raw seaweeds suggest Bacillus species may pose a potential biological hazard.

Clostridium contains several species which grow under oxygen-free (anaerobic) conditions, and like *Bacillus*, are capable of forming resilient endospores. Some *Clostridium* species can cause foodborne illness by producing harmful toxins (Roy et al., 2024). The two species of greatest food safety concern are Clostridium perfringens and *Clostridium botulinum*. *Clostridium perfringens* is commonly found in a variety of environments, including soil and marine waters (Matches et al., 1974). It is also prevalent in the intestines of animals, and its levels in seawater tend to increase near sources of wastewater contamination. At least one study has detected *Clostridium perfringens* on raw seaweed (Kim et al., 2006), suggesting that it may pose a risk—particularly if seaweed is consumed raw, or processed into vacuum-packed or low-oxygen packaging without an effective step to eliminate the pathogen.

Clostridium botulinum has not been detected in raw seaweeds to date, although relatively few studies have screened for it specifically. It is generally considered more likely to enter the product during processing rather than from the natural environment. The food safety risks associated with *Clostridium botulinum,* particularly those related to inadequate processing and low-oxygen packaging, are addressed in more detail in Chapter 12.

Other Bacterial Pathogens

Several other types of bacteria known to cause foodborne illness have been found on raw seafood and, in some cases, on raw seaweeds. These include species from the genera *Aeromonas*, *Campylobacter*, *Enterococcus*, *Staphylococcus*, and *Yersinia* (Vairappen and Suzuki, 2000; Gupta et al., 2010; Beleneva et al., 2011; Picon et al., 2021; Kreissig et al., 2023; see Appendix A, Table A-1).

Some of these, like *Aeromonas*—which naturally occurs in aquatic environments—and Staphylococcus, which can tolerate salty conditions, may pose potential food safety risks in raw seaweed products (Banach et al., 2020; Lovdal et al., 2021). However, the others have not been linked to significant health risks in raw seaweeds specifically (Banach et al., 2020; Cavallo et al., 2021; Lovdal et al., 2021). Instead, they are more commonly associated with contamination that occurs during handling or processing, which is addressed in Chapter 11.

Viruses

Norovirus is a highly contagious virus and a leading cause of foodborne illness outbreaks across all age groups. A small number of outbreaks have been associated with seaweed consumption, including one linked to green seaweed served in schools in South Korea (Park et al., 2015), several involving nori or laver in Japan (Kusumi et al., 2017; Noda et al., 2017; Sakon et al., 2018; Somura et al., 2017), and one linked to wakame in Norway (Whitworth, 2019). However, investigations into these incidents point to contamination occurring during processing, not from the marine environment itself.

Additionally, some studies have found no evidence of Norovirus in freshly harvested seaweed (Faasen et al., 2024; Oliveira et al., 2024). More research is needed to understand whether Norovirus can attach to seaweed surfaces and whether raw seaweeds could serve as a route for virus transmission.

Hepatitis A Virus (HAV) and **Hepatitis E Virus** (HEV) are both found in areas affected by wastewater contamination and are known to cause serious illness when transmitted through contaminated seafood (Roy et al., 2024). Other viruses commonly found in sewage-contaminated seawater that may also be linked to seafood include Sapovirus, Astrovirus, and Rotavirus (Cioffi, 2021). However, to date, no studies have specifically examined whether these viruses are present on raw seaweeds.

Health Risks Associated with Bacterial and Viral Pathogens

The health risks associated with pathogens depend on several factors, including the specific species and strain of the microorganism, the amount needed to cause infection (known as the infectious dose), a person's underlying health conditions, and how often the contaminated food is consumed. Most of the pathogens discussed above (such as STEC and *Vibrio parahaemolyticus*) typically cause gastrointestinal illness, with symptoms ranging from mild to severe and including vomiting, abdominal cramping, bloating, and diarrhea. In contrast, infection with *Listeria monocytogenes* may go unnoticed in healthy individuals but can have serious consequences for certain groups. In pregnant women, it can lead to miscarriage or birth defects, and in older adults or those with weakened immune systems, it can cause life-threatening conditions such as meningitis or encephalitis.

Some bacteria, such as *Bacillus* and *Clostridium* species, cause illness not through the bacteria themselves but through the production of harmful toxins. These toxins can lead to a range of symptoms, from vomiting and diarrhea to paralysis or even fatal bloodstream infections (sepsis).

The amount of a pathogen required to make someone sick varies widely. For example, *Vibrio cholerae* generally requires around 10,000 bacterial cells to cause illness (Kothary and Babu, 2001), whereas Norovirus is highly infectious and can cause infection from exposure to just a single viral particle (Teunis et al., 2008). For toxin-producing bacteria, determining an infectious dose is more complex, as illness results from the toxins they produce rather than the number of bacteria present. Toxin production can vary significantly depending on the bacterial species and environmental conditions that influence growth and toxin production. Regardless of the infectious dose, frequent consumption of contaminated seaweed can increase the risk of illness and lead to repeated infection (caused by consuming live pathogens) or intoxication (caused by ingesting toxins produced by bacterial pathogens), which may result in long-term health impacts.

Determining if the Hazard is Significant

If pathogens are found at or near levels known to cause illness, they are considered a significant hazard—either "reasonably likely to occur" (HACCP) or "hazard requiring a preventive control" (PCHF)—that must be controlled. To clearly determine whether a hazard exists, it is important to understand which bacterial and viral pathogens are commonly linked to the particular seaweed species being cultivated, as well as the specific characteristics and quality of the water body where it is grown.

Seaweeds cultivated or harvested from waters contaminated with untreated human waste present a serious risk to public health due to potential exposure to a variety of harmful pathogens (as discussed above). Appropriate control measures should be put in place to reduce this risk and help ensure consumer safety.

Control measures for pathogens present in the harvest area may not be required if the seaweed is intended for processing using methods that have been validated to effectively kill or eliminate the specific pathogen(s) of concern.

Hazard Controls and Critical Control Points

To help keep raw seaweed safe to eat, two of the most important safety steps are:

1. Harvesting from clean, approved areas (sourcing), and
2. Keeping the seaweed cold during storage and transport (temperature control).

These steps help lower the chance of pathogens from the water making people sick.

Sourcing—Considerations for Site Selection and Water Testing

- When choosing a farm or harvest location, it's important to consider how the surrounding land and water can affect the safety of the seaweed. For example, pollution from untreated human or animal waste—such as sewage overflows, failing septic systems, or wastewater treatment plant discharges—can introduce harmful pathogens into the water where seaweed is grown. These concerns may be considered and addressed during the permitting process for commercial seaweed cultivation and harvesting.

- Check whether there are large numbers of birds or marine mammals near the site, since their waste can carry pathogens that may contaminate the seaweed. In some cases, the farm's floating equipment may attract these animals, so routine monitoring of the site is recommended.
- To help assess water quality, tests can be done for bacteria such as total and fecal coliforms. These are used as indicators of fecal (waste) contamination. In some cases, more direct testing for specific disease-causing microbes (pathogens) in the water may be used to better understand potential biological risks—especially for those that naturally occur in marine environments. Acceptable levels of these bacteria may differ depending on state regulations.
- Many state agencies classify waterways as approved or conditionally approved for harvesting seafood or seaweed based on safety standards, which can vary from one state to another.
- For more information on how to identify possible biological hazards in source waters, see Table 5-2 below.

Temperature Control

Even when harvesting seaweed from approved or conditionally approved waters, pathogens may still be present. If the seaweed is going to be consumed raw, it's important to maintain temperature controls after harvest. Without proper temperature control during storage and transport, these pathogens can grow to dangerous levels.

For example, *Vibrio vulnificus* can multiply quickly in oysters that aren't stored under refrigeration (Cook, 1997). Storing raw seaweed in seawater at room temperature (68–71°F or 20–22°C) can maintain or even increase the amount of bacteria present. This includes both harmful and non-harmful types of E. coli, as well as *Listeria monocytogenes*, *Salmonella enterica,* and *Vibrio parahaemolyticus* (Akomea-Frempong et al., 2023; Swinscoe et al., 2020). To ensure food safety, seaweed should be chilled as soon as feasible after harvest and kept cold during holding, transport, and processing. See Chapter 10 for more information on how to prevent bacterial growth caused by temperature abuse.

Critical Control Point (CCP): Upon receiving product at their facility, primary processors are responsible for ensuring that appropriate controls are in place to reduce or eliminate this hazard. While these controls are typically implemented by producers, processors must verify that appropriate measures have been taken to ensure the product is safe at the point of receipt.

Table 5-2: *Sources of information for identifying possible biological hazards in source waters.*

#	Department / Resource	Description
1	State Health Department	In some states, local health departments will monitor water bodies for wastewater contamination. For example, in New York, the Department of Health (DOH) monitors local fresh and marine waters for fecal contamination including *E. coli* and *Enterococci*. Based on the results, they issue advisories related to swimming safety and seafood consumption.
2	State Environmental and/or Natural Resource Department	In some states, agencies responsible for environmental protection and/or natural resources may also monitor water bodies for wastewater discharge or provide information about sources of contamination. For example, in New York, the Department of Environmental Conservation (DEC) publishes information about known (point) sources of wastewater pollution, such as outflows from Combined Sewage Outfalls (CSOs).
3	State Department of Agriculture	Agriculture Departments in many states are typically responsible for overseeing food safety and agriculture production. Local Agriculture Departments may also be a helpful resource for identifying potential contaminants of concern.
4	State Shellfish Control Authority	States where shellfish are farmed or harvested will have a Shellfish Control Authority that typically monitors marine waters for bacterial and viral hazards, including fecal indicator bacteria. This authority also determines which coastal waters are approved for safe shellfish harvesting, which may apply to seaweed production and harvest.
5	State Land Grant and Sea Grant Extension	State Land Grant Extension and Sea Grant Extension programs may have specialists who may be able to assist with identifying contaminants of concern in your region.
6	Federal Environmental Protection Agency (EPA)	The EPA manages the ECHO (Enforcement and Compliance History Online) database, which can be used to identify point sources of microbial pollution (Category: Pathogen Indicators) across the U.S. https://echo.epa.gov/
7	Tribal Governments	Tribal governments may have independent permitting processes and standards for approving waters for harvest and aquaculture practices. These organizations may also monitor

#	Department / Resource	Description
		water bodies adjacent to tribal lands for wastewater or other sources of pathogen contamination.
8	Business Planning for Kelp Farming: Resources Annex	Connecticut Sea Grant's *Business Planning Guide for Kelp Farming* (PDF) has an annex of resources that could provide additional contacts by state who could support in identifying potential contaminants of concern.
9	Citizen Science and/or Non-Profit Environmental Organizations	Local citizen science and/or environmental outreach programs may have on-going water quality monitoring programs that include data from testing for fecal indicator bacteria.

Control Strategies

Table 5-3: *Control Strategies for Pathogens in the Harvest Area for Seaweeds*

Control Strategy	Primary Processor	Secondary Processor
Source Control	✓	
Temperature Control	✓	

Control Strategy 1 – Source Control

- If the seaweed will be eaten raw, the Primary Processor should not accept the seaweed if:
- The harvest area is closed to fishing or farming by any government or tribal authority, OR
- There is a public health advisory warning people not to eat seafood from that area, OR
- The species is known to carry or be contaminated with unsafe levels of specific pathogens.

Critical Limit(s)/Parameter(s) and Value(s)

- Seaweed is grown and/or harvested from approved waters with no health or consumption advisories by federal, state, tribal, territorial, local, or foreign regulatory authorities

    - NOTE: Most advisories are written for fish or shellfish. Unless a state has a program to test and certify seaweed-growing waters specifically, these advisories may not directly mention seaweed.

OR

- A supplier certification or letter of guarantee is provided with each shipment, confirming the seaweed was harvested from waters safe for production, with no history of significant microbial contamination.

Monitoring – What, How, How Often, Who

- What will be monitored?
    - The status of the harvest location, confirming that it is open and not under closure or subject to any consumption advisories related to bacterial or viral pathogens.

  OR

    - A signed supplier certification or letter of guarantee indicating that the product was harvested from waters safe for seaweed production that would not cause high levels of microbial contamination in seaweed products.
- How will monitoring be done?
    - Obtain (and review) harvester or grower records provided at receipt indicating harvest location and date/time of harvest. Review harvest location and check for closures or advisories on water bodies at the time of harvest.

  OR

    - Visual check for certificate or letter of guarantee.
- How often will monitoring be done?
    - At the time of receipt for every lot received.
- Who will do the monitoring?
    - An individual with an understanding and knowledge of the relevant controls and procedures for monitoring.

Corrective Action/Corrections

- If the harvest location is closed to harvesting **OR** the harvest area is under a consumption advisory; then reject the lot.
- If proper documentation (letter of guarantee) confirming the harvest area is approved or conditionally approved was not provided, then hold the product **AND** contact the supplier to request proper source documentation to verify safety **OR** reject the lot.

AND address the root cause to prevent future occurrence.

- Review receiving requirements with the supplier and discontinue use until corrected to help prevent future errors.

Verification

- Within one week of when monitoring or corrective action records are made, review them to make sure all steps were completed correctly.
- Regularly monitor websites or reports from federal, state, local, or foreign regulatory authorities for any harvest restrictions or consumption advisories for the water bodies where the seaweed is grown or harvested.

Records

- **Monitoring Records:** Receiving log including the harvest date, harvest location, quantity of seaweed, harvester contact or permit information (if purchased directly from the producer), along with verification of the harvest location's current status OR receiving log indicating receipt of a supplier certificate or letter of guarantee, with a copy of the certificate or letter kept on file.
- **Corrective Action Records:** Documentation of any corrective actions taken (if needed).
- **Verification Records:** Documentation of periodic reviews (at least once a year) of harvest locations for closures or consumption advisories.
- **Training Records:** A record of all relevant training completed.

Example HACCP Plan for Source Control

Below are examples showing what a food safety plan could look like for this hazard. It is intended for illustrative purposes only. Each producer must develop a plan tailored to their unique products, production and processing methods, and regulatory requirements. **These examples should not be copied and used without modification to fit your specific operation.**

Control Strategy: Source Control
Critical Control Point (HACCP): Receiving Step
Hazard: Pathogens in the Harvest Area

Parameters, Values, Critical Limits	Monitoring				Corrective Action	Verification	Records
	What	How	When	Who			
No seaweed is grown or harvested from waters where federal, state, tribal, territorial, local, or foreign authorities have issued health or consumption advisories stating that the water is unsafe for food production or that the seaweed from that area is unsafe to eat.	The status of harvest location is not under closure or subject to consumption advisories for bacterial and/or viral pathogens.	Obtain (and review) harvester or grower record indicating harvest location and date/time of harvest. Review harvest location and check for closures or advisories on waterƒ bodies at the time of harvest.	At time of receipt for all lots received	Receiving Manager	If seaweed is received from waters known to be contaminated or under a consumption advisory, reject the lot. Stop using that supplier until they provide evidence that harvesting now takes place in approved waters with no consumption advisories.	Review of monitoring and corrective action records within one week of preparing to ensure they were completed appropriately. Periodic monitoring of federal, state, local, or foreign regulatory authorities' websites or reports on harvest restrictions and consumption advisories for water bodies products are sourced from.	Receiving log including the harvest date, harvest location, quantity of seaweed, and harvester contact or permit information , along with verification of the harvest location's current status. Corrective action records, if necessary. Verification records including harvest restriction reports or checks.

Example Food Safety Plan for Source Control

Facilities regulated under the Preventive Controls for Human Food (PCHF) rule that identify a supply-chain-applied preventive control must establish and implement a supply-chain program. This program should detail how suppliers are selected, approved, and verified to ensure they effectively control the identified hazard. For more detailed guidance, refer to Chapter 15 of the FDA's *Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food* (USFDA, 2024).

Control Strategy: Source Control
Supply Chain Preventive Control (PCHF): Receiving Step
Hazard: Pathogens in the Harvest Area

Raw Material / Ingredient	Approved Supplier	Date of Approval	Hazard Requiring PC	Preventive Control Applied by Supplier	Verification Activities Supplier	Verification Procedures Buyer	Corrective Actions	Records
Sugar Kelp	ABC Kelp Co. 123 Sugar Dr. Somewhere, NY 55555	Jan. 2, 2024	Pathogens in the Harvest Area	Pre-harvest check for harvest area closures and advisories.	Annual review of federal, state, local, or foreign regulatory authorities' websites or reports on harvest restrictions and consumption advisories for water bodies products are sourced from.	Obtain a copy of producer records indicating harvest area and water body status at the time of harvest.	If producer records are not received, then, reject the lot **OR** hold until documentation is received **AND** discontinue use of the supplier until evidence is obtained that record requirement can be met.	Receiving log that indicates the location and status of the harvest area and harvester information. Corrective action records, if necessary. Supplier verification records including harvest restriction reports or checks. PCQI Training records

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Chapter 6 Parasites

General Background: Understanding the Potential Hazard

Parasites are organisms that live on or inside a host, relying on them for survival. Some parasites can infect humans when ingested, so their presence in food can pose a health risk. This chapter will review common human parasites found in the marine environment and summarizes current knowledge about their presence in seaweed species. However, since there have been no reported cases of parasitic infections from consuming seaweed, this chapter does not include detailed guidance on parasite control for seaweed.

Protist Parasites

Protists are unicellular organisms, such as microalgae and protozoan parasites, capable of causing disease in humans. Some protists, like certain microalgae, produce toxins that enter the surrounding water and can bioaccumulate (build up) in fish and/or shellfish. More detailed information about these natural toxins produced by microalgae protists and how they affect seaweed safety is covered in Chapter 9 of this guide. Disease causing protozoans enter the body when people accidentally swallow their cysts, which may be present in food or water contaminated with feces. However, processing steps, such as cooking, usually kill these cysts, making the food safe. Some protozoan parasites linked to illnesses from eating fish and shellfish include *Toxoplasma gondii*, *Giardia* species, *Cryptosporidium* species, and *Acanthamoeba* species (Shamsi, 2019). Because *Toxoplasma gondii* and *Giardia* are found more often and could pose a higher risk to seaweed consumers, they are explained further below.

Toxoplasmosis

Toxoplasmosis is primarily contracted by ingesting the dormant cyst form of the Toxoplasma gondii parasite through water contaminated with fecal matter. In healthy individuals, the illness usually causes mild symptoms. However, if a person is exposed for the first time during pregnancy, it can lead to miscarriage or birth defects. It can also cause serious brain infections (encephalitis) in people with weakened immune systems. More information can be found on the Center for Disease Control's website.

Marine mammals, such as dolphins, seals, and sea otters, can also become infected with *Toxoplasma gondii* (Dubey et al., 2020). The cysts of *Toxoplasma gondii* are commonly found in coastal marine environments and can remain infectious in seawater for several months (Lindsay & Dubey, 2009). These cysts can accumulate in shellfish such as oysters, mussels, and clams (Cong et al., 2021). Lab experiments have shown that *Toxoplasma gondii* cysts can adhere to the surface of kelp (Shapiro et al., 2014). Although *Toxoplasma gondii* has not been detected in wild seaweed, and no cases of toxoplasmosis have been linked to eating seaweed, the presence of this parasite in marine mammals and the potential for seaweed to carry *Toxoplasma gondii* cysts means it should be considered a potential hazard when assessing risk associated with growing or harvesting waters.

Giardiasis

Giardiasis is an infection caused by various species of the *Giardia* parasite (including *Giardia lamblia, Giardia duodenalis*, and *Giardia intestinalis*) and is the most common cause of intestinal parasite infections in humans worldwide. Symptoms may include nausea, chills, fever, abdominal pain, and foul-smelling diarrhea that can contain mucus and blood.

Giardiasis is mainly contracted by ingesting the dormant cyst form of *Giardia* through freshwater contaminated with fecal matter. However, *Giardia duodenalis* has also been found in dolphins, sharks, farmed fish, and wild fish, which can introduce *Giardia* cysts into marine environments where seaweed grows (Yang et al., 2010). One documented case linked *Giardia lamblia* transmission to canned salmon (Osterholm et al., 1981).

To date, *Giardia* species have not been detected in wild seaweed, and there are no reports of giardiasis resulting from seaweed consumption. Nonetheless, similar to toxoplasmosis, the presence of giardiasis in marine mammals indicates that *Giardia* should be considered a potential hazard when assessing risk associated with growing or harvesting waters.

Helminth Parasites

Helminth parasites, commonly known as worms, fall into three main groups: nematodes (or roundworms), trematodes (or flukes), and cestodes (or flatworms). There are no helminth parasites that infect seaweeds and also infect humans. However, several helminth parasites are associated with the consumption of raw fish and shellfish. Seafood-related roundworms include (but are not limited to) the following species *Anisakis simplex* and *Pseudoterranova decipiens*, both of which can cause the disease anisakiasis), as well as *Eustrongylides* species and *Gnathosoma* species (Sakanari et al., 1995; Shamsi 2019). Tapeworms linked to seafood include *Diphyllobothrium* species (Sakanari et al., 1995; Shamsi 2019). Finally, seafood-associated flukes include *Clonorchis sinensis*, *Opisthorchis* species, *Heterophyes* species, *Metagonimus* species, *Nanophyetus salmonicola*, *Paragonimus* species, and *Phagicola* species (Sakanari et al., 1995; Shamsi 2019).

These helminth parasites live in the tissues of fish and shellfish, and processing steps, such as cooking, effectively kill their eggs and larvae in seafood products. No cases of these parasites have been documented in relation to seaweed consumption. However, since eggs or larvae of these parasites can be temporarily free-living in the water column, these parasites may pose a potential biological hazard for the consumption of raw or unprocessed seaweed if present at high levels in the growing or harvest waters.

Controlling Parasites

When growing and harvesting seaweed from new areas, it is important to learn about the waterbody and nearby environment to assess if parasites need to be monitored or tested for. However, this may be difficult. For example, there is currently no USDA or FDA approved method for testing for *Toxoplasma gondii* in water or food samples. Therefore, when selecting a cultivation or harvest site, consider whether there are large populations of marine mammals nearby and check if any marine mammal strandings in the area have been linked to parasite infections. If growing seaweed under floating structures, monitor for the presence of birds or marine mammals that may be attracted to those structures. In addition, regularly monitoring consumer complaints and documented cases of parasitic infection linked to your products or other products sourced from your growing or harvest waters can be a good indicator of this hazard.

If you know or reasonably suspect that parasites may be present in the water where seaweed is grown or harvested, appropriate controls should be implemented to reduce the risk of parasitic infection. Parasites can be controlled through processes such as heat treatment and freezing. For more information on controlling parasites see Chapter 5 of the FDA's *Fish and Fishery Products Hazards and Controls Guide* (USFDA, 2022).

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Chapter 7 Environmental Chemical Hazards

General Background: Understanding the Potential Hazard

Seaweeds, like other foods, can absorb and store contaminants from the waters where they grow (Mohammed & Khaled, 2005). They can bioaccumulate environmental chemicals such as heavy metals to hazardous concentrations, potentially posing a food safety risk. The overall food safety risk associated with seaweed is influenced by both consumption patterns and the wide variability in contaminant levels, which depend on the seaweed species and the environmental conditions in which the seaweed is grown.

The extent of bioaccumulation of environmental chemical hazards varies. Factors that can influence contaminant concentrations include the type of seaweed (e.g., brown, red, or green), environmental conditions (e.g., salinity, sunlight, water current, temperature, and pH), seasonal variation, and the depth at which the seaweed grows (Sharma et al., 2018). Studies have also found that contaminant concentrations, such as heavy metals, can vary significantly depending on which part of the seaweed is analyzed (Burger et al., 2006; Shaughnessy et al., 2023). Figure 7–1 shows the anatomy of different seaweed species and can be used as a reference to understand where heavy metals may build up.

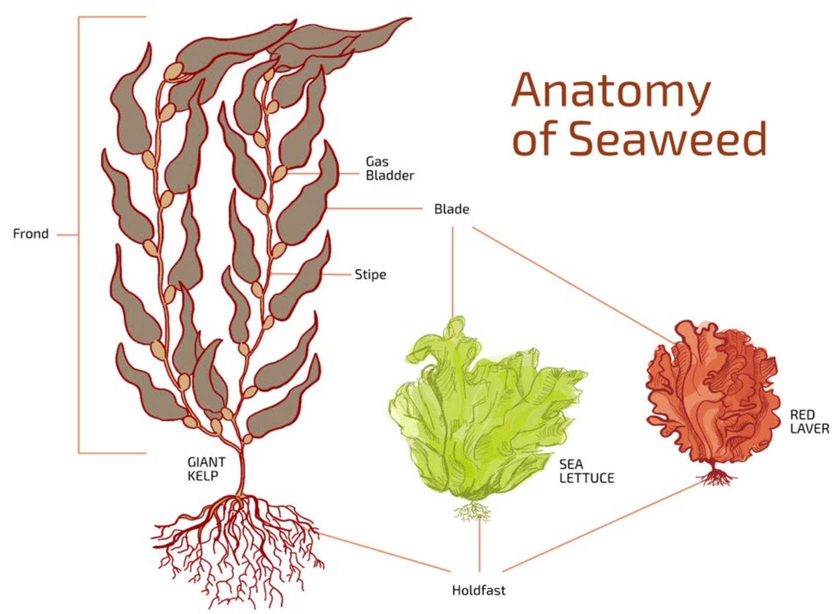

Figure 7-1 Anatomy of Seaweed

Monitoring is especially important near urbanized estuaries, where industrial activity and urban runoff can elevate environmental contaminant levels. For example, metal concentrations in seaweed grown near urban areas such as the Bronx River Estuary can approach regulatory limits for certain metals like lead, demonstrating the importance of site-specific hazard assessment (Kim et al., 2019). With nearly 40% of the U.S. population living in coastal zones (NOAA, 2014)—and the majority of marine pollution originating from land-based sources—seaweed processors must be especially cautious when sourcing from areas affected by urban or industrial discharge.

This chapter provides an overview of environmental chemical hazards relevant to edible seaweed production and processing, both domestic and imported. Although the U.S. seaweed industry is growing, imports dominate the market (Cai et al., 2021; Kotowicz et al., 2024). It is essential for processors to ensure compliance with U.S. food safety regulations regardless of origin, as importers are required to ensure that products are processed in compliance with U.S. food safety regulations. For this reason, background information relevant to both domestic and international seaweed products will be provided in this chapter.

This chapter is meant to serve as a general guideline for processors of both wild-harvested and farmed seaweed. The origin of the seaweed—whether farmed or wild—may influence the types and levels of environmental chemical hazards present. Therefore, processors must assess and manage these hazards based on the specific conditions under which their seaweed was harvested or cultivated. Additionally, current food safety standards do not fully account for the unique characteristics of seaweed consumption, such as product form, serving size, and how the body absorbs nutrients and contaminants (bioavailability). Because seaweed-specific regulatory thresholds are still limited, the most practical approach for now is to rely on existing data and general food safety guidelines to inform preliminary recommendations. As the domestic seaweed industry expands and more research becomes available, these guidelines will be updated and refined to better reflect real-world consumption patterns and product use in the U.S.

This chapter also includes multiple tables (Tables 7-1 through 7-5) to support food safety decision-making for processors of wild-caught and farm-raised seaweeds. These tables summarize key information, including heavy metal hazard rankings, known toxicological effects, regulatory thresholds, global monitoring data, and hazard control strategies.

Heavy Metals and Health Risks

Heavy metals are naturally occurring elements of 5.0 g/cm^3 or greater (Duffus, 2002). While some heavy metals are essential for biological processes in trace amounts, others are toxic even at low concentrations (Dufus, 2002). Seaweed can accumulate heavy metals to levels several orders of magnitude higher than the surrounding seawater, making them not only a highly effective indicator of marine pollution (called biomonitors)—but also a potential food safety concern (Morrison et al., 2008). If seaweed products intended for human consumption or animal feed contain toxic levels of contaminants, this can pose a risk to consumer health, especially with frequent consumption.

Among heavy metals, arsenic (As), cadmium (Cd), lead (Pb), and mercury (Hg) are particularly concerning due to their well-documented health risks (Choi et al., 2021; Chowdhury et al., 2018; Ding et al., 2005; Halabisky et al., 2000; Huang et al., 2025; Kim et al., 2014; Peng et al., 2020; Tellez-Plaza et al., 2013; Wang et al., 2022; Wang & Du, 2013; WHO, 2022; Yu et al., 2024). Chronic exposure to these elements can cause serious conditions, including cancer, neurological damage, kidney disease, and cardiovascular problems. Table 7-1 provides a summary of negative health effects from these toxic heavy metals.

Heavy metals toxicity depends on several factors, including the chemical species (i.e., organic versus inorganic forms), dose, route of exposure, and frequency of consumption, as well as individual characteristics such as age, gender, genetics, and nutritional status (Tchounwou et al., 2012). Evaluating potential dietary exposure to these toxic elements through seaweed consumption remains challenging in the U.S. and globally, due to limited data on seaweed consumption patterns.

Given the recognized negative health effects of As, Hg, Cd, and Pb, several national and international authorities have identified these four heavy metals as priority contaminants. The European Food Safety Authority (EFSA) identified them as major contaminants in seaweed (Sá Monteiro et al., 2019), and the World Health Organization (WHO) includes them among the “ten chemicals of public health concern” (WHO, 2022). The U.S. Food and Drug Administration (FDA) also lists these elements as toxic environmental contaminants in the food supply (USFDA, n.d.). The following section provides an overview of the levels, sources, and implications of these metals in seaweed intended for human consumption.

Note: While these four contaminants are highlighted due to their prevalence and potential health risks, seaweed processors should also consider the potential presence of other heavy metals and/or metals that may pose a risk in their specific products. If such contaminants are suspected or identified, it is the responsibility of the processors to conduct appropriate testing and provide evidence that their products are safe for consumption.

Table 7-1: Summary of negative health effects of heavy metals.

Heavy Metal	Health Effects	References
Arsenic (As)	Carcinogenicity (skin, lung), cardiovascular disease, anemia, oxidative stress, damage to erythrocytes and DNA	Ding et al., 2005; Huang et al., 2025; WHO, 2022; Yu et al., 2024
Cadmium (Cd)	Carcinogenicity (bladder, kidney, liver), neurotoxicity (cognitive impairment, calcium signaling disruption), cardiovascular disease	Halabisky et al., 2000; Peng et al., 2020; Tellez-Plaza et al., 2013; Wang & Du, 2013
Lead (Pb)	Neurotoxicity (cognitive decline, behavioral problems), cardiovascular disease (coronary heart disease, stroke), irreversible developmental damage in children	Chowdhury et al., 2018; Wang et al., 2022
Mercury (Hg)	Neurotoxicity (vision loss, seizures, intellectual disability), hepatotoxicity (liver dysfunction), developmental delays in children	Choi et al., 2021; Huang et al., 2025; Kim et al., 2014

Arsenic (As)

Arsenic (As) exists in both organic and inorganic (iAs) forms. Of the two types, iAs is far more toxic, with chronic exposure linked to serious health risks such as cancer, skin lesions, developmental defects, and cardiovascular diseases (see Table 7-1). Brown seaweeds, such as kombu (*Laminaria* species) and hijiki (*Sargassum fusiforme*), can contain elevated levels of As (EFSA, 2023). Hijiki, in particular, has raised concerns due to its high iAs concentrations—ranging from 32.1 to 69.5 mg/kg—prompting some health agencies to advise against its consumption (Besada et al., 2009). Certain samples of *Laminaria digitata* from Maine contained iAs levels of 2.8–20.4 mg/kg, which could pose a health risk if consumed in large quantities (Taylor & Jackson, 2016).

Total arsenic (AsT) concentrations in brown seaweeds can exceed 100 mg/kg, with significant variability depending on environmental conditions and farming practices, even within the same species (Desideri et al., 2016). A study of seaweed harvested in New England found that *Laminaria digitata* contained AsT concentrations as high as 106 mg/kg, of which more than 85% of the As was present as arsenosugars. The toxicity of arsenosugars is still under investigation; they are generally considered to have low cytotoxicity and limited intestinal absorption compared to iAs. Nevertheless, arsenosugars are metabolized in the human body and are therefore considered bioavailable to humans. Additionally, some of their metabolites—such as thio-DMA—exhibit cytotoxic effects (Leffer et al., 2013a).

A recent study on farmed and wild-harvested *Saccharina latissima* in New England found AsT concentrations frequently exceeded European Union limits for animal feed, especially in samples from the base of the kelp blades (Shaughnessy et al., 2023). However, when speciated, the more toxic iAs levels remained low—less than 1% of AsT in most samples—and were below levels of regulatory concern, including California's Proposition 65 Safe Harbor limits (Safe Drinking Water and Toxic Enforcement Act of 1986). Notably, samples from areas near known contamination sources, such as Gallops Island in Boston Harbor, had higher iAs levels, with some exceeding 2% of AsT.

Kim et al. (2019) found similar results when analyzing *Saccharina latissima* and Gracilaria tikvahiae grown in urbanized estuaries in Long Island Sound and New York coastal waters. Both species had AsT concentrations below international regulatory limits, though Saccharina latissima showed higher AsT than *Gracilaria tikvahiae*. Limited As speciation data makes it difficult to fully assess health risks, since AsT levels alone don't indicate toxicity. Therefore, more focus on As speciation analysis is essential to accurately assess the potential health risks of seaweed consumption. Given the elevated iAs levels reported in Laminaria species in the literature, testing this genus for arsenic speciation is strongly recommended to ensure the safety of food and feed products (Taylor & Jackson, 2016).

Cadmium (Cd)

Cadmium (Cd) is a toxic heavy metal often found in red and brown seaweeds and is a contaminant of potential health concern, primarily affecting the kidneys (EFSA 2009a). Analysis of more than 2,000 seaweed samples revealed that red algae, such as dried laver, had the highest average Cd concentration with levels reaching 1,675 µg/kg (EFSA, 2023). Brown algae, including wakame, also contained high Cd levels (~1,276 µg/kg), while green algae generally had lower levels

The maximum allowable level of Cd in edible seaweed varies globally. For example, France recommends a limit of 0.5 mg/kg (CSHPF), while the European Commission sets a limit of 0.3 mg/kg for food supplements containing at least 80% dried seaweed. Taiwan's limit is 1.0 mg/kg for Cd in seaweed. In the U.S., the FDA applies a toxicological reference value (TRV) of 0.21–0.36 µg/kg body weight per day to assess health risks and determine action levels when contaminants exceed safe thresholds.

A study conducted by Kim et al. (2019) measured Cd concentrations in two seaweed species—*Gracilaria tikvahiae* (a red alga) and *Saccharina latissima* (a brown alga)—cultivated in urbanized estuaries in the Northeastern United States. Cd concentrations were 0.072 mg/kg in Gracilaria and 0.118 mg/kg in Saccharina, both well below France's regulatory limit of 0.5 mg/kg. However, Cd levels were significantly higher in samples from the Western Long Island

Sound and Bronx River Estuary compared to laboratory-grown controls. This suggests that while Cd levels in U.S.-cultivated seaweed were generally low, local environmental factors—such as proximity to industrial activity or wastewater discharge—can increase Cd concentrations. In contrast, analysis of wild and farmed *Saccharina latissima* in New England found that Cd concentrates at higher levels at the base of *Saccharina latissima* blades, and those concentrations frequently exceed levels of regulatory concern, regardless of proximity to sources of contamination (Shaughnessy et al., 2023).Ongoing monitoring is therefore essential, especially for seaweed harvested from or near urban coasts.

Lead (Pb)

Lead (Pb) exposure is especially harmful to vulnerable groups, such as children, due to its neurotoxic effects, including impaired cognitive development (Roleda et al., 2019). Data from nearly 2,000 samples analyzed by the European Union show that Pb concentrations in seaweed can contribute 10–30% of total dietary Pb exposure (EFSA, 2023). This does not mean that seaweed alone causes Pb toxicity, but rather that it can make a measurable contribution to overall exposure.

Brown seaweeds such as kombu (*Laminaria* species), tend to have higher Pb concentrations compared to red and green seaweeds. For example, Pb levels in sea lettuce (*Ulva lactuca*) have been measured at 6.7 mg/kg, exceeding permissible limits in some regions (Martín-León et al., 2021). Shaughnessy et al. (2023) reported Pb concentrations in *Saccharina latissima* from New England ranging from 0.024 to 0.066 mg/kg dry weight. Similar to Cd, Pb accumulation varied by site and tissue type, with slightly higher concentrations in tissue from younger blade sections. While these values remain below international safety thresholds, the findings highlight the need for monitoring—especially in seaweeds grown near contaminated or urbanized areas—since they can reflect localized environmental contamination.

Mercury (Hg)

Mercury (Hg) exists in several forms: elemental, inorganic, and organic. The most toxic form, the organic form methylmercury, is a potent neurotoxin that poses risks to fetal brain development and adult cardiovascular health. In seaweed, Hg is typically measured as total Hg and is generally present at lower levels than other heavy metals, though concentrations vary by species and origin (Banach et al., 2020a). Reported Hg concentrations range from as low as 0.002 mg/kg in *Saccharina latissima* to as high as 0.055 mg/kg in *Eisenia bicyclis* (Desideri et al., 2016).

Shaughnessy et al. (2023) reported that Hg concentrations in wild and cultivated Saccharina latissima from New England ranged from 0.005 to 0.021 mg/kg dry weight, consistent with earlier studies suggesting that Hg—particularly methylmercury—is present at very low concentrations in this seaweed species. Similarly, Kim et al. (2019) measured total Hg in farmed *Gracilaria tikvahiae* and *Saccharina latissima* from Long Island Sound and New York City Estuaries. The highest concentrations in both species were 88–93% below the FDA's allowable limit for seafood, suggesting very low concern. Notably, Hg in *Gracilaria* was higher at the Western Long Island Sound site compared to the Bronx River Estuary and lab-grown controls, whereas *Saccharina latissima* showed the opposite pattern, with higher levels toward eastern sites. These variations reflect local environmental influences and underscore the importance of site-specific monitoring.

Data on mercury speciation (proportions of total, organic, and inorganic mercury) in seaweed remain limited, making it difficult to fully assess health risks. Current evidence suggests that methylmercury is present at minimal levels in seaweed (EFSA, 2023), but more research is needed to confirm this.

Heavy Metals Hazards Ranking in Seaweed

Table 7-2 summarizes the hazards ranking for heavy metals in edible seaweeds, based on the comprehensive food safety hazards report by Banach et al. (2020). The ranking is qualitative and considers four factors: (a) potential health effects on humans, (b) potential health effects on animals, (c) frequency of reporting in the EU Rapid Alert System for Food and Feed (RASFF), and (d) stakeholder concerns from survey data.

Hazards were scored and classified as follows:

- **Major Hazard:** Score 1.75–1.50
- **Moderate Hazard:** Score 1.49–1.25
- **Minor Hazard:** Score 1.24–0.75

According to this ranking, methylmercury and Pb are considered major hazards, while Cd and iAs are considered moderate hazards.

Table 7-2: *Heavy metals sources and associated hazards rankings, as described by Banach et al., 2020.*

Heavy Metal	Main Form of Concern	Typical Sources	Seaweed Accumulation	Hazard Ranking
Arsenic (As)	Inorganic Arsenic (iAs)	Soil, water, fertilizers, industrial emissions	Very high in hijiki (*Sargassum fusiforme*); brown seaweeds most affected	Major
Cadmium (Cd)	Cd	Industrial runoff	Often higher in red seaweeds; seasonal and geographic variation	Major
Lead (Pb)	Pb	Historical use in paint, petrol, and industry	Varies by species, site, and season; higher near industrial areas	Moderate
Mercury (Hg)	Methylmercury	Natural and industrial sources, found in seafood	Higher in brown seaweeds; varies by region	Moderate

Safe Level of Heavy Metal Intake and Regulatory Threshold Criteria

Safe intake levels for heavy metals in food are typically established by regulatory agencies such as the WHO, EFSA, FDA, and national food safety authorities in individual countries. Table 7-3 provides an overview of regulatory action limits for heavy metals in seaweed available at the time of publication.

Because there are relatively few regulations specifically targeting individual seaweed species, Table 7-3 combines general limits set for seaweed with broader regulations that apply to similar food categories (e.g., fruits and vegetables). In the U.S., seaweed food safety planning often references seaweed-specific legislation developed by the European Union (Shaughnessy et al., 2023).

Additional Information on heavy metals detected in seaweed worldwide can be found in Table B-1 in Appendix B of this guidance.

Table 7-3: *Available regulatory standards on the allowable maximum level of heavy metals in seaweed (if available) and other food categories.*

Heavy Metal	United States Standards	European Union Standards	France Standards	Taiwan Standards	China Standards	World Health Organization PTWI[2]
Total Arsenic (AsT)	0.01 mg/kg for fruit and vegetables[1]	*No Standard*	3.0 mg/kg	1.0 mg/kg	0.3 mg/kg dry weight for seaweed additive or supplements for infants 0.5 mg/kg dry weight for aquatic seasoning containing seaweed	*No Standard*
Inorganic Arsenic (iAs)	*No Standard*	0.3 mg/kg dry matter (ANSES, 2020) 0.2 mg/kg for rice (JECFA, 2017) 0.5 mg/kg for aquatic food containing seaweed seasoning	1 mg/kg (FSANZ, 2004)	*No Standard*	*No Standard*	0.015 mg/kg of body weight

[1] FDA, CFR Title 21, Part 17
[2] **Provisional Tolerable Weekly Intake (PTWI)** is a safety guideline established by organizations like the WHO or Joint FAO/WHO Expert Committee on Food Additives (JECFA) to estimate the amount of a potentially harmful substance, such as a heavy metal, that can be ingested weekly over a lifetime without posing significant health risks. Refer to Appendix F for additional guidance on how facilities can calculate safe consumption thresholds for their specific products and serving sizes, using published values such as the PTWI, Provisional Tolerable Monthly Intake (PTMI), or Minimum Risk Levels (MRLs).

Heavy Metal	United States Standards	European Union Standards	France Standards	Taiwan Standards	China Standards	World Health Organization PTWI[2]
Cadmium (Cd)	*No Standard*	0.5 mg/kg dry matter (ANSES, 2020)	*No Standard*	1.0 mg/kg	*No Standard*	0.007 mg/kg of body weight
Total Mercury	1.0 mg/kg (USFDA; EPA)	0.1 mg/kg dry matter (ANSES, 2020) No more than 0.10 mg/kg wet weight for seaweed derived for supplements (Commission Regulation (EC) 1881/2006).	*No Standard*	*No Standard*		0.0016 mg/kg of body weight
Methylmercury	*No Standard*	0.01 mg/kg	*No Standard*	*No Standard*	*No Standard*	*No Standard*
Lead	0.01 mg/kg (USFDA)	5 mg/kg dry matter (ANSES, 2020)	*No Standard*	1.0 mg/kg	0.5 mg/kg wet weight for fresh seaweed 1.0 mg/kg dry weight for seaweed-based products	0.025 mg/kg of body weight

California Proposition 65 Safe Harbor Levels for Heavy Metals

Under California's Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986), the Office of Environmental Health Hazard Assessment (OEHHA) establishes Safe Harbor Levels for chemicals known to cause cancer, birth defects, or other reproductive harm. These Safe Harbor Levels include:

- **No Significant Risk Levels (NSRLs):** Exposure thresholds for carcinogens.
- **Maximum Allowable Dose Levels (MADLs):** Exposure thresholds for reproductive toxicants.

Table 7-4*: No Significant Risk Levels (NRSLs) and Maximum Allowable Dose Levels (MADLs) for arsenic, cadmium, lead, and mercury.*

Heavy Metal	Inorganic vs. Organic	Safe Harbor Level	Type (NSRL/MADL)
Arsenic (As)	iAs & Compounds	0.001 µg/day	NSRL
Cadmium (Cd)	Cd & Cd Compounds	0.2 µg/day	NSRL & MADL
Lead (Pb)	Pb & Pb Compounds	15 µg/day	NSRL
Mercury (Hg)	Methylmercury & Hg Compounds	0.3 µg/day	NSRL & MADL

Pesticides

Pesticides are substances used to control, repel, or eliminate pests such as insects, weeds, and fungi. They include a wide range of chemical and biological compounds—such as organochlorines, organophosphates, carbamates, pyrethroids, and biological agents—each tailored to specific uses and target organisms.

Pesticides can enter marine environments through agricultural runoff or aquaculture operations. In agriculture, pesticides are applied during specific times in the growing season. This can lead to peak concentrations in fresh and coastal waters, particularly in spring after heavy rainfall or during flooding over short time frames (Carafa et al., 2007). In aquaculture, pesticides are sometimes used to address pest and disease issues, such as managing salmon lice (Garicia-Rodriquez et al., 2012).

Types of Pesticides and Their Characteristics

Seaweed contamination may involve modern pesticides commonly used in agriculture and aquaculture such as organophosphates, carbamates, and pyrethroids (Garcia-Rodriquez et al., 2012). These pesticides tend to be more water-soluble and break down faster than older classes like organochlorines. But they can still enter marine environments through agriculture runoff, aerial drift, or discharges from aquaculture, especially in nearshore growing areas.

Older organochlorines—such as Dichlorodiphenyltricholoethane (DDT) and its metabolites Dichlorodiphenyldichloroethane (DDD) and Dichlorodiphenyldichloroethylene (DDE), as well as Hexochlorochyclohexane (HCH), Hexachlorobenzene (HCB), and cyclodienes—were widely used in the past and remain persistent in some environments. Although now banned or restricted in many countries, they remain in use in some regions, and their residues can persist in sediments and aquatic organisms due to their stability and tendency to bioaccumulate in lipid-rich tissues (Pavonie et al., 2003; Polat et al., 2017).

Environmental Persistence and Accumulation in Seaweeds

Organochlorines have high environmental persistence and bioconcentration potential. They accumulate in suspended particulate matter (SPM)—small solid particles in water—and sediments (Pavoni et al., 2003).

Factors influencing organochlorine pesticide contamination in seaweed include:

- **Morphology**: Seaweeds with large surface areas and rough or mucilaginous textures (e.g., due to hairs, paraphyses, or epiphytic diatoms) can trap more SPM, increasing contaminant load (Pavoni et al, 2003).
- **Life Cycle:** Perennial seaweeds such as *Cystoseira*, *Fucus*, and *Gracilaria* accumulate more contaminants than short-lived ones, like *Porphyra*, *Ulva*, and *Grateloupia*, likely due to longer exposure (Pavoni et al., 2003).
- **Lipid Content:** Seaweeds with higher lipid content, such as *Undaria* (3.2% fat) compared to Ulva (O.6%), may retain more fat soluble (lipophilic) pesticides (Pavoni et al., 2003).
- **Water Column Position:** Seaweeds growing near or in contact with contaminated sediments are more likely to bioaccumulate sediment-associated contaminants (Pavoni et al., 2003).

Seasonal Dynamics

Organochlorine pesticide accumulation in seaweed often peaks during the reproductive (fruiting) season. During this time, many seaweeds increase fatty acid synthesis to support spore development, enhancing their affinity for fat-soluble pesticides. Structural changes in the thallus (Figure 1-1) during spore release may also increase surface area or alter surface properties, potentially increasing contact with contaminated particles in the surrounding environment

(Pavoni et al., 1990; Pinto et al., 2014; Sundhar et al., 2020). This seasonal pattern may be useful for interpreting monitoring results, but it is not intended as a basis for control strategies.

Global Surveys and Site Specificity

Pesticide contamination in seaweed has been documented worldwide, with results varying by regional pesticide use, environmental conditions, and proximity to sources of contamination (Table 7-3). Most studies report residue levels below established maximum residue limits (MRLs), particularly for modern pesticides. However, persistent organochlorines such as DDT, HCH, and endosulfan are still detected in elevated concentrations in some locations—especially in areas with historical use or insufficient regulation (El-Maradny et al., 2020; Sundhar et al., 2020).

This variability underscores the need to assess local contamination risks—such as agriculture runoff, industrial discharge, and aquaculture activities—when assessing seaweed safety. While routine monitoring is not universally mandated, exporters and harvesters should consider risk-based residue testing, especially in areas with known contamination or ongoing pesticide use. Global surveys show that contamination is highly site-specific and strongly influenced by local agricultural and aquaculture practices (Banach et al., 2019; Carafa et al., 2007; El-Maradny et al., 2020; Garcia-Rodriguez et al., 2012; Hahn et al., 2022; Lee et al., 2024; Li et al., 2018; Pavoni et al., 2003; Polat et al., 2018; Qiu et al., 2017; Sundhar et al., 2020).These findings reinforce the need for targeted monitoring, particularly in areas affected by high agricultural runoff or industrial activities.

Table 7-5: *Global pesticide residues reported in seaweeds.* ***DDT*** *stands for Dichlorodiphenyltrichloroethane,* ***HCH*** *for Hexachlorocyclohexane,* ***HCB*** *for Hexachlorobenzene, and* ***DDE*** *for Dichlorodiphenyldichloroethylene.*

Location	Seaweed Types	Pesticides Detected	Notable Findings	Reference
Italy	*Ulva rigida*	Herbicides and metabolites	Seasonal variation, influenced by agriculture	Carafa et al., 2007
Lagoon or Venice, Italy	*Ulva, Gracilaria, Porphyra, Graeloupia, Undaria, Fucus, Cystoseira*	Organochlorines (e.g., DDT, HCH, HCB)	Levels <5 ppb; legacy contamination observed	Pavoni et al., 2003
Iskenderun Bay, Turkey	*Cystoseira, Jania rubens, Corallina elongata*	Metribuzin DADK, Molinate, Pyrethrin I & II	Detected modern pesticides, no organochlorines found	Polat et al., 2018
Salish Sea, U.S.A.	*Fucus distichus, Fucus spiralis, Nereocystis luetkeana*	alpha-HCH, gamma-HCH, DDE, DDT	Only 4 pesticides detected above LOQ, levels low	Hahn et al., 2022
Northwest Spain	*Ascophyllum nodosum, Fucus vesiculosus,* and others	Cypermethrin, Tetramethrin	Traces found in wild and commercial samples, all <EU MRLs	Vargia-Rodriguez et al., 2012
Abu Gir Bay, Egypt	*Janie rubens*, and others	Organochlorines	Highest total OCP: 21.1 ppb in *Janie rubens*	El-Maradny et al., 2020
Gulf of Mannar, India	*Sargassum, Gracilaria, Ulva*	HCH, DDT, Endrin, Endosulfan	Several samples exceeded EU MRLs	Sundhar et al., 2020
South Korea	*Sargassum fusiforme*	Ametryn, Prometryn	Detected in 1 of 20 samples; within South Korean MRLs	Lee et al., 2024
South China	*Ulva lactuca*	DDTs, HCHs	Detected at 8.4-33.1 ppb; lower than in phytoplankton	Qui et al., 2017
Yellow Sea, China	*Ulva prolifera*	Organochlorines, Organophosphates, Pyrethroids	All residues well below risk thresholds.	Li et al., 2018

Radionuclides

Naturally occurring radioactive material (NORM) in the form of radionuclides is present throughout marine environments. Anthropogenic sources such as nuclear power plants, weapons testing, phosphate processing, oil and gas exploration, metal processing, fossil fuel combustion, desalination plants, shipping, and agricultural activities can contribute to elevated concentrations of radionuclides in the marine environment (Khandaker et al., 2019; Linsley et al., 2004).

Like heavy metals and other chemical pollutants, radionuclides can be absorbed and bioaccumulate in seaweed tissues when present in the growing waters (Abbasi et al., 2023; Hou et al., 2000; Ryan et al., 1999; Tejera et al., 2019; Wan Mahmood et al., 2018). For this reason, seaweed is often used for environmental monitoring of radionuclide contamination (Abbasi et al., 2023; Hunt et al., 2023). A list of radionuclides identified in seaweed is provided in Appendix B, Table B-2.

Contamination levels depend on radionuclide concentrations in the water. Control measures include knowing the growing area's environmental history and proximity to contamination sources such as nuclear power plants or past weapons testing sites. If risks are present, seaweed testing should ensure radionuclide levels do not exceed the FDA's Derived Intervention Levels, which represent the maximum safe concentrations in foods that would not warrant the introduction of protective measures or thresholds (USFDA, 2020).

Persistent Organic Pollutants (POPs)

Persistent organic pollutants (POPs), such as polychlorinated biphenyls (PCBs) and polybrominated diphenyl ethers (PBDEs), are notable for their environmental persistence, bioaccumulation potential, and harmful effects on human and environmental health. These pollutants—often originated from industrial or electronic waste—have raised concerns due to their widespread environmental distribution and toxicity.

POPs have a high affinity for accumulating in tissues with high fat content. Although seaweed is low in fat, it can still accumulate POPs if concentrations are high in surrounding waters. For example, kelp has been found to bioaccumulate PCBs, PBDEs, and emerging flame retardants at levels within international standards. Due to potential long-term risks, monitoring is still advised (Cheng et al., 2024). *Ulva compressa* and *Pterocladia capillacea* have shown significant bioaccumulation of carcinogenic PAHs and PCBs, raising concerns about their use in food products (El-Maradny et al., 2021; El Zokm et al., 2022).

Seaweed species with mucilaginous surfaces or micro-epiphytic layers of diatoms, may trap SPM more efficiently, thereby increasing POP uptake. Differences in lipid content between species can also influence POP retention (Pavoni et al., 2003). Despite low levels of contamination, monitoring remains essential due to the persistence and bioaccumulative nature of POPs (Duinker et al., 2020).

Controlling Environmental Chemical Contaminants

Most seaweed is sold and consumed dried. While drying does not increase the total amount of contaminants, the removal of water concentrates them—often making levels appear 5 to 10 times higher than in raw seaweed (Duinker et al., 2020). Although serving sizes for dried products are usually small (e.g., snacks and seasonings), this concentration effect must be considered when setting safety thresholds, especially for frequently consumed products and vulnerable populations.

Determining Whether the Potential Hazard is Significant

It is reasonably likely that, without proper controls, unsafe levels of environmental chemical contaminants—including pesticides—could enter seaweed products at the receiving step. To evaluate whether an environmental chemical contaminant is a significant hazard—either “reasonably likely to occur” (HACCP) or “hazard requiring a preventive control” (PCHF)—and can pose high risk:

1. Determine if the species is known to accumulate environmental contaminants at levels of concern and whether growing or harvest waters contain elevated levels of such contaminants.
2. Review existing data or conduct testing to identify potential chemical hazards, such as pesticides, POPs, heavy metals, and industrial pollutants.
3. Assess the farm’s location and surrounding environment (e.g., type of water body, proximity to agricultural runoff, pesticide application, industrial discharge, or wastewater effluents) for potential contamination sources.
4. Consider the intended use of seaweed—small-portion products, like umami seasoning, generally pose lower risk than large-portion products like snack sheets.

Considering these factors, processors should treat environmental chemical contaminants as significant hazards when:

- They are present in edible seaweeds at or near levels known to cause negative health effects.
- The harvest area is near agricultural activity, industrial processes, or wastewater discharge.

- Seaweed is sourced from waters known to contain potentially harmful levels of contaminants.

To determine whether contaminants are present, it is important to identify the types of chemical hazards commonly associated with the seaweed species and the water bodies where they are or will be grown or harvested (e.g., pesticides and industrial byproducts). The presence of nearby agricultural activity, industrial facilities, or wastewater discharge into coastal waterways can signal potential contamination risks.

When evaluating or selecting a farm or harvest site, processors should review land-based practices in the surrounding watershed. The EPA provides resources (see Table 7-6) to help identify potential contaminant sources that can be used when assessing or siting seaweed farms. Until a formal risk assessment is completed, seaweed from new farms or harvest locations should be considered at risk for chemical contamination and handled accordingly.

Hazard Controls and Critical Control Points

There are several control strategies for ensuring chemical contaminants are not likely to cause harm upon consumption of edible seaweed. Table 7-6 includes the available resources for conducting hazard analysis and developing a Food Safety or HACCP plan as it pertains to environmental chemical contaminants.

Table 7-6: *Available resources for conducting hazard analysis and developing Food Safety and HACCP plans as it pertains to environmental chemical contaminants.*

#	Department / Resource	Description
1	Local Government	In some states local governments will monitor water bodies for contaminants. For example, in New York, the Department of Health (DOH) monitors contaminants in local water bodies and publishes consumption advisories.
2	Shellfish Control Authority	States with shellfish production will have a Shellfish Control Authority that likely monitors marine waters for potential contaminants.
3	Environmental Protection Agency (EPA)	The EPA manages the Enforcement and Compliance History Online database (ECHO), which can be used to identify industrial practices and potential contaminants across the U.S.
4	Regional Integrated Pest Management (IPM) Centers	Regional IPM Centers can provide additional insights into agricultural practices and potential pesticide use regionally.
5	State Department of Agriculture	Agriculture Departments in States across the country are typically responsible for regulating food safety and agriculture production. Your Local Agriculture Department may also be able to assist in identifying potential contaminants of concern.
6	State Land Grant and Sea Grant Extension Programs	State Land Grant Extension and Sea Grant Extension programs may have specialists who can assist with identifying contaminants of concern in your region.
7	Business Planning for Kelp Farming: Resources Annex	Connecticut Sea Grant's *Business Planning Guide for Kelp Farming* (PDF) has an annex of resources (page 69) that could provide additional contacts by state who could support in identifying potential contaminants of concern.

Control Strategies

The following table provides the recommended control strategies for environmental chemical contaminants. These include source control, supplier certification, and testing of seaweed. Seaweed processors are permitted to use control strategies other than those listed, provided such approaches meet the requirements of relevant food safety regulations. Refer to Chapter 9 of the FDA's *Fish and Fishery Products Hazards and Controls Guide* for additional control strategy options that may be relevant to controlling environmental chemical contaminants (USFDA, 2022).

Periodic testing of seaweed samples might have been suggested within a specific control strategy for verification; however, this does not mean that the frequency of testing is prescribed. The term "*periodically*" is context-dependent and may vary according to factors such as farm location, cultivation method, and species. Processors may establish monitoring intervals appropriate to their operations and to maintain written records documenting the rationale for these intervals (e.g., environmental conditions, historical farm data, or scientific evidence) to demonstrate that the selected frequency is scientifically justified. This frequency can change over time based on historical testing results (e.g., years of stable concentrations can be used to justify reduction in testing frequency).

Table 7-7: *Control Strategies for Environmental Chemical Contaminants in Seaweeds*

Control Strategy	Primary Processor	Secondary Processor
Source Control	✓	
Supplier's Certification	✓	
Product Testing	✓	✓

Control Strategy 1 – Source Control

This control strategy can be used in locations where agencies evaluate and certify water bodies for food production and harvest. Note that current testing and evaluation of open certified water bodies is specifically for shellfish and finfish species and may not be sufficient for seaweed given the difference in bioaccumulation. If aware of bioaccumulation of potentially toxic compounds in certified waters, producers are responsible for controlling these hazards.

Critical Limit(s)/Parameter(s) and Value(s)

- Seaweed is grown and/or harvested from clean waters without any chemical-related health or consumption advisories by federal, state, tribal, territorial, local, or foreign regulatory authorities.
    - **NOTE:** consumption advisories will likely be fish or shellfish specific unless a state has a program/process for testing and certifying seaweed specific growing waters and harvest areas.

Monitoring – What, How, How Often, Who

- What will be monitored?
    - Producer records including date/time of harvest and harvest location along with verification that the harvest location is not under closure or subject to consumption advisories for environmental contaminants and/or pesticides.
- How will monitoring be done?
    - Obtain harvester/grower records indicating location of farm or harvest date **AND** confirm that the harvest site was not closed or under consumption advisory by the state, tribal, territorial, local, federal, or foreign authorities at the time of harvest.
- How often will monitoring be done?
    - At time of receipt for all lots received.
- Who will do the monitoring?
    - An individual with an understanding and knowledge of the controls and procedures for monitoring.

Corrective Action/Corrections

- If seaweed received is harvested from waters known to be contaminated or under consumption advisories, then reject the lot.

AND address the root cause to prevent future occurrence.

- Discontinue use of the supplier until evidence is obtained that harvesting practices have been changed by confirming harvest from approved waters without consumption advisories.

Verification

- Review of monitoring and corrective action records within one week of preparation to ensure they were completed appropriately.
- Periodic monitoring of federal, state, local, or foreign regulatory authorities' websites or reports on harvest restrictions and consumption advisories for water bodies that products are sourced from.

- Periodic product testing to verify that status of harvest waters is effectively controlling the environmental chemical contaminant hazard. Refer to Appendix F for detailed guidance on determining safe consumption levels for seaweed products.

Records

- **Receiving Records:** Including the harvest date, harvest location, quantity of seaweed, and harvester contact or permit information (if purchased directly from the producer) along with verification of the harvest location's current status.
- **Corrective Action Records:** Documentation of any corrective actions taken (if needed).
- **Verification Records:** Documentation of periodic reviews (at least once a year) of harvest locations for closures or consumption advisories. Testing results from periodic product testing.
- **Training Records:** A record of all relevant training completed

Example HACCP Plan for Source Control

Below is an example showing what a food safety plan could look like. It is intended for illustrative purposes only. Each producer must develop a plan tailored to their unique products, production and processing methods, and regulatory requirements. **These examples should not be copied and used without modification to fit your specific operation.**

Control Strategy: Source Control
Critical Control Point (HACCP): Receiving
Hazard: Environmental Contaminants

Parameters, Values, Critical Limits	Monitoring				Corrective Action	Verification	Records
	What	How	When	Who			
No seaweed is grown and/or harvested from waters with any health or consumption advisories by federal, state, tribal, territorial, local, or foreign regulatory authorities indicating that the water body is unsafe for food production, harvest, or the seaweed itself is unsafe for consumption.	Producer records including date/time of harvest and harvest location along with verification that the harvest location is not under closure or subject to consumption advisories for environmental contaminants and/or pesticides.	Obtain and review harvester/ grower records and verify that the harvest site is safe for food production and no consumption advisories are in place.	At time of receipt for all lots received.	Receiving Manager	If seaweed received is harvested from waters known to be contaminated or under consumption advisories, then, reject the lot **AND** Discontinue use of the supplier until evidence is obtained that harvesting practices have been changed by confirming harvest from approved waters without consumption advisories.	Review of monitoring and corrective action records within one week of taking to ensure they were completed appropriately. Periodic monitoring of federal, state, local, or foreign regulatory authorities' websites or reports on harvest restrictions and consumption advisories for water bodies the products are sourced from. Periodic product testing to confirm sourcing controls adequately control the contaminant hazard.	Receiving log that indicates the location and status check for the harvest area. Corrective action records, if necessary. Verification records including harvest restriction reports or checks and testing results

Control Strategy 2 – Supplier Certification Control

This control strategy can be used in locations if open certified bodies of water are regularly tested for potential environmental chemical hazards contaminants, and bioaccumulation is historically not prevalent. This could also be used for farmed seaweeds in land-based systems. Note that current testing and evaluation of open certified water bodies is specifically for shellfish and finfish species and may not be sufficient for seaweed given the difference in bioaccumulation. If aware of bioaccumulation of potentially toxic compounds in certified waters, producers are responsible for controlling these hazards.

Critical Limit(s)/Parameter(s) and Value(s)

- A letter of guarantee is provided with each shipment, confirming the seaweed was harvested from waters safe for production, with no history of significant bioaccumulation or contamination.

OR

- A letter of guarantee is provided with each shipment from the farmer or supplier, certifying that the seaweed products have been tested and found to be free from contaminants at levels that would pose a risk to human health. Refer to Appendix F for detailed guidance on determining safe consumption levels for seaweed products.

Monitoring – What, How, How Often, Who

- What will be monitored?
    - A signed supplier certification or letter of guarantee indicating that the product was harvested from waters safe for seaweed production that would not cause high levels of contamination in seaweed products.

    OR

    - A signed supplier certification or letter of guarantee indicating that the product has been tested and does not have high levels of contamination in seaweed products.
- How will monitoring be done?
    - Visual check for certificate or letter of guarantee
- How often will monitoring be done?
    - At time of receipt for all lots received.

- Who will do the monitoring?
    - An individual with an understanding and knowledge of the controls and procedures for monitoring.

Corrective Action/Corrections

- If a product is received without a certificate or letter of guarantee, then reject the lot **OR** hold the lot until a certificate or letter of guarantee is provided **OR** hold and test the lot for chemical contaminants that are reasonably likely to be present.

AND address the root cause to prevent future occurrence.

- discontinue use of the supplier until evidence is obtained that they will abide by established receiving requirements in place.

Verification

- Review of monitoring and corrective action records within one week of preparation to ensure they were completed appropriately.

AND

- Visit all new growers within the year and all existing suppliers at a predetermined frequency to review agricultural and industrial practices in the area immediately surrounding the production site and/or collect and analyze seaweed tissue samples, as appropriate, for those environmental chemical contaminants and pesticides that are reasonably likely to be present.

OR

- If testing is performed in the processor's laboratory, periodically send the sample to a credible third-party laboratory to verify the adequacy of the testing methods and equipment (e.g., by comparing results with those obtained using an Association of Official Analytical Collaboration (AOAC) International (https:// www.aoac.org/about-aoac-international/) or equivalent method, or by analyzing proficiency samples;

AND

- If raw material is collected and delivered by a middleman, request a list of growers/harvesters the middleman bought from with affiliated lot's numbers.

Records

- **Receiving Records:** That indicate the certificate or letter of guarantee was received with each lot **AND** a copy of the certificate or letter of guarantee
- **Corrective Action Records:** Documentation of any corrective actions taken, if necessary.
- **Verification Records:** Documentation of initial and periodic farm visits and assessments. Testing records for potential contaminants in seaweed.
- **Recall Plan:** A written recall plan is required for any products with significant hazards if regulated under preventive controls for human foods.
- **Training Records:** Training records for the preventive controls qualified individual (PCQI) must be maintained if regulated under preventive controls for human foods. While the HACCP rule requires a HACCP trained individual, records of that training are not explicitly required (federally, may vary by state).

Example HACCP Plan for Supplier Certification Control

Below are examples showing what a food safety plan could look like. It is intended for illustrative purposes only. Each producer must develop a plan tailored to their unique products, production and processing methods, and regulatory requirements. **These examples should not be copied and used without modification to fit your specific operation.**

Control Strategy: Supplier Certification
Critical Control Point (HACCP): Receiving Step
Hazard: Environmental Contaminants

Parameters, Values, Critical Limits	Monitoring				Corrective Action	Verification	Records
	What	How	When	Who			
A Letter of Guarantee is provided with each shipment.	Presence of Letter of Guarantee.	Visual observation.	At receipt of each lot.	Receiving Manager	If a product is received without a certificate or letter of guarantee, then, reject the lot **AND** Discontinue use of the supplier until evidence is obtained that they will abide by established receiving requirements in place.	Review monitoring and corrective action records within one week **AND** Visit all new growers within the year and all existing suppliers at least annually to review agricultural and industrial practices in the area immediately surrounding the production site and/or collect and analyze seaweed tissue samples, as appropriate, for those environmental chemical contaminants and pesticides	Receiving records that indicate the certificate or letter of guarantee was received with each lot **AND** a copy of the certificate or Letter of Guarantee. Corrective action records as needed. Verification records including report of farm/harvester visit and testing results if applicable. PCQI training records (PCHF only).

Example Food Safety Plan for Supplier Certification Control

Facilities regulated under the Preventive Controls for Human Food (PCHF) rule that identify a supply-chain-applied preventive control must establish and implement a supply-chain program. This program should detail how suppliers are selected, approved, and verified to ensure they effectively control the identified hazard. For more detailed guidance, refer to Chapter 15 of the FDA's *Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human* Food (USFDA, 2024).

Control Strategy: Supplier Certification
Supply Chain Preventive Control (PCHF): Receiving Step
Hazard: Environmental Contaminants

Raw Material / Ingredient	Approved Supplier	Date of Approval	Hazard Requiring PC	Preventive Control Applied by Supplier	Verification Activities Supplier	Verification Procedures Buyer	Corrective Actions	Records
Gracilaria *Gracilaria tikvahiae*	Gracilaria Ltd. 123 Red Dr. Somewhere, NY 55555.	Jan. 2, 2022	Environmental Contaminants	Pre-harvest laboratory testing for contaminants of concern.	Annual evaluation of land use and industrial practices and local, state, tribal advisories to identify new contaminants of concern around harvest site.	A letter of guarantee is provided with each shipment from the farmer or supplier, certifying that the seaweed products have been tested and found to be free from contaminants at levels that would pose a risk to human health. Annual review of supplier land use report.	If seaweed is received without the letter of guarantee, then hold product until documentation is received **OR** reject the lot **OR** test product before use **AND** Discontinue use of the supplier until receiving practices are modified and a valid documentation can be provided upon receipt of future shipments.	Receiving log that indicates shipment arrived with a letter of guarantee indicating seaweed is free from contaminants at levels that would pose a risk to human health. Corrective action records, if necessary. Supplier verification records land use reports. PCQI Training records

Control Strategy 3 – Product Testing

If you are processing a species of seaweed for which heavy metals or other environmental chemical contaminants may be a concern, product testing can be used as a control strategy to prevent these hazards. This approach is particularly relevant when historical data or scientific literature indicate that certain contaminants—such as As, Cd, Hg, or Pb—are likely to be present at levels that could pose a public health risk. Product testing should be conducted as needed to reflect the specific species, harvest location, and seasonality, as these factors can significantly influence contaminant levels. Testing may be especially important for species known to accumulate particular heavy metals or for products intended for sensitive populations (e.g., young children or pregnant individuals).

Critical Limit(s)/Parameter(s) and Value(s)

- No lot may contain residues of environmental chemical contaminants or pesticides at levels that pose a risk to human health. Refer to Appendix F for detailed guidance on determining safe consumption levels for seaweed products.

Monitoring – What, How, How Often, Who

- What will be monitored?
    - Contaminant level in seaweed
- How will monitoring be done?
    - A representative number of samples are analyzed using a validated method.
- How often will monitoring be done (frequency)?
    - At time of receipt for all lots received.
- Who will do the monitoring?
    - Individual with an understanding and knowledge of the controls and procedures for monitoring, sample collection and testing.

Corrective Action/Corrections

- If the contaminant concentration is above levels that would pose a risk to human health, then reject the lot OR redirect for non-food purposes

AND address the root cause to prevent future occurrence.

- discontinue use of the supplier until evidence is obtained that production or harvest practices have been adjusted to address the contamination and contaminant concentrations are within safe limits.

Verification

- Review of monitoring and corrective action records within one week of preparation to ensure they were completed appropriately.
- Validate testing methods for contaminant analysis if the analysis will be performed in an in-house laboratory **AND** periodically send the sample to a credible third-party laboratory to verify the adequacy of the testing methods and equipment
- Periodic monitoring of federal, state, local, or foreign regulatory authorities' websites or reports on harvest restrictions and consumption advisories for water bodies products are sourced from.
- Periodic review of testing standards and requirements as well as actionable or tolerable levels.

Records

- **Monitoring Records:** Testing results records.
- **Corrective Action Records:** Documentation of any corrective actions taken, if necessary.
- **Verification Records:** Documentation of periodic reviews (at least once a year) of harvest locations for closures or consumption advisories, review of testing standards/procedures and changes to safe levels for contaminants. Validation of in-house testing methods, if applicable.
- **Recall Plan:** A written recall plan is required for any products with significant hazards if regulated under preventive controls for human foods.
- **Training Records:** Training records for the preventive controls qualified individual (PCQI) must be maintained if regulated under preventive controls for human foods. While the HACCP rule requires a HACCP trained individual, records of that training are not explicitly required (federally, may vary by state).

Example HACCP/Food Safety Plan for Product Testing Control

Below is an example showing what a food safety plan could look like. It is intended for illustrative purposes only. Each producer must develop a plan tailored to their unique products, production and processing methods, and regulatory requirements. This example should not be copied and used without modification to fit your specific operation.

Control Strategy: Product Testing
Critical Control Point/Process Preventive Control Step: Receiving Step
Hazard: Environmental Contaminants

Parameters, Values, Critical Limits	Monitoring				Corrective Action	Verification	Records
	What	How	When	Who			
No lot may contain residues of environmental chemical contaminants or pesticides at levels that pose a risk to human health.	Environmental Chemicals contaminant concentrations.	Product testing will be done on each lot using a validated technique for contaminants of concern.	Before harvest	Quality Assurance Manager	If the contaminant concentration is at levels that pose a risk to human health, then discard the lot OR redirect the lot to other non-food use **AND** Discontinue use of the supplier until evidence is obtained that production or harvest practices have been adjusted to address the contamination and contaminant concentrations are within safe limits.	Review or monitoring and corrective action records within one week of taking to ensure they were completed appropriately, **AND** Periodic monitoring of state, local, or foreign regulatory authorities' websites or reports on harvest restrictions and consumption advisories for water bodies products are sourced from to identify new contaminants of concern.	Testing results records Corrective action records, if necessary. Verification records PCQI training records (PCHF only)

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Chapter 8 Iodine

General Background: Understanding the Potential Hazard

Iodine Consumption and Human Health

Iodine is a trace element and an essential component of thyroid hormones, which regulate key biochemical processes in the body (National Institute of Health, 2024). Thyroid hormones support protein synthesis, enzymatic activity, and the development of the brain, muscle, heart, pituitary gland, and kidneys (National Institute of Health, 2024).

Iodine deficiency can cause serious health problems, including intellectual disabilities, hypothyroidism, goiter, cretinism, and other growth and developmental disorders (Institute of Health, 2001; WHO, 2014). Recognition of these effects in the early 20th century prompted the implementation of salt iodization programs (Leung, 2012). In the U.S., voluntary salt fortification began in 1924 (Institute of Medicine, 2003), and since then, most areas have had adequate iodine intake. While many believe iodine deficiency is an issue of the past, some research suggests that declining use of iodized salt nationally could increase the risk of deficiency (Dasgupta et al., 2008; Hatch-McChesney and Lieberman, 2022).

Seaweeds can be rich in iodine. While iodine is an important component of a healthy diet and integral for thyroid function, excess iodine intake can negatively impact thyroid function and health (Circuncisão et al., 2018; Mussig, 2009; National Institute of Health, 2024), especially in those with existing thyroid issues. For adults in the U.S., the tolerable upper intake level (UL) for iodine is 1,100 µg/day, and the recommended daily allowance (RDA) is 150 µg/day (Institute of Medicine, 2001; NIH, 2024). In Europe, the daily UL is lower: 600 µg/day (EFSA, 2006). The RDA for children under 14 years is lower and varies by age. Pregnant and breastfeeding women require more iodine: 220 and 290 µg/day, respectively (CDC, 2024).

Because some seaweeds contain very high levels of iodine, consuming them in amounts above recommended limits can be harmful. Those at greater risk include people with existing thyroid conditions and pregnant women (Leung & Braverman, 2014). More than 12% of Americans will experience a thyroid disorder in their lifetime (American Thyroid Association, 2024). When iodized salt was first introduced in the U.S. in the 1920s, some individuals developed hyperthyroidism from excess iodine (Hartstock, 1927). People with thyroid conditions may experience adverse health effects—such as hyperthyroidism or hypothyroidism—when exposed to high levels of iodine through their diet (Lee et al., 1999). In countries with high seaweed consumption, elevated iodine intake has been linked to thyroid disorders including goiter, hypothyroidism, and Hashimoto's thyroiditis (Farebrother et al., 2019; Mussig, 2009).

With the increasing interest in seaweed as a nutritious food, there is growing concern for the potential increase in exposure to iodine concentrations well above the UL (Aakre et al., 2021; Redway & Combet, 2023). While certain species are high in iodine, moderate consumption—about one 5g dry weight serving per week—likely poses little risk for healthy individuals (Sá Monteiro et al., 2019). For instance, the average estimated iodine intake in Japan is 1,000 to 3,000 µg/day, which is generally well-tolerated in people without thyroid problems (Zava & Zava, 2011). However, because long-term effects of high iodine exposure are not fully understood, higher-risk populations (e.g., pregnant women, children, and those with thyroid issues) should avoid consuming iodine-rich seaweeds that exceed the UL (Monteiro et al., 2019). Choosing species closer to the RDA is recommended.

Given that reducing iodine intake can mitigate adverse health effects from overexposure, that individual sensitivities and absorption rates vary, and that iodine concentrations in seaweed and seaweed products are highly variable, labeling iodine content on these products is essential to help consumers make informed health decisions.

Iodine in Seaweed

All seaweeds absorb substances from their environment, but different species vary in how much they can absorb and bioaccumulate (Aakre et al., 2021). As a result, some seaweeds can contain significantly higher concentrations of minerals and trace elements than are present in the surrounding water (Saenko et al., 1978; Young & Langille, 1958). Brown seaweeds, in particular, can bioaccumulate iodine at levels far higher than in the surrounding environment (Fievet et al., 2023). Studies have found:

- **Brown Species:** Approximately 12 µg/g to 10,203 µg/g dry weight (Appendix D, Table D-2)
- **Red Species:** 4.3 µg/g to 353 µg/g dry weight (Appendix D, Table D-3)
- **Green Species:** 12.9 µg/g to 154 µg/g dry weight (Appendix D, Table D-4)

Iodine (I_2) concentrations in seaweed vary by season, often peaking in winter due to environmental factors like iodide (I^-) availability and water temperature (Nitschke et al., 2018). While I_2 refers to the elemental, molecular form of iodine commonly found in seaweed, I^- is the ionic form dissolved in seawater and taken up by seaweed. Species differences also affect bioavailability (Aquaron et al., 2002; Domínguez-González et al., 2017), and absorption rates vary from person to person (Barandiaran et al., 2024).

Controlling Iodine

Processing

Processing methods can significantly reduce iodine levels in seaweed, though results depend on the species and method used. Techniques studied include boiling, blanching, fermenting, and steaming have (Banach et al., 2024; Dujardin et al., 2023; Sun et al., 2021; Lüning & Mortensen, 2015; Nielsen et al., 2020; Nitschke & Stengel, 2016; Sun et al., 2022; Trigo et al., 2023). Examples include:

- Rinsing *Saccharina latissima* in saltwater or freshwater reduced iodine levels by 59–73%, while
- Steaming resulted in a 26% reduction (Krook et al., 2023), and
- Combining saltwater blanching with fermentation achieved an 81% reduction in iodine content (Banach et al., 2024).

However, these treatments can also change the flavor, texture, and nutritional composition of products (Krook et al., 2023; Stévant et al., 2018). Boiling, while effective, may increase the bioavailability of the remaining iodine, potentially raising exposure risks for iodine-sensitive individuals (Sun et al., 2022). Chemical composition also plays a role—higher protein may reduce iodine absorption, while more carbohydrates and fiber may increase it (Romarís-Hortas et al., 2012).

Even after processing, seaweeds high in iodine can still exceed the adult UL of 1,100 µg/day (Banach et al., 2024, Institute of Medicine, 2001). In such cases, producers should carefully consider serving size and consumption frequency when developing seaweed-based products. Processing alone may not sufficiently reduce iodine concentrations below this threshold.

Many factors influence iodine exposure risk from seaweed: type of seaweed, geographic origin, storage and cooking methods, climate, individual health status, individual dietary practices, and consumption frequency (Teas et al., 2004). For naturally high-iodine species like the brown seaweed *Saccharina latissima*, reducing serving size, combining processing methods, or both may be necessary to reduce concentrations below daily tolerable levels. If these measures are insufficient, labeling iodine content should be used as a control measure to inform consumers and support informed decision-making. These variables make it difficult to predict the exact health impact of iodine exposure from seaweed consumption across different populations.

Labeling

There are no current regulations mandating iodine content labeling in foods, and it is rare worldwide (Redway & Combet, 2023; Bouga & Combet, 2015). For people sensitive to iodine, labeling is crucial for effectively managing dietary intake. Recognizing this, the Norwegian Seaweed Association (2021) recommends that producers voluntarily label the iodine content, including:

> *“The "seaweed / kelp species" has a naturally high iodine content. The recommended daily intake of iodine is 0.15 mg. Excessive iodine intake over time can affect the thyroid gland.”*

Serving Size

Traditionally, a typical serving of seaweed is approximately 5 grams, particularly in regions where seaweed is regularly consumed. The U.S. Food and Drug Administration (FDA) also identifies 5 grams as the Reference Amount Customarily Consumed (RACC) for seaweed (21 CFR Part 101.12, Table 1). Similarly, Mouritsen (2013) recommends a daily intake of 5–10 grams of dried seaweed, and many research studies examining seaweed as a food ingredient use 5 grams as a standard serving size (Dawczynski et al., 2007; Monteiro et al., 2019).

Serving sizes can vary based on product type—for example, spice blends or seasoning mixes use much less than whole dried sheets. For naturally high-iodine species, smaller serving sizes can help prevent excessive iodine intake.

Determining if the Hazard is Significant

If iodine levels in a typical serving of seaweed product would exceed the UL of 1,100 µg/day, the seaweed operation should treat iodine as a significant hazard—either “reasonably likely to occur” (HACCP) or “hazard requiring a preventive control” (PCHF)—and include control measures in the food safety plan.

Hazard Controls and Critical Control Points

The following control strategies provide guidance on designing effective measures to manage iodine when it is identified as a significant hazard—either “reasonably likely to occur” (HACCP) or “hazard requiring a preventive control” (PCHF)—in your operation.

Table 8-1: Control Strategies for Iodine in Seaweeds

Control Strategy	Primary Processor	Secondary Processor
Processing Control	✓	✓
Labeling Control	✓	✓

Control Strategy 1 – Processing Control

Critical Limit(s)/Parameter(s) and Value(s)

- A validated study should be conducted or identified to support iodine reduction practices, including detailed treatment parameters such as time and temperature for methods like fresh or saltwater rinses, blanching, boiling, or steaming. Currently, no published, widely accepted validated studies for iodine reduction in seaweed are available.

Monitoring – What, How, How Often, Who

- What will be monitored?
  - Process parameters (e.g., time and temperature)
- How will monitoring be done?
  - Time recording/measuring device and thermometer
- How often will monitoring be performed (frequency)?
  - Every batch
- Who will do monitoring?
  - An individual with an understanding of the control and trained to carry out the required monitoring procedures.

Corrective Action/Corrections

- If treatment time is not achieved, then wait until time is met.
- If the required temperature is not achieved, then; reprocess the product to meet the specified time and temperature parameters **OR** discard the product.

AND address the root cause to prevent future occurrence.

- Assess and address the root cause of the deviation to prevent future deviations (For example: Repair/Replace equipment, calibrate temperature reading device, retrain staff, etc.).

Verification

- Validation study to determine effective processes for achieving desired iodine reduction. Equipment accuracy checks and calibration as needed.
- Periodic testing to verify iodine reduction and iodine concentrations.
- Review or monitoring and corrective action records within one week of preparation to ensure they were completed appropriately.

NOTE: If processing is not reducing iodine concentrations to the upper tolerable limit of 1,100 µg or below, then additional labeling controls should also be considered.

Records

- **Monitoring Records:** Such as a processing log including all necessary parameters outlined in validated study, such as time and temperature for blanching, steaming or soaking the product.
- **Corrective Action Records:** Any records indicating what was done to address potential deviations from parameters, values, or critical limits.
- **Verification Records:** Including a validated study indicating methods for desired iodine reduction and periodic testing results of iodine concentrations in treated products. Records of equipment accuracy checks and/or calibration as needed.
- **Recall Plan:** A written recall plan is required for any products with significant hazards if regulated under preventive controls for human foods.
- **Training Records:** Training records for the preventive controls qualified individual (PCQI) must be maintained if regulated under preventive controls for human foods. While the HACCP rule requires a HACCP trained individual, records of that training are not explicitly required (federally, may vary by state).

Example HACCP/Food Safety Plan for Processing Control

Below is an example showing what a food safety plan could look like. It is intended for illustrative purposes only. Each producer must develop a plan tailored to their unique products, production and processing methods, and regulatory requirements. **This example should not be copied and used without modification to fit your specific operation.**

Control Strategy: Processing Control

Process Preventive Control Step: Blanch Step

Hazard: Iodine

Parameters, Values, Critical Limits	Monitoring				Corrective Action	Verification	Records
	What	How	When	Who			
120 second treatment time 113°F (45°C) freshwater 1 kg kelp / 5L freshwater (Nielsen et al. 2022)	Time Temperature Weight / Volume	Watch Thermometer Scale / measuring device	Every batch.	Line Cook	If water temperature is not achieved, then the product will be re-treated to achieve the proper blanch time and temperature exposure **AND** The cause of the deviation will be assessed and corrected to prevent future occurrence.	Rinse study reviewed at least annually or as needed and re-evaluated as needed (Krook et al 2023). Annual iodine content analysis results to verify expected iodine reduction. Thermometer accuracy checks daily before use and calibration checks as needed and at least once a year.	Batch log including blanch time, water temp., weight of kelp, and volume of freshwater. Thermal log including accuracy checks and calibration when needed. Lab analysis reports Blanch validation study on file Corrective Action Record(s), as needed.

Control Strategy 2 – Labeling Control

Note that labeling operations among food facilities vary greatly, while these example control strategies provide insights into who one might consider controlling the iodine hazard with labeling, you will need to adjust your food safety plan to work with your labeling practices.

Critical Limit(s)/Parameter(s) and Value(s)

Seaweed product is labeled with iodine content

Monitoring – What, How, How Often, Who

- What will be monitored?
  - Presence of iodine content on label
- How will monitoring be done?
  - Visual inspection for presence of label on package with iodine concentration
- How often will monitoring be done (frequency)?
  - At the start of production and at least every two hours throughout production.

  OR

  - Every new roll/box of labels opened.
- Who will do the monitoring?
  - An individual with an understanding of the control and trained to carry out the required monitoring procedures.

Corrective Action/Corrections

- If the label is not present or incorrect during inspection, then; stop production to prevent further deviation **AND** check all packages since the last accurate inspection to ensure proper labeling, **AND** re-label all affected products with proper label.

AND address the root cause to prevent future occurrence.

- Identify the root cause of the mislabeling and correct the issue to prevent re-occurrence.

Verification

- Review or monitoring and corrective action records within one week of preparation to ensure they were completed appropriately.
- Periodic iodine analysis (e.g., annually or seasonally), depending on species and harvest frequency, should be conducted to confirm accurate label concentrations. Testing frequency may be adjusted over time based on historical results and observed variations in iodine levels.

Records

- **Monitoring Records:** Labeling log indicating the presence of the label and frequency of checks.
- **Corrective Action Records:** Any records indicating what was done to address potential deviations from parameters, values, or critical limits.
- **Verification Records:** Iodine analysis and reviewed monitoring records.
- **Recall Plan:** A written recall plan is required for any products with significant hazards if regulated under preventive controls for human foods.
- **Training Records:** Training records for the preventive controls qualified individual (PCQI) must be maintained if regulated under preventive controls for human foods. While the HACCP rule requires a HACCP trained individual, records of that training are not explicitly required.

Example HACCP/Food Safety Plan for Labeling Control

Below is an example showing what a food safety plan could look like. It is intended for illustrative purposes only. Each producer must develop a plan tailored to their unique products, production and processing methods, and regulatory requirements. **This example should not be copied and used without modification to fit your specific operation.**

Control Strategy: Labeling Control
Critical Control Point/Process Preventive Control Step: Labeling Step
Hazard: Iodine

Parameters, Values, Critical Limits	Monitoring				Corrective Action	Verification	Records
	What	How	When	Who			
Iodine content listed on package label.	Iodine content on label	Visual inspection for presence of label with iodine content	At start of labeling and at least every two hours	Line Supervisor	If the label is not present or is inaccurate, then stop labeling AND recheck all products since the last correct check AND relabel all incorrectly labeled products. **AND** Determine cause of deviation and make corrections to prevent future deviations.	Annual analysis to confirm accurate iodine content of seaweed products. Weekly review of label monitoring records.	Monitoring Record: Label Log with frequency and results of label checks Corrective Action Records, when needed Verification Records: Laboratory report for iodine content analysis PCQI training records (PCHF only)

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Chapter 9 Natural Toxins

General Background: Understanding the Potential Hazard

Natural Toxins

Some seaweeds produce toxic compounds (Sato et al., 1996) that should be carefully monitored and controlled in products intended for consumption. Seaweeds can also absorb natural toxins from their surrounding waters, produced by other organisms (Cheney, 2016; Haddock & Cruz, 1991). These natural toxins—chemical substances made by living organisms such as plants, fungi, bacteria, algae, and animals, often as a defense mechanism—can cause adverse health effects when ingested (USFDA, 2019). Consumption of seaweeds that produce or absorb these toxins can result in foodborne intoxication (Yotsu-Yamashita et al., 2004). This chapter provides an overview of natural toxins associated with seaweed species, including those produced by the seaweeds themselves and those absorbed from contaminated growing waters. Appendix C, Table C-1 lists specific toxin levels detected in various species.

There are six recognized natural toxin poisoning syndromes associated with the consumption of fish and fishery products contaminated by natural toxins in growing or harvest waters (USFDA, 2019):

- Amnesic Shellfish Poisoning (ASP)
- Azaspiracid Shellfish Poisoning (AZP)
- Ciguatera Fish Poisoning (CFP)
- Diarrhetic Shellfish Poisoning (DSP)
- Neurotoxic Shellfish Poisoning (NSP)
- Paralytic Shellfish Poisoning (PSP)

Although intoxication from these seafood-specific toxins is not directly linked to seaweed consumption, their causative agents can be present in marine waters worldwide. Therefore, seaweed producers and harvesters should exercise caution when harvesting seaweed from areas where such toxins are known to occur. For more information on these toxins, see Chapter 6 of the FDA's *Fish and Fishery Products Hazards and Controls Guidance* (USFDA, 2019).

Neurotoxic Amino Acids

Neurotoxic amino acids are naturally occurring compounds that disrupt normal nervous system function and can cause a range of adverse neurological effects when ingested. These toxins are commonly produced by marine organisms—including diatoms and some seaweeds—either as a defense mechanism or as a by-product of metabolic activity (Lundholm et al., 2018). Two notable neurotoxic amino acids include:

- **Domoic Acid:** Associated with ASP. Domoic acid poisoning is rare but can cause gastrointestinal symptoms within 24 hours, and neurological symptoms within 48 hours of consumption. Reported symptoms include nausea, vomiting, abdominal cramps, diarrhea, headache, visual disturbances, weakness, altered mental status, cranial nerve palsies, autonomic dysfunction, amnesia, pain, seizures, coma, and death (Sobel & Painter, 2005). While ASP typically results from seafood contaminated by toxic diatoms in growing waters (*Pseudo-nitzschia* species), some red seaweeds such as *Chondria armata* also produce domoic acid (Noguchi & Arakawa, 1996; Sato et al., 1996; Sobel & Painter, 2005; Steele et al., 2022). In the United States, the federal action level for domoic acid in seafood products is 20 ppm (USFDA, 2021). In Japan, domoic acid levels in seaweed samples have ranged from <1 ppm to as high as 4,300 ppm (Noguchi & Arakawa, 1996).
- **Kainic Acid:** A neurotoxin first isolated from the red seaweed *Digenea simplex* (Olney et al., 1974), and later found in other species, including dulse (*Palmaria palmata*) (Higa & Kuniyoshi, 2000; Impellizzeri et al., 1975; Jørgensen & Olesen, 2018).

Diethyl Peroxide

Diethyl peroxide, the suspected toxin responsible for Mozuku poisoning, induces gastrointestinal distress (Fusetani & Hashimoto, 1981). Two documented cases of Mozuku poisoning have occurred in Japan following the consumption of the seaweeds *Nemacystus decipiens* and *Cladosiphon okamuranus* (Kumar & Sharma, 2021). Diethyl peroxide has also been detected in other seaweed species, including *Sphaerotrichia divaricata*, *Cladosiphon okamuranus*, *Analipus japonicus*, and *Gracilariopsis* chorda. Notably, the formation of diethyl peroxide occurs only when these seaweeds are heated in water (Fusetani & Hashimoto, 1981).

Caulerpicin and Caulerpin

Caulerpicin is a chemical compound identified by Doty and Aguilar-Santos (1966) during their investigation into the peppery taste sometimes associated with the green alga *Caulerpa racemosa*. Consumption of *Caulerpa* containing caulerpicin can lead to mild anesthetic effects, which may intensify with repeated exposure. Reported symptoms include numbness in the extremities, cold sensations in the feet and fingers, rapid or difficulty breathing, slight depression, and loss of balance (Doty & Aguilar-Santos, 1966).

Caulerpin, a compound believed to have comparable effects, has also been detected in various Caulerpa species (Doty & Aguilar-Santos, 1970), as well as in the red alga *Chondria armata* (Govenkar & Wahidulla, 2000).

While historically associated with toxicity, some studies report no toxic effects from caulerpin and caulerpicin compounds individually (Vidal et al., 1984). However, aqueous extracts of *Caulerpa* have shown toxicity, suggesting unidentified agents may be responsible (Vidal et al., 1984). Therefore, although the specific toxic agents in *Caulerpa* remain under debate, the toxicity of *Caulerpa* species is not and should be taken into consideration when harvesting and processing them for consumption.

Prostaglandin E2 (PGE2)

Prostaglandin E2 (PGE2) is believed to be the causative agent of *ogonori* poisoning, typically inducing vomiting and diarrhea within an hour of consumption. In severe cases, PGE2 can cause dangerously low blood pressure (hypotension), shock, and even death (Hammann et al., 2016). PGE2 has been linked to seaweed-related foodborne intoxication, particularly following consumption of *Gracilaria verrucosa* and *Gracilaria chorda*, which caused symptoms ranging from nausea, vomiting, abdominal pain, and diarrhea to sometimes fatal outcomes (Fusetani & Hashimoto, 1984). Several *Gracilaria* species produce PGE2 when under stress (Fusetani & Hashimoto, 1984; Gregson et al., 1979; Hsu et al., 2008; Noguchi et al., 1994). For example:

- *Gracilaria tenuistipitata* shows elevated PGE2 levels under various environmental and stress conditions, including changes in temperature, salinity, irradiance, and air exposure (Hsu et al., 2008).
- *Gracilaria vermiculophylla* produces PGE2 when damaged or grazed upon by herbivores—production is elevated when growing in non-native waters (Hammann et al., 2016).

Even when raw seaweed doesn't contain PGE2, it can still be produced later. This happens when enzymes from the seaweed, the body, or other consumed foods break down unsaturated fatty acids present in those same sources after harvest or during digestion (Noguchi et al., 1994). Commercial processing practices, such as lime treatment (Noguchi et al., 1994) could reduce the risk of *oginori* poisoning. Cooking may also degrade it (Hsu et al., 2008), as shown in cooked salmon (Raatz et al., 2011).

Cyanobacteria: Aplysiatoxin and Debromoaplysiatoxin

Aplysiatoxin and debromoaplysiatoxin are toxic alkaloids produced by marine cyanobacteria (blue-green algae). These cyanobacteria are known to grow as epiphytes on marine seaweed, including *Gracilaria coronopifolia*. The toxic alkaloids produced by these epiphytic organisms have been linked to foodborne poisoning, causing symptoms such as gastrointestinal distress and a burning sensation in the mouth and throat. At least two such cases have been documented in Hawaiʻi, following contaminated seaweed consumption (Nagai et al., 1996; Nagai et al., 1997).

Polycavernoside A

Polycavernoside A is Isolated from *Gracilaria edulis* (formerly *Polycavernosa tsudai*) and is believed to cause both gastrointestinal and neurological effects (Yotsu-Yamashita et al., 2004). It has been linked to 22 cases of foodborne intoxication and 5 deaths during two outbreaks in Guam and the Philippines (Cheney, 2016).

Mycotoxins

Certain foods can harbor fungi and molds that produce toxic compounds known as mycotoxins. Although typically associated with dried foods such as grains, beans, fruits, and coffee (USFDA, 2024), mycotoxins have also been detected in seaweeds (Kononenko et al., 2021; Burkin & Kononenko, 2023; see Appendix C, Tables C-2 and C-3). Levels in seaweeds are generally below those causing intoxication, and no cases of seaweed-related mycotoxin poisoning have been reported.

Many other natural toxins are present in marine environments, although not specifically associated with seaweeds. Seaweed producers and harvesters aware of potential toxins in their growing or harvest waters should implement effective controls to minimize exposure and protect public health.

Determining if the Hazard is Significant

Seaweeds grown or harvested from waters with reported occurrence of natural toxins, or harvest of seaweeds that naturally produce toxins of concern, pose a significant hazard—either “reasonably likely to occur” (HACCP) or “hazard requiring a preventive control” (PCHF)—to human health. Controls should be implemented to reduce hazard risk and protect public health. To assess risk:

- Review historical toxin occurrence using resources such as the Harmful Algal Blooms: NOAA State of the Science Fact Sheet and Woods Hole Oceanographic Institute’s Harmful Algae website.
- Consult with local, state and federal agencies involved in managing water quality.

- Search the credible literature and media outlets for intoxication events specifically linked with the growing or harvest waters.

Hazard Controls and Critical Control Points

The following control strategies provide guidance on designing effective measures to manage natural toxins when they are identified as a significant hazard—either "reasonably likely to occur" (HACCP) or "hazard requiring a preventive control" (PCHF)—in your operation.

Table 9-1: Control Strategies for Natural Toxins in Seaweeds

Control Strategy	Primary Processor	Secondary Processor
Source Control	✓	✓
Processing Control*	✓	✓

*Not all natural toxins can be reduced or eliminated through processing. This control strategy applies only to those toxins that are known to be reduced or destroyed by such methods. Based on a review of the available literature, only PGE2 has been identified as having the potential to be reduced through processing.

Control Strategy 1 – Source Control

Critical Limit(s)/Parameter(s) and Value(s)

Primary processors may not receive seaweed when the harvest locations are:

- Closed to fishing by foreign, federal, state, tribal, territorial, or local authorities,

OR

- Subject to a consumption advisory.

Monitoring – What, How, How Often, Who

- What will be monitored?
    - The status of the harvest location is not closed or subject to a consumption advisory.

OR

    - Presence declaration from the producer stating that the harvest areas or products are free from natural toxins or grown/harvested from areas with no history of toxin.

- How will monitoring be done?
    - Visual observation of the status of the harvest location and/or declaration identifying the harvest area location is not under a restriction, advisory or prohibited from fishing by any foreign, federal, state tribal, territorial, or local authorities.
- How often will monitoring be done (frequency)?
    - Every shipment received.
- Who will do the monitoring?
    - An individual with an understanding of the control and trained to carry out the required monitoring procedures.

Corrective Action/Corrections

- If harvest location is closed to harvest **OR** harvest area is under consumption advisory, then reject lot.
- If proper declaration of harvest area is free of toxins was not provided, then hold shipment and contact suppliers to confirm and request proper source information to confirm safety **OR** reject the lot.

AND address the root cause to prevent future occurrence.

- Discontinue use of suppliers until shipment practices are adjusted to prevent future errors upon receipt.

Verification

- Review or monitoring and corrective action records within one week of preparation to ensure they were completed appropriately.
- Periodically monitor governmental and other resources for the most current information regarding harvest restrictions, advisories, and waterbody closures due to natural toxins.
- Conduct an annual assessment of consumer complaints to identify any signs or evidence of potential natural toxin presence in products.

Records

- **Monitoring Records:** Receiving logs indicating visual checks that source information was cross referenced to confirm no closures or consumption advisories. Supporting documentation including harvest location and declaration of no toxins, if relevant.
- **Corrective Action Records:** Any records indicating what was done to address potential deviations from parameters, values, or critical limits.
- **Verification Records:** Periodic (at least annually) evaluation of harvest locations for closures for advisories.
- **Recall Plan**: A written recall plan is required for any products with significant hazards if regulated under preventive controls for human foods.
- **Training Records:** Training records for the preventive controls qualified individual (PCQI) must be maintained if regulated under preventive controls for human foods. While the HACCP rule requires a HACCP trained individual, records of that training are not explicitly required.

Example HACCP Plan for Source Control

Below are examples showing what food safety plans could look like. They are intended for illustrative purposes only. Each producer must develop a plan tailored to their unique products, production and processing methods, and regulatory requirements. **These examples should not be copied and used without modification to fit your specific operation.**

Control Strategy: Source Control
Supply Chain Preventive Control (PCHF): Receiving Step
Hazard: Natural Toxins

Parameters, Values, Critical Limits	Monitoring				Corrective Action	Verification	Records
	What	How	When	Who			
Harvest location is not closed to fishing by foreign, federal, state, tribal, territorial, or local authorities OR Subject to a consumption advisory **OR** The species is not known to contain unsafe levels of the toxin.	Seaweed received comes with a supplier declaration stating that the harvest areas are free from natural toxins and not known to produce natural toxins.	Visual observation for declaration.	Every Lot	Receiving Manager	If a proper declaration is not provided, then, hold the lot until the declaration is received **OR** Reject the lot **AND** Discuss with supplier shipment requirements to prevent future errors upon receipt.	Weekly review of monitoring and corrective action records Periodically monitor governmental and other resources for the most current information regarding harvest restrictions, advisories, and waterbody closures due to natural toxins. Conduct an annual assessment of consumer complaints to identify any signs or evidence of potential natural toxin presence in products.	Monitoring record indicating receipt of declaration and declaration itself. Corrective action records, if necessary Verification records indicating periodic review of harvest location status and consumer complaints report.

Example Food Safety Plan for Source Control

Facilities regulated under the Preventive Controls for Human Food (PCHF) rule that identify a supply-chain-applied preventive control must establish and implement a supply-chain program. This program should detail how suppliers are selected, approved, and verified to ensure they effectively control the identified hazard. For more detailed guidance, refer to Chapter 15 of the FDA's *Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food* (USFDA, 2024).

Control Strategy: Source Control
Supply Chain Preventive Control (PCHF): Receiving Step
Hazard: Natural Toxins

Raw Material / Ingredient	Approved Supplier	Date of Approval	Hazard Requiring PC	Preventive Control Applied by Supplier	Verification Activities Supplier	Verification Procedures Buyer	Corrective Actions	Records
Bull Kelp *Nereocystis luetkeana*	ABC Seaweed Co. 123 Sugar Dr. Somewhere, NY 55555	July. 5, 2025	Natural Toxins	Pre-harvest review of growing waters for active HAB occurrence or advisories by relevant regulatory authorities.	Annual assessment of potential intoxication events or toxin occurrence in growing/ harvest waters.	Producer records indicating harvest location and visual verification that location is not closed to harvest or under a consumption advisory. Producer record of annual verification practices. Annual assessment of consumer complaints.	If seaweed is received without appropriate producer records indicating harvest location, then, hold product until records are received **OR** reject the lot **AND** discontinue use of the supplier until receiving practices are modified to prevent reoccurrence. If records indicate seaweed was harvested from waters with an active consumption advisory or closure then, reject the lot OR divert to a non-food use AND discontinue use of the supplier until practices are modified to prevent reoccurrence.	Receiving log that indicates shipment arrived with appropriate records and harvest location was verified as open and safe for consumption. Corrective action records, if necessary. Supplier verification records. PCQI Training records

Control Strategy 2 – Processing Control

NOTE: There are currently no validated methods for controlling natural toxins in seaweeds. Facilities must work with qualified experts to validate any proposed processing methods for toxin control before implementation.

Critical Limit(s)/Parameter(s) and Value(s)

- Seaweed is processed according to a scheduled process validated to effectively control the toxin(s) of concern.

Monitoring – What, How, How Often, Who

- What will be monitored?
    - Processing criteria outlined in the scheduled process (e.g., time, temperature, weight or volume etc.)
- How will monitoring be done?
    - Visual observations or measurements with relevant equipment (e.g., calibrated thermometers)
- How often will monitoring be done (frequency)?
    - Every batch
- Who will do the monitoring?
    - An individual with an understanding of the control and trained to carry out the required monitoring procedures.

Corrective Action/Corrections

- If the required criteria outlined in the scheduled process are not met, **then** reprocess the product to ensure the required criteria are met **OR** discard the product **OR** divert to non-food use.

AND address the root cause to prevent future occurrence.

- Determine the cause of the deviation critical limit and adjust procedures as needed to prevent it from happening again.

Verification

- Review or monitoring and corrective action records within one week of preparation to ensure they were completed appropriately.
- The adequacy of the processing method should be confirmed through a validation study. This study, kept on file, must demonstrate that the method effectively reduces toxin concentrations to safe levels.
- Periodic accuracy checks and calibration of measuring devices used.

Records

- **Monitoring Records**: Processing logs with all required parameters recorded.
- **Corrective Action Records:** Any records indicating what was done to address potential deviations from parameters, values, or critical limits.
- **Verification Records:** Accuracy checks, calibration, validated scheduled process (e.g., cook study)
- **Recall Plan:** A written recall plan is required for any products with significant hazards if regulated under preventive controls for human foods.
- **Training Records:** Training records for the preventive controls qualified individual (PCQI) must be maintained if regulated under preventive controls for human foods. While the HACCP rule requires a HACCP trained individual, records of that training are not explicitly required.

Example HACCP/Food Safety Plan for Source Control

Below are examples showing what a food safety plan could look like. It is intended for illustrative purposes only. Each producer must develop a plan tailored to their unique products, production and processing methods, and regulatory requirements. **This example should not be copied and used without modification to fit your specific operation.**

Control Strategy: Processing Control
Critical Control Point/Process Preventive Control Step: Boiling Step
Hazard: Natural Toxins

Parameters, Values, Critical Limits	Monitoring				Corrective Action	Verification	Records
	What	How	When	Who			
Boiling procedures in accordance with a prescribed and validated scheduled process designed to sufficiently reduce or eliminate natural toxins of concern.	Process Parameters (time and temperature)	Thermometer and Timer	Every Batch	Cook Staff	If processing parameters are not met, then reprocess **OR** discard the product **OR** divert to a non-food use **AND** Identify the cause of the deviation and correct to prevent future occurrence.	Validated study on file indicating required parameters for processing sufficiently to reduce or eliminate toxins. Accuracy checks and calibration of temperature recording devices. Weekly review of monitoring and corrective action records.	Monitoring records including all required processing parameters outlined in the scheduled process. Corrective action records, as needed. Verification records including the validation study and scheduled process on file. PCQI training records (PCHF only)

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Chapter 10 Pathogen Growth Due to Temperature Abuse

General Background: Understanding the Potential Hazard

Numerous species of human pathogens have been identified on freshly harvested seaweeds as a result of contamination from their growing/harvest areas (see Chapter 5). Pathogens may also be introduced during postharvest handling, storage, or processing (see Chapter 11). The risk of illness from pathogens directly relates to how many of them are present. While some pathogens can cause illness even in small amounts, the risk is higher when their numbers are greater. One of the main ways pathogens grow to unsafe levels is through temperature abuse—when seaweed or seaweed products are kept too long at temperatures that allow bacteria to multiply. Maintaining proper temperature control from throughout the supply chain (e.g., harvest through delivery to the consumer) is therefore essential for food safety. Growth due to temperature abuse applies only to bacterial and fungal pathogens, since viruses and parasites don't replicate in foods. Although toxin-producing fungi (and mycotoxins) have been found on various seaweeds (see Chapter 9), there are no known cases of mycotoxin levels in seaweeds high enough to cause illness, so the risk from these is considered low.

Bacterial growth depends on the natural characteristics of the seaweed and on how it is handled and stored. This chapter explains what is known about how temperature affects the growth of bacteria—especially harmful ones (pathogens)—on different seaweed species and provides information (where available) on how many of these bacteria it takes to cause illness.

Characteristics of Raw Seaweed and Effects on Bacterial Growth

Whether bacteria can grow on a food depends on certain properties of that food including (but not limited to):

- **Water Activity:** The amount of water available for bacteria to use (not just the total moisture content)
- **Acidity (pH):** How acidic or alkaline the food is
- **Salinity:** The amount of salt present
- **Nutrients:** The availability of carbohydrates, proteins, fats, vitamins, and minerals that bacteria need to survive

Freshly harvested seaweeds typically have very high water activity (0.95–0.99), which means they contain enough available water to support the growth of pathogens (Bayomy, 2022; Ershov et al., 2023; Perry et al., 2019; Silva et al., 2008; Vall-llosera et al., 2024; Wirenfeldt et al., 2022).

NOTE: Water activity is not the same as moisture content. Even though the two are related, you cannot determine the risk of bacterial growth just by measuring moisture content—water activity must be measured directly.

Average pH (acidity) of freshly harvested seaweeds is usually between 5.5 and 6.75 (Del Olmo et al., 2019; Sánchez-García et al., 2021; Standal et al., 2024), which is the range suitable for the growth of many pathogens. For more information about the conditions that allow specific pathogens to grow see Appendix 3, Table 3-A of the FDA's *Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food* (USFDA, 2024).

Studies have shown that the overall number of bacteria (aerobic mesophilic bacteria, sometimes called "total bacteria") can increase on many types of seaweed during storage, whether the seaweed is kept at room temperature or under refrigeration (Table 10-1). Later in this chapter, you will find a summary of research that specifically examines how harmful bacteria (pathogens) behave on seaweeds under different storage conditions.

Table 10-1: *Studies documenting growth of aerobic mesophilic bacteria on seaweeds.*

Species	Reference(s)
Alaria esculenta	Lytou et al., 2022
Anthospira platensis	Martelli et al., 2021
Gracilaria tikvahiae	Nayyar & Skonberg, 2019
Hizikia fusiformis	Martelli et al., 2021
Laminaria ochroleuca	Del Olmo et al., 2019; López-Pérez et al., 2020
Palmaria palmata	Liot et al., 1993; Martelli et al., 2021; Nayyar & Skonberg, 2019
Saccharina latissima	Standal et al., 2024
Ulva rigida	Liot et al., 1993; Sánchez-García et al., 2021

There are several ways to prevent the growth of bacteria in foods These include reducing the amount of available water, adding salt, or increasing acidity. However, these methods change the taste, texture, and other characteristics of the final product. For raw foods, the most effective way to control bacterial growth is temperature management—keeping the product outside the temperature range where bacteria grow best. Most harmful bacteria found in food are *mesophilic*, meaning they grow fastest at temperatures close to the human body temperature (95-98.6°F/35-37°C). These bacteria multiply most quickly in what is known as the "danger zone"—from 40–140°F (4.5–60°C) (USDA, 2020). Within this temperature range, bacterial numbers can double in as little as 20 minutes, depending on conditions such as water activity, pH, and nutrient availability.

Some bacteria, like *psychrotrophs* and *psychrophiles*, can grow outside of the danger zone, even at cooler temperatures. However, their growth is much slower when products are kept at proper refrigeration temperatures (at or below 40°F / 4°C). Whether a person becomes ill after eating food contaminated with harmful bacteria depends on two main factors:

1. The strength or harmfulness of the pathogen (virulence).
2. The vulnerability of the consumer (for example, children, elderly adults, pregnant women, and people with weakened immune systems can get sick from lower levels of pathogens or toxins).

Scientists often measure virulence using the median infectious dose (ID50), or the number of bacterial cells that would make 50% of a group of people sick. Another way to estimate risk is by studying actual amounts of pathogens found in contaminated foods from past outbreaks (when leftover product was available for testing). The number of cells needed to cause illness can vary a lot due to differences between strains of the same pathogen or the immune status of the consumer (e.g., children, the elderly, pregnant women, and immunocompromised individuals will become ill at lower dosages). Different strains of the same pathogen may behave differently, and the type of food it's in can also affect how easily the bacteria survive and cause illness. Table 10-2 below shows examples of the amounts of bacteria linked to illness in real outbreaks for certain pathogens relevant to seaweed food safety.

Some pathogens, like *Staphylococcus aureus* and *Bacillus cereus*, cause illness because they produce toxins in the food before it is eaten. The risk of illness depends on how much toxin is present. These bacteria usually need to reach very high numbers—more than 1 million cells per gram of food—before producing enough toxin to cause sickness. This means that small amounts of these bacteria are unlikely to cause illness unless temperature abuse occurs, allowing them to multiply to dangerous levels. Other pathogens, such as *Salmonella* or shigatoxigenic *E. coli*, can cause illness even in very small amounts. For these pathogens, **any detection** is a concern. While temperature abuse will not be the only factor leading to illness, it can greatly increase the risk by allowing their numbers to grow before the food is eaten.

Table 10-2: *Ranges of confirmed pathogen doses linked to various foodborne outbreaks from multiple food vehicles and types of foods.*

Pathogen	Mean Total Number of Cells Consumed	References
Bacillus cereus	> 15,000,000	Delbrassinne et al., 2015
Enterotoxigenic *E. coli*	< 1,000	Hara-Kudo & Takatori, 2011
Listeria monocytogenes	150,000,000 – 1,400,000,000	Pouillot et al., 2015
Salmonella (serovars include: Eastbourne; Enteritidis; Javiana; Montevideo; Napoli; Rubislaw; Saintpaul; Typhimurium)	4 – 2,000,000	D'Aoust et al., 1975; Greenwood & Hooper, 1983; Hara-Kudo & Takatori, 2011; Hennessy et al., 1996; Kapperud et al., 1990; Lehmacher et al., 1995; Ratnam & March, 1986; WHO, 2002
Shigatoxigenic *E. coli* (STEC)	31 – < 216	Hara-Kudo & Takatori, 2011; Teunis et al., 2004

When and How Temperature Abuse Can Occur

Temperature abuse (exposing seaweed to temperatures that promote pathogen growth) can happen at any stage from harvest to final packaging. Duration of harvest activities can vary but may last several hours. Key points where this risk is especially high include:

- **During Harvest:** If temperature control is not employed immediately upon harvest, portions of the product may be exposed to temperatures in the danger zone for too long before reaching shore.
- **Transport:** If mechanical refrigeration is not available during transport, other methods of cooling should be utilized (e.g., ice or cooling packs).
- **Storage:** If seaweed is harvested into very large containers, the seaweed at the center of that container may not cool to the desired temperature even if stored below 40°F.
- **During Processing:** If processing does not take place in a climate-controlled environment, the process time should be kept as short as possible. If drying, reduce water activity below 0.85 quickly to prevent bacterial growth (note: lowering water activity prevents growth but does not kill existing pathogens).

- **After Heating:** Heat processes are widely used to decrease the risk of pathogen contamination (see Chapter 13) but some organisms, particularly spores, may survive these treatments. Any time spent between 40°F (4.4°C) and 140°F (60°C) should be minimized (for example, by rapidly cooling cooked products).

The risk from temperature abuse depends on both the temperature and the amount of time the product is held there (e.g., exposure at 90°F poses a higher risk than the same amount of time at 60°F). Short-term exposures usually do not make food unsafe, but the risk increases with longer exposure times.

For detailed guidance on maximum cumulative time limits for exposure to unsafe temperatures, see Appendix 3 of the FDA's *Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food* (USFDA, 2024).

Bacterial Pathogens Associated with Macroalgae

Pathogenic Escherichia coli

Most types of *Escherichia coli* (*E. coli*) naturally live in the intestines of humans and animals without causing illness. However, some types—called pathogenic strains—can cause disease. These are grouped into categories called pathotypes (also called virotypes) and named for the kind of illness they cause. The most severe types of illnesses are caused by shigatoxigenic *E. coli* (STEC; sometimes called enterohemorrhagic *E. coli*, or EHEC). This strain can cause hemorrhagic colitis, which leads to severe, bloody diarrhea and can progress to more serious conditions such as hemolytic uremic syndrome, which can cause kidney failure and other long-term health issues.

STEC and EHEC are especially dangerous because it may take fewer than 100 bacterial cells to cause illness (see Table 10-1). Other pathotypes of *E. coli*, such as enteroaggregative and enterotoxigenic strains, usually require much higher numbers to cause disease (summarized in Kothary & Babu, 2001), and have been linked to outbreaks from contaminated seaweeds such as *Condracanthus tenellus* and *Undaria pinnatifida* (wakame), (Hamada et al., 1999; Kashima et al., 2021, respectively).

Research has shown that STEC can survive well on some seaweeds. In one study, *Saccharina latissima* blades inoculated (infected) with STEC serotypes stored in refrigeration for one week at 50°F and 40°F (10°C and 4.4°C) showed a small drop in bacteria during the first two days, but the numbers then stayed the same for the rest of the week—showing greater survival than *Vibrio* or *Listeria monocytogenes* (Akomea-Frempong et al., 2023). In a similar study, STEC numbers increased by 90% in just 48 hours at room temperature and stayed steady when stored at 50°F or 40°F (Vorse et al., 2023). However, on rockweed (*Ascophyllum nodosum*), STEC numbers dropped significantly at all storage temperatures.

Salmonella

Salmonella is a type of bacteria that can cause gastrointestinal illness in humans. It is often carried by reptiles and birds and is the leading cause of bacterial foodborne illness in the United States. While *Salmonella* has long been linked with eggs and poultry, it is now also found in a wide range of foods, including those with very low water activity (a measure of available moisture). Although *Salmonella* vegetative cells cannot grow when the water activity is below 0.94 (USFDA, 2022a), research has shown that it can survive for long periods in dry foods including tree nuts and spices (Farakos et al., 2017; Xie et al., 2022). The amount of *Salmonella* needed to cause illness can be very small. Data from multiple outbreaks suggest that as few as 36 bacterial cells may cause illness in half of the people who consume them (Teunis et al., 2010).

Studies show that *Salmonella* can also survive on seaweeds. On inoculated *Saccharina latissima* (sugar kelp), bacterial levels increased by more than 90% within just three hours at room temperature (71.6 °F / 22 °C) (Akomea-Frempong et al., 2023). Another study found similar results, with population growth of up to 90% after 48 hours at room temperature (Vorse et al., 2023). Storing *Saccharina latissima* under refrigeration—either at 50 °F (10 °C) or 40 °F (4.4°C)—for up to seven days prevented further growth but did not reduce bacterial numbers (Akomea-Frempong et al., 2023; Vorse et al., 2023). Results were different for rockweed (*Ascophyllum nodosum*). In this species, Salmonella levels dropped after 48 hours at room temperature and stayed the same under refrigeration (Vorse et al., 2023).

Vibrio Species

Vibrio bacteria are common in marine environments, making them some of the most likely pathogens to be present on seaweeds. Similar to *E. coli*, not all *Vibrio* species are harmful to humans. However, three species are of particular concern for foodborne illness: *Vibrio parahaemolyticus*, *Vibrio cholerae*, and *Vibrio vulnificus*. The infectious dose (the amount needed to cause illness) can vary. For *Vibrio parahaemolyticus*, experimental studies have estimated a range of 10,000 to 100,000 bacterial cells (Sanyal & Sen, 1974). However, evidence from a 1997 outbreak of vibriosis linked to raw oysters showed contamination levels between 2,000 and 11,000 cells per oyster (CDC, 1997), suggesting illness may occur at lower doses under certain conditions. Seaweed studies show mixed results for *Vibrio* survival. In one experiment, *Saccharina latissima* (sugar kelp) blades inoculated with both *Vibrio parahaemolyticus* and *Vibrio vulnificus* and stored under refrigeration for seven days showed a reduction of about 99.9% of the inoculated bacteria (Akomea-Frempong et al., 2023). In contrast, another study found that refrigeration of *Saccharina latissima* (sugar kelp) or *Ascophyllum nodosum* (rockweed) at 50 °F (10 °C) or 40 °F (4 °C) kept *Vibrio parahaemolyticus* populations stable, while ambient storage for 48 hours caused a 90–99% increase in *Vibrio parahaemolyticus* on sugar kelp but no increase on rockweed (Vorse et al., 2023). In this same study, *Vibrio vulnificus* behaved differently: its numbers decreased significantly (by more than 90%) during refrigerated storage of sugar kelp but increased slightly at ambient temperature. For rockweed, refrigeration led to a significant reduction in *Vibrio vulnificus* levels.

Listeria monocytogenes

Listeria monocytogenes is one of the most dangerous foodborne bacterial pathogens (Jordan & McAuliffe, 2018). It can grow at temperatures below 32°F (0°C) and can cause a serious invasive illness called **listeriosis**. In pregnant women, listeriosis often results in miscarriage or fetal health problems. This pathogen is known for its ability to survive and grow in hard-to-clean areas of food processing facilities, making it a key target for routine environmental sampling. In ready-to-eat (RTE) foods, the presence of *Listeria monocytogenes* is considered an adulterant, meaning any RTE food that tests positive for the pathogen is illegal to sell. Although refrigeration slows its growth, *Listeria monocytogenes* can still multiply at proper cold storage temperatures. The time between eating contaminated food and showing symptoms (the incubation period) can be several weeks, making it difficult to link illness to a specific food in outbreak investigations. Based on available data, the estimated dose required to make half of the general population sick (ID_{50}) is more than 100 million cells (Pouillot et al., 2015).

In seaweed studies, *Listeria monocytogenes* has shown different survival patterns depending on species and storage conditions. On *Saccharina latissima*, populations increased between 4 and 8 hours at room temperature (Akomea-Frempong et al., 2023). Refrigerated storage at 50 °F (10 °C) or 40 °F (4 °C) reduced populations by about 3 log CFU/g after seven days. In another study, room temperature storage for 48 hours caused a significant decrease in *Listeria monocytogenes* levels, while refrigeration kept populations stable (Vorse et al., 2023). On rockweed (*Ascophyllum nodosum*), Listeria monocytogenes levels remained unchanged regardless of storage temperature (Vorse et al., 2023).

Staphylococcus aureus

The original source (reservoir) of *Staphylococcus aureus* is human skin and mucous membranes. Because of this, contamination of seaweed products is most likely to occur during handling and processing, rather than during harvest from the marine environment. Illness from *Staphylococcus aureus* occurs when a person eats food containing a toxin the bacteria have already produced. This toxin is only made when the bacterial population reaches high levels and when storage temperatures are above 50 °F (10 °C) (Bergdoll & Wong, 2006). As a result, toxin production typically occurs only if the product has been temperature abused—kept in conditions that allow bacterial growth. Once formed, the toxin is heat-stable, meaning it will survive cooking or other heat treatments and cannot be removed from the food. In a storage study, *Staphylococcus aureus* populations on *Saccharina latissima* and *Ascophyllum nodosum* decreased significantly under both ambient and refrigerated conditions (Vorse et al., 2023).

Campylobacter Species

Compared to other bacterial pathogens discussed in this chapter, there is relatively little research on how *Campylobacter* species survive on foods other than poultry. *Campylobacter* was first recognized as a human pathogen in 1973, making it a relatively recent concern in food safety. It is unusual in that it requires a microaerophilic environment (one with less oxygen than normal air but not completely without oxygen) to grow. Because of this, it cannot multiply in standard ambient air conditions. This pathogen is included here because it has been detected on beach-cast seaweed (*Furcellaria lumbricalis*) (Kalvaitienė et al., 2024) and in shellfish grown in floating cages (Caron et al., 2023). However, the infectious dose for humans is not well established. Some studies have shown that as few as 800 cells of *Campylobacter jejuni* can cause illness, but the relationship between dose and illness does not follow the typical pattern seen in other pathogens (Black et al., 1988), making it difficult to assess the exact risk. *Campylobacter* is easily damaged by exposure to oxygen, so its numbers are generally expected to decline in most foods over time. However, the rate of decline varies depending on the specific food type and storage conditions (Kärenlampi & Hänninen, 2004).

Clostridium Species

Members of the *Clostridium* genus are spore-forming bacteria that grow best in environments without oxygen. *Clostridium botulinum* is discussed separately in Chapter 12 and will not be covered here.

Clostridium perfringens is one of the five most common causes of bacterial foodborne illness in the United States and is most often linked to temperature abuse. Illness occurs when the bacteria are consumed in food and then produce toxins in the intestines during spore formation. Because large numbers of *Clostridium perfringens* are needed to cause illness, proper refrigeration is an effective control strategy. However, this pathogen has been found in seaweed. In a 2006 survey of retail products in Korea, *Clostridium perfringens* was detected in two samples of unprocessed brown seaweeds (Kim et al., 2006).

Bacillus Species

Bacillus species are widespread in the environment and are frequently found in many types of foods. Because they can form resistant spores, they often survive drying processes and are common in dried food products. Most *Bacillus* species are considered spoilage organisms rather than pathogens. However, *Bacillus cereus* is a well-known foodborne pathogen that can cause two types of illness: an emetic (vomiting) form and a diarrheal form. These illnesses are caused by two different toxins—one produced in the food before it is eaten (emetic), and the other produced in the intestines after consumption (diarrheal). Some strains of *Bacillus cereus* are psychrotrophic, meaning they can grow slowly even under refrigeration (Webb et al., 2019). The toxin responsible for the emetic form of illness is generally not produced until bacterial populations exceed about 10 million cells per gram of food (Schraft & Griffiths, 2006). The diarrheal form, however, is believed to occur at much lower infectious doses. In a survey of retail products in Korea, *Bacillus cereus* was found in 20% of unprocessed brown seaweed samples at an average level of 100 colony-forming units (CFU) per gram, and in 10% of unprocessed laver samples at levels below 10 CFU/g (Kim et al., 2006).

Determining if the Hazard is Significant

While the likelihood of pathogens being present in a seaweed cultivation area can vary depending on fixed factors (such as nearby land use) and changing conditions (such as weather and season), the presence of pathogens on harvested seaweed should be considered significant—either “reasonably likely to occur” (HACCP) or “hazard requiring a preventive control” (PCHF).

Once harvest begins, seaweed temperature should be controlled as quickly and consistently as possible to reduce potential risks to public health. Extra care is needed when seaweed will be consumed raw.

- **Temperature Control for Raw Consumption:** Seaweed intended to be eaten raw should be cooled to below 40 °F (4.4 °C) using ice, gel packs, or mechanical refrigeration within two hours from the start of harvest.
- **Using Ice:** If ice is used, place a clean barrier (such as a plastic bag) between the ice and the seaweed to prevent freezing damage, quality loss from freshwater melt, and possible contamination from the freshwater source.
- **Using Gel Packs:** Gel packs must be clean and sanitized before use. Use enough gel packs to ensure the seaweed cools quickly and stays at the proper temperature.
- **Short-Term Temperature Increases:** Brief exposures to temperatures above 40 °F generally do not make food unsafe, but the risk increases with the length of time at elevated temperatures. For detailed limits on allowable cumulative time above safe temperatures, refer to the FDA’s *Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food*, Appendix 3 (USFDA, 2024).

Hazard Controls and Critical Control Points

Table 10-3: *Control Strategies for Pathogen Growth Due to Temperature Abuse*

Control Strategy	Primary Processor	Secondary Processor
Transit Control / Supply Chain Preventive Control	✓	✓
Refrigerated Storage or Processing Control	✓	✓
Cooling After Cooking Control	✓	✓
Unrefrigerated Processing Control	✓	✓

Control Strategy 1 – Transit Control (HACCP) / Supply Chain Control (PCHF)

Critical Limit(s)/Parameter(s) and Value(s)

- Harvested kelp should be kept at or below 40 °F (at or below 4.4 °C) during transit using mechanical refrigeration, ice or gel packs to ensure safe temperatures. Acceptable conditions include:
    - Refrigeration temperatures at or below 40°F during transit

OR

- Ice or gel packs or cooling media remain frozen **AND** product temperature (center of container) in a representative number of containers is below 40°F.

Monitoring – What, How, How Often, Who

- What will be monitored?
    - Ambient air temperature of transport unit

    OR

    - Adequacy and frozen status of ice or gel packs **AND** product temperature in a representative number of samples
- How will monitoring be done?
    - Receiving temperature log from the supplier for the transport unit

OR

  - Visual checks of ice or gel pack status **AND** product temperature measurements

- How often will monitoring be done (frequency)?
  - Every lot received
- Who will do the monitoring?
  - An individual trained and knowledgeable in these controls and monitoring procedures

Corrective Action/Corrections

- If refrigeration temperatures exceed 40°F (4.44°C) during transit, then reject the product **OR** place it under refrigeration and evaluate the safety of the product **OR** divert to non-food use. Any product exposed to significant temperature abuse that could allow pathogen growth or toxin formation should be discarded, processed to eliminate the hazard, or diverted to a non-food use.

- If ice or gel packs are not present or adequately frozen and/or product temperature is above 40 °F (4.44°C), then reject the lot **OR** place it under refrigeration, and evaluate the safety of the product **OR** divert to non-food use. Any product exposed to significant temperature abuse that could allow pathogen growth or toxin formation should be discarded, processed to eliminate the hazard, or diverted to a non-food use.

AND address the root cause to prevent future occurrence.

- Discontinue use of the supplier until transport procedures are corrected to maintain safe temperatures and prevent future occurrences.

Verification

- Review monitoring and corrective action records within one week of preparation to ensure all entries were completed correctly and accurately.
- Check the accuracy of temperature measuring devices regularly and perform periodic calibration as needed or according to the manufacturer's instructions.
- For refrigerated transport, conduct periodic internal temperature checks (e.g., quarterly for new suppliers and annually thereafter) by measuring the center of the container to verify that refrigeration consistently maintains seaweed at or below 40°F (4.44°C).

Records

- **Monitoring Records:** A transport log that includes time and temperature measurements or observations of presence and status of ice or gel packs, the number of containers examined, and the total number of containers in the lot.
- **Corrective Action Records:** Document actions taken when critical limits were not met, including any adjustments or product disposition.
- **Verification Records:** Include results of temperature device accuracy checks and periodic calibrations. Records of internal temperature checks, if needed, including date, time and temperature.

Example HACCP Plan for Transit Control

Below are examples showing what food safety plans could look like. They are intended for illustrative purposes only. Each producer must develop a plan tailored to their unique products, production and processing methods, and regulatory requirements. **These examples should not be copied and used without modification to fit your specific operation.**

Control Strategy: Transit Control
Critical Control Point: Receiving
Hazard: Pathogen Growth Due to Temperature Abuse

Parameters, Values, Critical Limits	Monitoring				Corrective Action	Verification	Records
	What	How	When	Who			
Harvested kelp should be maintained at a temperature of ≤40°F (4.44°C) during transit.	Ambient temperature of transport unit	Temperature log of unit temperatures during transit from supplier	At receipt of every batch	QA Staff	If refrigeration temperatures during transit exceed 40°F at any point, then, reject the product **OR** place it under refrigeration and evaluate the safety of the product **AND** Discontinue use of the supplier until transport procedures have been corrected to maintain safe temperatures to prevent future occurrences.	Weekly review of monitoring and corrective action records. Product temperature checks quarterly for new suppliers and annually thereafter in the center of the container.	Refrigerated truck temperature logs indicating time throughout transit. Corrective action records if necessary Verification records of periodic product temperature checks. PCQI training records (PCHF only).

Example Food Safety Plan for Source Control

Control Strategy: Source Control
Supply Chain Preventive Control (PCHF): Receiving Step
Hazard: Pathogen Growth Due to Temperature Abuse

Raw Material / Ingredient	Approved Supplier	Date of Approval	Hazard Requiring PC	Preventive Control Applied by Supplier	Verification Activities Supplier	Verification Procedures Buyer	Corrective Actions	Records
Winged Kelp *Alaria esculenta*	123 Kelp Co 123 Sugar Dr. Somewhere, NY 55555	Jan. 2, 2024	Pathogen growth due to temperature abuse.	Harvested kelp is placed in coolers with gel media packs within two hours of harvest.	Review of time and temperature records for harvest weekly.	Harvest records indicating time of harvest and placement in the cooler. Check that gel packs are frozen upon receipt and internal temperature check in a representative number of containers.	If harvest record is not received, then, reject the lot **OR** hold until documentation is received **AND** Discontinue use of the supplier until evidence is obtained that record requirement can be met. If harvest record indicates time to cold storage exceeds two hours, **OR** gel packs are not frozen, **OR** product temperature is above 40 °F (4.44°C), then, reject the lot **OR** place under refrigeration, and evaluate the safety of the product **AND** Discontinue use of the supplier until evidence is obtained that appropriate preventive controls are in place.	Receiving logs that indicate harvest records were received, frozen status of gel packs on arrival, and product temperature checks. Corrective action records, if necessary. PCQI Training records

Control Strategy 2 – Refrigerated Storage or Processing Control

Critical Limit(s)/Parameter(s) and Value(s)

- Harvested kelp should be maintained at ≤ 40°F (4.44°C).

Monitoring – What, How, How Often, Who

- What will be monitored?
  - Ambient temperature of mechanical refrigeration unit or processing room.
- How will monitoring be done?
  - Continuous temperature recording device with visual checks of device.
- How often will monitoring be done (frequency)?
  - Continuously, with visual check at least once per day.
- Who will do the monitoring?
  - The temperature recording device itself, supported by an individual trained in the controls and monitoring procedures.

Corrective Action/Corrections

- If temperature is above 40°F (4.44°C), then chill and hold affected products to evaluate for safety **OR** cook the product to effectively eliminate potential food safety hazards **OR** divert product to a non-food use.

AND address the root cause to prevent future occurrence.

- Fix the broken refrigerator to prevent future deviations from the critical limit.

Verification

- Review or monitoring and corrective action records within one week of preparation to ensure they were completed appropriately.
- Perform regular accuracy checks and periodic calibration of temperature recording device(s) as needed or according to the manufacturer's instructions.

Records

- **Monitoring Records:** Include continuous temperature readings and visual observations.

- **Corrective Action Records:** Document all actions taken in response to deviations from critical limits.
- **Verification Records:** Include results of temperature device accuracy checks and periodic calibrations.
- **Recall Plan:** A written recall plan is required for any products with significant hazards if regulated under preventive controls for human foods.
- **Training Records:** Training records for the preventive controls qualified individual (PCQI) must be maintained if regulated under preventive controls for human foods. While the HACCP rule requires a HACCP trained individual, records of that training are not explicitly required (federally, may vary by state).

Example HACCP/Food Safety Plan for Storage Control

Below is an example showing what a food safety plan could look like. It is intended for illustrative purposes only. Each producer must develop a plan tailored to their unique products, production and processing methods, and regulatory requirements. **This example should not be copied and used without modification to fit your specific operation.**

Control Strategy: Storage Control
Critical Control Point/Process Preventive Control: Refrigerated Raw Material Storage
Hazard: Pathogen Growth Due to Temperature Abuse

Parameters, Values, Critical Limits	Monitoring				Corrective Action	Verification	Records
	What	How	When	Who			
Harvested kelp should be maintained at a temperature of ≤40°F (4.44°C) during transit.	Temperature of walk-in cooler	Continuous temperature recording device and visual observation	Continuously with visual check at least once daily	Warehouse Associate	If cooler temperature is above 40°F (4.44°C), then chill and hold affected product to evaluate for safety, **OR** divert to cook the product to effectively eliminate potential food safety hazards risks, **OR** divert product to a non-food use **AND** Address the root cause by fixing the refrigerator to prevent future deviations from the critical limit.	Weekly review of monitoring and corrective action records Daily accuracy checks and periodic calibration of temperature recording device as per manufacturer's instructions	Continuous temperature log for the cooler with record of visual observations Corrective action records, if necessary Verification records with daily accuracy checks and periodic calibration activities PCQI training records (PCHF only)

Control Strategy 3 – Cooling After Cooking Control

Critical Limit(s)/Parameter(s) and Value(s)

- The product is cooled from 135°F (57.2°C) to 70°F (21.1°C) within 2 hours; **AND** from 135°F (57.2°C) to 40°F (4.4°C) within a total of 6 hours from time of harvest.

OR

- Maintain the minimum or maximum values for critical factors that affect cooling speed, based on a validated cooling rate study. These factors may include:
    - Starting internal temperature of the product
    - Cooler temperature
    - Amount of ice or cooling media used
    - Product size or quantity
    - Product formulation
    - How the product is arranged in the cooler

Monitoring – What, How, How Often, Who

- What will be monitored?
    - The length of the cooling cycle (time elapsed) and the internal temperature of the product.

  OR

    - The critical factors established through the cooling rate study (e.g. cooler temperature, product size, starting temperature etc.).
- How will monitoring be done?
    - A clock and thermometer or continuous temperature recording device.

  OR

    - According to the requirements of the specific process and equipment being used to monitor the critical factors identified.
- How often will monitoring be done (frequency)?

    - For cooling time and internal temperature, at least every two hours during cooling. For continuous monitoring systems, visual checks of temperature should be performed at least every two hours and at the end of the cooling period.

  OR

    - For critical factors, as often as needed to ensure all factors remain within validated control limits.

- Who will do the monitoring?
    - A trained individual with knowledge of the controls and monitoring procedures.

Corrective Action/Corrections

- If cooling time/temperature or critical factor requirements are not met, then reprocess the product **OR** dispose of the product **OR** divert product to a non-food use.

AND address the root cause to prevent future occurrence.

- Determine the cause of the deviation and adjust procedures to prevent future occurrences (e.g., equipment maintenance, employee training, etc.).

Verification

- Review of monitoring and corrective action records within one week of preparation to ensure accuracy and completeness.
- Regular accuracy checks of temperature reading/recording devices and periodic calibration.
- A cooling rate study identifies the critical factors that influence cooling and evaluates the effectiveness of the cooling process, if applicable.
- Additional verification procedures may be required depending on the specific critical factors applied.

Records

- **Monitoring Records**: A cooling log documenting times and temperatures recorded throughout the cooling cycle or observations of critical factors outlined in the cooling rate study.
- **Corrective Action Records:** Record any actions taken in response to deviations from the critical limit(s).

- **Verification Records:** Validated cooling rate study on file for the cooling process, accuracy and calibration records for equipment used.
- **Recall Plan:** A written recall plan is required for any products with significant hazards if regulated under preventive controls for human foods.
- **Training Records:** Training records for the preventive controls qualified individual (PCQI) must be maintained if regulated under preventive controls for human foods. While the HACCP rule requires a HACCP trained individual, records of that training are not explicitly required (federally, may vary by state).

Example HACCP/Food Safety Plan for Cooling After Cooking Control

Below is an example showing what a food safety plan could look like. It is intended for illustrative purposes only. Each producer must develop a plan tailored to their unique products, production and processing methods, and regulatory requirements. **This example should not be copied and used without modification to fit your specific operation.**

Control Strategy: Cooling After Cooking Control
Critical Control Point/Process Preventive Control: Cooling
Hazard: Pathogen Growth Due to Temperature Abuse

Parameters, Values, Critical Limits	Monitoring				Corrective Action	Verification	Records
	What	How	When	Who			
The product is cooled to 70°F (21.1°C) within 2 hours and within no more than 4 more hours from 70°F (21.1°C) to 40°F (4.4°C). Product temperature reaches 40°F within no more than 6 hours.	Length of cooling cycle Seaweed Temperature	Watch Thermometer	Every Batch	Line Cook	If cooling time/temperature are not met, then reprocess the product **OR** dispose of the product **OR** divert product to a non-food use. **AND** Determine the cause of the deviation and adjust procedures to prevent future occurrences (e.g., equipment maintenance, employee training, etc.).	Weekly review of monitoring and corrective action records. Thermometer accuracy checks daily before use and calibration checks as per manufacturer instructions.	Cooling log including cooling time and temperature checks. Corrective action records, as necessary. Verification records, including thermometer accuracy checks and calibration records. PCQI training records (PCHF only)

Control Strategy 4 – Unrefrigerated Processing Control

When processing raw ready-to-eat products, it is essential to prevent significant pathogen growth throughout the process. For cooked ready-to-eat products, this also applies after the cook step. If any unrefrigerated processing steps occur, producers must assess the associated risks and implement appropriate controls to prevent pathogen growth during these steps. For detailed guidance, refer to Chapter 12 of the FDA's *Fish and Fishery Products Hazards and Controls Guidance* (USFDA, 2022b). A seaweed-specific example food safety plan for a cooked ready-to-eat seaweed product is provided on the following page.

Example HACCP/Food Safety Plan for Unrefrigerated Processing Control

Below is an example showing what a food safety plan could look like. It is intended for illustrative purposes only. Each producer must develop a plan tailored to their unique products, production and processing methods, and regulatory requirements. **This example should not be copied and used without modification to fit your specific operation.**

This example is continued on the next page.

Example HACCP/Food Safety Plan for Unrefrigerated Processing Control (continued)

Control Strategy: Unrefrigerated Processing Control

Critical Control Point/Process Preventive Control: Packing Step

Hazard: Pathogen Growth Due to Temperature Abuse

Parameters, Values, Critical Limits	Monitoring				Corrective Action	Verification	Records
	What	How	When	Who			
The seaweed is held at internal temperatures below 50°F (10°C) throughout packing.	Temperature	Thermometer	Continuously during packing, with visual checks at least every 30 minutes and just before returning to the refrigerated unit.	QA Staff	If the temperature exceeds 50°F (10°C) at any time, then the product is discarded **OR** diverted to non-food use. **AND** The cause of the deviation is evaluated and identified. Procedures are updated to prevent future deviations from the critical limit.	Weekly review of monitoring and corrective action records. Thermometer accuracy checks daily before use and calibration checks as needed and at least once a year.	Packing log including continuous temperature recording and visual checks throughout packing and just before returning to refrigeration. Corrective action records, as necessary Verification records, including thermometer accuracy checks and calibration records. PCQI training records (PCHF only)

NOTE: Although pathogen growth is slow below 50°F (10°C), extended exposure at this temperature can still support growth. When unrefrigerated processing steps approach the **maximum cumulative exposure** times outlined in Appendix C, Table C-B of the FDA's *Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry* (USFDA, 2024), a more rigorous critical limit should be applied. This limit must closely monitor both internal product temperature and total exposure time to ensure food safety.

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Chapter 11 Pathogen Contamination

General Background: Understanding the Potential Hazard

As discussed in Chapter 5, several bacterial, viral, and fungal pathogens can be present in seaweed cultivation and harvest areas. Pathogens can also be introduced post-harvest during handling, transport, processing or storage. The risk of postharvest contamination is particularly important when the final processing step is not a kill step designed to reduce or eliminate pathogens of concern.

The level of risk from various microbial pathogens depends on the type of processing applied and the storage conditions of the finished product. For example, *Bacillus cereus* contamination is of particular concern for dried food products, whereas *Listeria monocytogenes* contamination is of particular concern in refrigerated food products. Certain pathogens, such as *Staphylococcus aureus* and Norovirus, are directly linked to human handling, while others, such as *Vibrio parahaemolyticus*, are more likely to pose a risk through **cross-contamination** during processing steps like washing or cutting, where multiple lots are combined (comingled).

This chapter will review processing technologies that are currently used in the production of seaweed products, highlighting pathogens relevant to these processes and summarizing their effects on pathogen presence on seaweeds whenever possible.

Maintenance of Clean and Sanitary Equipment and Facility

Many instances of contamination during handling, processing and storage of foods occur because proper cleaning and sanitation procedures are not followed. Compliance with current Good Manufacturing Practices (GMPs), which includes establishment of and adherence to sanitation standard operating procedures (SSOPs), is required for food processors subject to FDA oversight and helps minimize this risk. Key practices include:

- All equipment and surfaces should be easily cleanable and maintained in good condition.
- Any equipment or surfaces coming into direct contact with seaweeds for human consumption should be maintained in a visually clean state and should be sanitized frequently.
- Avoid contact between harvested seaweeds and non-potable water.
- Harvested seaweeds should be protected from contact with adulterants such as petroleum products.

- All personnel within a facility should be trained on good hygiene practices including proper hand washing and sanitizing.

Proper sanitation is particularly important for reducing viral contamination, as viruses are often introduced through human handling or contact with contaminated water and may not be inactivated by heat processing. Hepatitis A virus (HAV) and Norovirus remain infectious at pH as low as 3.0 (Cliver et al., 2006). HAV can survive in ambient temperature tap water for up to 50 days (Enriquez et al., 1995), and refrigeration only extends the amount of time it survives.

Listeria monocytogenes is a high-risk pathogen during processing. Due to several unique characteristics of this pathogen, such as its ability to grow at refrigerated temperatures (Walker et al., 1990), and its high tolerance to salt and sanitizers (McClure et al., 1989 and Aase et al., 2000, respectively), *Listeria monocytogenes* is commonly found in processing environments (Tompkin, 2002) and persists long-term in commercial processing facilities (Ferreira et al., 2014; Malley et al., 2015). Listeriosis, the illness caused by *Listeria monocytogenes*, has an estimated mortality rate of approximately 20% (CDC, 2024). As a result, vegetative *Listeria monocytogenes* in ready-to-eat (RTE) foods is considered unacceptable ("zero tolerance") in the U.S. and most Western nations.

Contamination After Application of Process Controls

It is important to note that even when process controls are applied correctly, contamination can still occur due to the processing environment or improper handling of the product. Common causes include:

- Poor cleaning and/or sanitation of equipment and surfaces
- Addition of contaminated ingredients after the process control step
- Improper storage or temperature control following the process control step
- Lack of or compromised packaging integrity

Producers should take reasonable steps to minimize the risk of post-process contamination.

Processes Commonly Applied to Commercial Seaweed Products

Washing

Raw seaweeds may be washed before further processing to remove epiphytes and marine invertebrates. Washing can be carried out using either potable or treated seawater. Seawater can be rendered safe for washing using technologies such as filtration and ultraviolet (UV) light. Untreated seawater should not be used, unless it is from the certified harvest area, as it may contain pathogens (see Chapter 5). Re-use of wash water should be managed to limit the potential for cross-contamination in the event that a small portion of harvested seaweed contains pathogens from the harvest area. Sanitizers such as chlorine or peracetic acid can be added to wash water to minimize the risk of cross-contamination (Good et al., 2021), however, sanitizers used in this way are generally not effective at reducing pathogen loads. Limited data exist on the efficacy and quality effects of sanitizers on seaweed, although one study reported potential benefits of aqueous hydrogen peroxide and sodium hypochlorite for maintaining microbial quality during storage (Kim et al., 2008).

Multiple studies have found that washing increases the levels of spoilage organisms and coliforms in sugar kelp and laver in laboratory (Wirenfeldt et al., 2022) and commercial settings (Son et al., 2014; Wang et al., 2023). Similarly, inoculation studies have shown that washing does not reduce levels of key pathogens, including *E. coli* O157:H7, *Listeria monocytogenes*, and *Vibrio parahaemolyticus* (Swinscoe et al., 2020). Collectively, these findings indicate that washing of seaweed is more likely to facilitate cross-contamination than it is to reduce microbial loads.

Thermal Processes: Blanching, Cooking, and Pasteurization

Heat-based processes are widely recognized for their ability to reduce overall microbial loads in most foods. When conducted properly—without exposure to non-potable cooling water—blanching and cooking present minimal risk of contamination. However, post-process contamination can still occur if there is a lack of adequate sanitary controls in place. It is important to note that most heat treatments do not inactivate bacterial spores produced by certain pathogens, such as *Bacillus cereus* and *Clostridium perfringens*, which may be able to germinate after processing depending on the characteristics of the resulting food product (pH, salinity, etc.). For heat treatments to serve as an effective processing control, procedures must be validated to confirm that they achieve the intended level of hazard reduction. Cooking and pasteurization are discussed in greater detail in Chapter 13.

Blanching is a heat process used primarily for food quality preservation, usually either to inactivate enzymes or to decrease the population of spoilage organisms, not as a kill step. Results from studies on *Saccharina latissima* (whole blades and shredded) indicate variable effectiveness. Treatments using hot water at 140–212°F (60–100°C) for durations ranging from 5 seconds to 5 minutes produced inconsistent outcomes: two studies reported no significant microbial reduction (Akomea-Frempong et al., 2022; Stévant et al., 2024), while one observed measurable decreases (Wirenfeldt et al., 2022). These findings demonstrate that the effectiveness of heat treatment depends on specific processing parameters and must be validated before it can be relied upon for microbial hazard control.

Reduction of Water Activity

Moisture content refers to the total amount of water contained in a food product. Some of this water is "bound" by its interaction with other components of the food and some of the water is "free." Water activity is a measure of free water in food, which is available for microbial growth. Because of this, it is a more relevant indicator of food safety than total moisture content. Water activity is expressed as a unitless number ranging from 0 to 1, where 1 represents pure water. According to USFDA (2024), foods can be categorized as:

- **Moist foods**, which have water activity above 0.85 and require refrigeration.
- **Intermediate-moisture foods (IMF),** which have water activity between 0.60 and 0.85. These foods do not require refrigeration, are susceptible to fungal spoilage, and may also utilize other strategies for microbial stability in addition to control of moisture.
- **Low-moisture foods,** which have a water activity below 0.60 and do not require refrigeration. These foods are generally resistant to microbial spoilage and are considered shelf stable.

The number of bacterial pathogens will not increase at a water activity below 0.85, but importantly, reducing water activity alone will not inactivate pathogens. For example, Shiga toxin producing *E. coli* has caused outbreaks from wheat flour with water activity as low as 0.341 (Gill et al., 2019) and has been shown to survive in flour for at least two years (Gill et al., 2020). Both salting and drying are common processing methods for reducing water activity in foods, including seaweeds.

Salting—Brining or Dry Salting

Salting is a long-established method of processing seaweeds. Salt may be applied directly to seaweed (e.g., dry salting) or by immersion into a salt brine solution. This process may also be referred to as "pickling" but in this context does not involve the use of acid—either by direct addition or through bacterial fermentation—for preservation. Most salting processes produce intermediate-moisture products which can be stored at ambient temperature, reducing the need for refrigeration while significantly extending the shelf life compared to fresh seaweed. Refrigeration of these products, although not required, can help delay fungal growth and further enhance food safety.

Several studies have shown that salting extends the shelf life of seaweeds with most experiments yielding positive results, however, data on the survival or growth of human pathogens in salted seaweeds remain limited. This knowledge gap prevents a comprehensive assessment of the safety of these products at this time.

Table 11-1: *Summary of published studies investigating salting treatments of seaweed.*

Species	Salt Level: Dry Salting	Salt Level: Brining	Final Water Activity	Result	Reference
Alaria esculenta	3–20% (wt/wt)	Not measured	0.97–0.84	No changes in microbial populations during 12 weeks of storage at 40°F	Perry, Brodt et al., 2019
Alaria esculenta	3–20% (wt/wt)	Not measured	0.97–0.84	Significant decreases in population over time recorded for all inoculated pathogens *Vibrio* species, *Listeria monocytogenes*, *S. aureus* and *Salmonella* remained detectable for up to 7, 26, 28, and 36 days, respectively, with no statistical impact of salt concentration	Perry, Nile et al., 2019
Caulerpa species	Not measured	10–30% (wt/wt)	Not measured	Low levels of bacteria and yeast maintained for 12 weeks of storage at 77°F	Pan-utai et al., 2023
Laminaria ochroleuca	40% (wt/wt)	Not measured	0.742	No change in microbial levels but decrease observed during subsequent refrigerated storage	Del Olmo et al., 2019
Saccharina latissima	30% (wt/wt)	40% (wt/wt)	<0.77	Significant decrease in microbial levels, no increase observed for 60 days under ambient (72°F) storage or 90 days under refrigeration (40°F)	Arya, 2025
Saccharina latissima	5–50% (wt/wt)	Not measured	0.95–0.75	Extension of shelf life from 6 (untreated) to 19 days	Klein et al., 2023
Ulva fenestrata	Not measured	0–25% (wt/wt)	0.98–0.89	Brining with ≥15% NaCl resulted in refrigerated shelf life of 78 days	Vall-Ilosera et al., 2024

Drying

The term "drying" refers to a range of processes aimed at reducing water activity or moisture content of seaweed. Common methods include (but are not limited to) sun or static air drying, forced air drying, hot air drying, and freeze drying (USFDA, 2018). Drying is the most common postharvest process method for edible seaweeds and is most often followed by additional processing steps including milling. Seaweeds may be heat treated (e.g., blanched or pasteurized) before drying to enhance safety and/or color (see Chapter 13). Lowering water activity (a_w) through drying renders seaweed shelf stable for long periods of time. At present, water activity of seaweeds cannot be accurately estimated from total moisture alone, so moisture contents should not be used to determine if a dried product is safe from microbial growth. Drying effectiveness depends on three main factors: the maximum temperature reached during drying, the time the product spends at temperature, and the final water activity of the finished product.

The FDA currently recommends drying to a water activity below 0.85 for products intended to be stored at ambient temperature (USFDA, 2024). As long as they are packaged to prevent moisture uptake from the environment, intermediate-moisture foods (IMF) should not support the growth of most microorganisms—including bacterial pathogens. However, there are some microorganisms, like toxigenic fungi, that may grow at a water activity as low as 0.6. If packaging is improper or compromised, IMF can rehydrate by absorbing moisture from the air, potentially reaching water activity levels that support bacterial growth—especially under ambient storage conditions. *Staphylococcus aureus* can grow at a water activity as low as 0.84, even with salt levels above 10% wt/wt (USFDA, 2022). *Aspergillus flavus*, a fungus that produces a potent carcinogen called aflatoxin, can grow at a water activity of 0.78 or higher and produce toxin at 0.83 or higher (Chu, 2006). Low-moisture foods, those with water activity less than 0.6, should be stable for extended periods even under ambient storage. Most dried seaweeds fall into this category.

However, as outlined in Chapter 10, some pathogens can cause illness without growing in the food. Low moisture products are often implicated in outbreaks and recalls. For example, *Salmonella* cannot multiply in dried products but can survive long enough to cause outbreaks if present (Beuchat et al., 2011). For this reason, it is essential to prevent contamination after harvest, especially for dried seaweed that consumers may eat without cooking. Levels of microorganisms on dried seaweeds can be high even though they don't allow for bacterial growth (see Table 11-2). While there are no legal limits for indicator microorganisms, the FDA's National Advisory Committee on Microbiological Criteria for Foods (MACMCF) suggests that fresh fruits and vegetables should contain less than 100 cells of *E. coli* per gram; dried fruits and vegetables should contain less than 0.36 cells of *E. coli* per gram, and heat-treated fruits and vegetables should contain less than 100 coliforms/gram (NACMCF, 2021). Seasonings produced under sanitary conditions should have less than 6-log CFU/g of aerobic mesophiles and less than 4-log CFU/g of coliforms.

Concerns around microbial safety vary widely depending on the drying process that is used . Sun drying is the oldest method of drying, where harvested seaweed is either laid flat on a surface (such as a tarp) or hung on a structure (like a clothesline) to dry outdoors at ambient temperature. While this process does not require an energy input, it is dependent on unpredictable local weather conditions such as temperature, relative humidity, and sunlight (UV exposure). Because these factors can be unpredictable, sun drying may be inefficient in some locations and can result in inconsistent moisture content in the final product. In addition, sun drying exposes seaweeds to contamination from sources including animals, insects, and contact with soil.

Several pathogens of concern can be a problem in dried products, including dried seaweed products. *Salmonella* can survive for long periods in dried foods and has a very low infectious dose—as few as 10 cells. It is often linked to contamination from birds and insects. *Bacillus cereus* is a spore forming pathogen commonly found in soil. Its spores can survive drying and may germinate when the product is rehydrated. Certain molds, like toxigenic fungi, are capable of reproducing in intermediate moisture foods (IMF) and produce harmful toxins. These fungi are also commonly associated with soil.

Table 11-2: *Reported microbial counts in dried seaweeds (log CFU/g). Cells labeled "**NA**" indicate the microbe was not assessed.*

Species	Source of Sample	AMB[a,d]	HMB[b]	Fungi	Coliform[c]	Fecal Coliform	Generic *E. coli*[d]	*Listeria* species	*Bacillus* species	Reference
Chondrus crispus	Farmed (integrated multitrophic aquaculture), commercially dried, subsequently freeze dried	4.3	4.9	NA	3.0	NA	**2.5**	NA	NA	Campos et al., 2022
Hizikia fusiformis	Retail, RTE samples purchased in Italy	2.8	2.2	3.3	<2.0	NA	NA	<2.0	<2.0	Martelli et al., 2021
Laminaria species	Retail, RTE samples purchased in Italy	2.9	3.4	2.7	2.2	NA	NA	<2.0	<2.0	Martelli et al., 2021
Palmaria palmata	Retail, RTE samples purchased in Italy	3.4	4.2	2.7	<2.0	NA	NA	<2.0	<2.0	Martelli et al., 2021
Palmaria palmata	Experimentally dried (32°C, 24h), a_w 0.28	3.0	NA	2.7	NA	NA	NA	NA	NA	Stévant et al., 2020
Palmaria palmata	Experimentally dried (32°C, 24h) and partially rehydrated, a_w 0.62	3.8	NA	NA[c]	NA[c]	NA	NA	NA	NA	Stévant et al., 2020
Palmaria palmata	Farmed (integrated multitrophic aquaculture), commercially dried, subsequently freeze dried	4.9	5.2	NA	2.5	NA	<1.0	NA	NA	Campos et al., 2022
Porphyra species	Farmed (integrated multitrophic aquaculture),	4.5	4.7	NA	2.0	<1.0	NA	NA	NA	Campos et al., 2022

[a] Aerobic mesophilic bacteria
[b] Heterotrophic marine bacteria
[c] Bolded values indicate values in excess of recommended levels for spices and herbs produced under sanitary conditions (NACMCF, 2024)
[d] Bolded values indicate values in excess of recommended levels for dehydrated fruit/vegetable produced under sanitary conditions (NACMCF, 2024)

Species	Source of Sample	AMB[a,d]	HMB[b]	Fungi	Coliform[c]	Fecal Coliform	Generic *E. coli*[d]	*Listeria* species	*Bacillus* species	Reference
	commercially dried, subsequently freeze dried									
Porphyra species	Commercially produced (Korea) dried, roasted laver snacks (different manufacturers)	2.2 5.9 1.3 4.7 4.8 1.9	NA	NA	NA	NA	NA	NA	NA	Choi et al., 2014
Porphyra species	Retail, RTE samples purchased in Italy	4.0	4.4	<2.0	<2.0			<2.0	<2.0	Martelli et al., 2021
Pyropia tenera	Retail samples purchased in Korea	2.6	NA	NA	<1.0	NA	NA	NA	NA	Kim et al., 2023
Porphyra yezoensis	Commercial laver snacks produced in China (different manufacturers)	5.7 **7.3** **6.0** **7.6**	NA	NA	>3.0 >2.0 3.6 >2.5	NA	NA	NA	NA	Ding et al., 2025
Porphyra yezoensis	Retail samples purchased in Korea	5.5 **6.6** **6.8** **6.3**	NA	NA	0.5 <0.3 0.8 1.3	<-0.7 <-0.7 <-0.7 <-0.7	NA	NA	NA	Son et al., 2014
Porphyra yezoensis	Commercial laver snacks produced in Korea (different manufacturers)	**6.7** **8.0** 5.7 **6.3** 5.6 **7.7** **6.1**	NA	NA	0.8 0.5 1.0 1.2 2.0 -0.3 2.4	<-0.7 <-0.7 <-0.7 <-0.7 <-0.7 <-0.7 <-0.7	NA	NA	NA	Son et al., 2014

Species	Source of Sample	AMB[a,d]	HMB[b]	Fungi	Coliform[c]	Fecal Coliform	Generic *E. coli*[d]	*Listeria* species	*Bacillus* species	Reference
Porphyra yezoensis	Commercial laver snacks produced in China (different manufacturers)	**7.3** **7.9**	NA	1.7 2.6	2.1 3.9	NA	NA	NA	NA	Wang et al., 2023
Porphyra yezoensis	Commercially dried ingredient for further processing (different manufacturers, China)	**7.0** 5.8 **6.6** 2.7	NA	1.0 <1.0 1.9 1.2	1.0 <1.0 <1.0 1.2	NA	NA	NA	NA	Zhou et al., 2023
Ulva species	Farmed (integrated multitrophic aquaculture), commercially dried, subsequently freeze dried	3.0	3.7	NA	2.2	NA	**1.0**	NA	NA	Campos et al., 2022
Ulva species	Retail, RTE samples purchased in Italy	4.2	4.2	2.6	3.5	NA	NA	2.8	2.9	Martelli et al., 2021
Undaria pinnatifida	Retail, RTE samples purchased in Italy	4.9	4.4	<2.0	<2.0	NA	NA	2.5	<2.0	Martelli et al., 2021
Undaria pinnatifida	Retail samples purchased in Korea	2.6	NA	NA	<1.0	NA	NA	NA	NA	Jeon et al., 2021

Solar Drying (Drying in a Greenhouse)

To reduce potential contamination risk from the open environment and to improve process control, some seaweed producers use greenhouse or solar drying. This process is similar to sun drying in that it uses solar energy and is still influenced by local temperature, UV and (to a lesser extent) humidity fluctuations. However, drying in a closed facility greatly reduces exposure to animals, insects, and soil. The enclosed space can also increase temperature for better drying efficiency. Greenhouses may be equipped with some form of air circulation (e.g., fans) either within or across the length of the structure to circulate air evenly or provide supplemental heat sources to maintain more stable drying conditions. These strategies can help to mitigate large temperature and humidity fluctuations that can occur between the day and evening hours which can negatively affect both food safety and product quality.

Mechanized Drying

Mechanized drying, which is performed in a contained environment, may be carried out as a batch or (semi) continuous process. Batch processes may use standard ovens or cabinet-style dryers that can range in size from small countertop units to room-size cabinets covering several hundred square feet. Continuous drying utilizes commercial drying units that move seaweed through different sections (via a tunnel) with controlled changes in temperature and/or humidity. These processes are preferable from a safety and quality standpoint because they allow for better control of environmental conditions (e.g., temperature, time, and humidity), which results in the production of more consistent, finished products and improves the ability to prevent or limit contamination during drying. Temperatures used in mechanized drying are typically between 104-140°F (40-60°C) and while they usually reduce the overall number of bacteria, the process should not be considered a strategy to eliminate dangerous pathogens.

Drying parameters have significant impacts on both product quality and safety. For example, Lytou et al. (2021) dried *Alaria esculenta* and *Saccharina latissima* at 104°F, 122°F and 140°F (40°C, 50°C and 60°C) and noted that total aerobic mesophile population increased by 99% at 104°F (40°C), while drying at 122°F (50°C) or 140°F (60°C) reduced these populations by approximately 99% (Lytou et al., 2021). This study also observed significant year-to-year variation in starting microbial counts of both seaweed species. In samples with lower starting microbial loads, *Bacillus* species were the most common microorganisms detected. Additional research by Sørensen et al. (2023) showed that *Salmonella* on experimentally inoculated *Alaria esculenta* dried at 104°F (40°C) did not reach the target 5-log CFU/g reduction, even after 150 minutes of drying. This highlights that drying alone—especially at lower temperatures—may not fully inactivate certain pathogens.

A survey of three commercial processing facilities in China producing dried laver snacks found that the drying process (104–122°F [40–50°C] for 2.5 hours followed by 95–194°F [35–90°C] for 3–4 hours) actually led to an *increase* in aerobic mesophile populations within the facilities (Wang et al., 2023). In a similar study of seven Korean manufacturing facilities, drying (exact conditions were not disclosed) did not significantly reduce either aerobic mesophilic bacteria or coliform levels (Son et al., 2014). Another research study examined the microbiological impact of roasting of commercially dried laver. In two of six Korean processing facilities, *Bacillus cereus* was identified in the incoming dried product (Choi et al., 2014). This pathogen was detected in laver at various steps of the manufacturing process in all six facilities, demonstrating that the risk of cross-contamination can occur during manufacturing. *Bacillus cereus* was detected in finished products from four of the six facilities tested, representing 50% of the finished products sampled in this study.

Conversely, a survey of 15 retail samples of dried Undaria pinnatifida in Korea did not detect coliforms, *E. coli*, *Staphylococcus aureus*, *Salmonella*, *Listeria monocytogenes*, *Bacillus cereus*, *Clostridium perfringens*, *Yersinia entrerocolitica*, *Campylobacter jejuni*, or *Vibrio* species. (Jeon et al., 2021).

Freeze Drying (Lyophilization)

Freeze drying (or lyophilization) is a less common but increasingly used method for dehydrating seaweed. Freeze drying produces a dried product with unique physical and chemical properties. It is especially valued for preserving and extracting bioactive compounds, since no heat is applied. In the freeze-drying process, seaweed is subject to low negative pressure (vacuum pressure) during freezing, resulting in conversion of ice to water vapor (sublimation). This allows for the removal of water without the application of heat. However, freeze drying has limitations as it requires expensive equipment, is usually done in small batches, and consumes large amounts of energy.

One study compared the effects of freeze drying and greenhouse drying on populations of pathogens inoculated on *Saccharina latissima* and *Ascophyllum nodosum* (Vorse et al., 2023), while both reduced microbial load freeze drying was less effective at reducing pathogen populations in nearly every scenario when compared to greenhouse drying.

Fermentation

This section highlights lactic acid fermentation of fresh, raw (non-dehydrated) seaweeds for use in food products. In terrestrial vegetables, such as cabbage, lactic acid bacteria are naturally present in sufficient amounts from the soil to allow spontaneous fermentation without adding starter cultures. In contrast, since seaweeds do not naturally carry enough of these bacteria, most fermentation processes will need an additional, commercial lactic acid bacterial culture to drive the fermentation process. Another challenge when fermenting seaweed is that seaweed tissues generally contain very low amounts of fermentable simple sugars, which delays the start of fermentation unless the seaweed is pretreated. Researchers have suggested utilizing heat treatments (Bruhn et al., 2019) or enzymatic digestion to break down complex carbohydrates into simple sugars, although results have been mixed. Gupta et al. (2011) recorded a 400% increase in sugars after heat treating *Himanthalia elongata*, *Laminaria digitata* and *Saccharina latissima*, but they were unsuccessful in fermenting treated *Himanthalia elongata* even using the common starter culture *Lactiplantibacillus plantarum*. Alternatively, another approach is to ferment seaweed together with other ingredients rich in simple sugars, as in mixed-substrate fermentations (Skonberg et al., 2021).

In one study, *Saccharina latissima* and *Alaria esculenta* were combined with shredded cabbage at different ratios of 25:75, 50:50 and 75:25 (weight-to-weight) and inoculated with a mixture of *Lactiplantibacillus plantarum* and *Leuconostoc mesenteroides* (Skonberg et al., 2021). Samples containing *Alaria esculenta* fermented significantly more quickly than those containing *Saccharina latissima*. All treatments reached pH below 4.6, which is considered a safe pH for many fermented foods. However, coliforms originating from the cabbage were detected in all treatments except the 75:25 *Alaria esculenta*: cabbage mix. Conversely, the 75:25 *Saccharina latissima* mix maintained a relatively high coliform level of approximately 2.5 log CFU/g—even after sixty days of post-fermentation refrigerated storage (see Appendix E for more information on measuring microorganisms in food). In a subsequent pathogen inoculation study, *Salmonella*, *Listeria monocytogenes*, *Vibrio* species, and *Staphylococcus aureus* were all undetectable within 10 days or less of fermentation, regardless of seaweed species or concentration used (Perry, Nile, & Skonberg, 2019).

A similar study conducted on *Saccharina latissima* and *Alaria esculenta* compared fermentation using natural microflora and *Lactiplantibacillus plantarum* (Sørensen et al., 2021). The naturally occurring flora were unable to reduce pH to a suitable level (below 4.6) and observed that *Alaria esculenta* again fermented faster than *Saccharina latissima* when inoculated. Also in this study, inoculated *Listeria monocytogenes* decreased from 3.8 log CFU/g to less than 1.0 log CFU/g in four days in both *Lactiplantibacillus plantarum* fermentation treatments. Although only two studies have examined pathogen survival during seaweed fermentation, both found consistent reductions in pathogen levels. These findings suggest that the use of acidification through lactic acid fermentation can produce safe finished products, provided that the seaweed species used and the final pH achieved are carefully controlled and fermentation methods are validated.

Freezing

Freezing can help seaweed maintain "fresh-like" qualities but is energy intensive. It also requires the subsequent availability of frozen storage and transport. Frozen seaweeds are often blanched or pasteurized before freezing in order to maintain quality during storage and may be used for further processing (e.g., fermentation or drying).

In a study on *Saccharina latissima*, the amount of *Bacillus* species increased from 1.1% to 80.3% after freezing relative to other taxa (Jönsson et al., 2023). This is important to note for previously frozen seaweeds that are thawed and dried, as *Bacillus* can produce spores that survive drying and may become active again when the seaweed is rehydrated. Significant decreases (by greater than 99%) in microbial populations were observed on *Laminaria ochroleuca* after 60 days of frozen storage (Del Olmo et al., 2019), but this trend was not observed in multiple studies of *Saccharina latissima* frozen for up to 12 months (Akomea-Frempong et al., 2021; 2022). In another study, raw laver stored frozen for 15 days showed a decrease in total mesophilic count, but the decline was not linear (Lee et al., 2023).

Multiple authors have reported increased fungal growth (visually or measured) on previously frozen seaweeds when compared to other samples (Akomea-Frempong et al., 2022; Del Olmo et al., 2019; Jönsson et al., 2023).

Disintegration (Shredding, Milling, Pureeing, etc.)

Processes that help in breaking down or separating ingredients (disintegration unit operations) are common in the processing of fresh seaweeds (e.g., slicing, shredding) as well as dried seaweeds (e.g., milling). It is well established that mixing of foods during disintegration carries a risk of cross-contamination (Buchholz et al., 2012; Scollon et al., 2016). Laboratory studies have shown that mechanical shredding of Saccharina latissima did not increase microbial loads (Akomea-Frempong et al., 2022). However, in a study of commercial processors in Korea manufacturing dried laver snacks, chopping resulted in increases in aerobic bacterial counts ranging from 0.4-4.4 log CFU/g (Son et al., 2014).

It is possible for pathogens to transfer from contaminated products to equipment surfaces and vice versa. For this reason, care should be taken to ensure proper sanitation of cutting and milling equipment, particularly in the handling of high moisture (e.g., not dried) seaweeds, which provide favorable conditions for pathogen growth.

Packaging

Packaging can influence the risk of foodborne pathogen growth by affecting environmental factors such as moisture, oxygen exposure, and temperature stability. Most bacterial pathogens of concern in seaweeds are facultatively anaerobic, meaning that they will survive and even reproduce—albeit more slowly—in the absence of oxygen. For this reason, vacuum packaging and modified atmosphere packaging (MAP) are usually used to preserve quality rather than improve safety. In an experimental investigation, the use of vacuum packaging and MAP (80% argon, 20% carbon dioxide) resulted in a significant decrease in heterotrophic marine bacterial counts on *Porphyra umbilicalis* (greater than 99.99% reduction) but had no effect on the same population on *Ulva lactuca* (Moreira-Leite et al., 2023). These results highlight the species-specific differences in bacterial behavior across various types of seaweed.

Clostridium botulinum, a strict anaerobe, is only considered to be a significant hazard in reduced oxygen packaged (ROP; e.g., vacuum packed in non-oxygen permeable package) products (see Chapter 12).

Proper packaging and storage of dried products are essential to prevent partial rehydration. Moisture absorbed from the air can increase water activity, creating conditions that support the growth of pathogens. In a study of dried seaweeds, aerobic bacterial populations rose significantly after 3–5 days of storage at 77°F (25°C) (ambient temperature) under 70% or more relative humidity (RH), while mold counts increased after just one day. In contrast, storage at 50% RH kept microbial levels relatively stable (Hyun et al., 2018). These results underscore the importance of using packaging that limits exposure to moisture during storage.

Other/Emerging Processes

A small number of publications discuss using processes including high pressure (HPP) and pulsed electric field (PEF) for the preservation of seaweeds. Recently, PEF has been investigated not as a standalone treatment but as a pretreatment for seaweed drying. Authors report improved drying efficiency (Le Loeuff et al., 2024), and reduction of iodine and arsenic (Blikra et al., 2022), through the addition of PEF to drying processes.

High pressure treatment of *Listeria ochroleuca* resulted in an immediate decrease of total viable bacteria by approximately 2-3 log CFU/g, a reduction that was maintained during subsequent storage at 4°C (Del Olmo et al., 2019). However, the combination of salting and HPP in this study did not result in improved microbial quality. HPP can be used as a processing control if the conditions applied are appropriately validated. At present, the use of HPP and PEF in seaweed processing is limited. The main challenges are the lack of available infrastructure and the high cost of specialized equipment.

Determining if the Hazard is Significant

Post-process-related contamination is considered a significant hazard—either “reasonably likely to occur” (HACCP) or “hazard requiring a preventive control” (PCHF)—particularly for ready-to-eat (RTE) foods, due to the ability of Listeria monocytogenes to establish itself in processing environments. This is especially important for RTE foods because they will not be cooked by the end user and there is no additional kill step to eliminate pathogens. Note that when operating under a HACCP system, sanitation controls can be part of a facility's prerequisite programs (such as GMPs) and do not need to be included in a HACCP plan. However, in a Preventive Controls Food Safety plan, sanitation controls necessary to prevent post-process cross-contamination and ensure safety must be included in the facilities Food Safety Plan.

Hazard Controls and Critical Control Points

***Table 11-3**: Control Strategies for Pathogen Contamination*

Control Strategy	Primary Processor	Secondary Processor
Sanitation Preventive Control	✓	✓

Control Strategy – Sanitation Preventive Control

NOTE: Facilities regulated under Seafood HACCP are not required to identify sanitation controls as Critical Control Points (CCPs) in their HACCP plans. Instead, these controls can be addressed through pre-requisite programs, such as Sanitation Control Procedures (SCPs).

In contrast, facilities regulated under the Preventive Controls for Human Foods (PCHF) rule must include any sanitation preventive controls necessary to prevent hazards directly in their written food safety plan.

Purpose (Sanitation Preventive Control)

- Clearly define the purpose of each sanitation control and specify the equipment or area of the facility to which it applies. **For example:** "*To ensure the processing table is thoroughly cleaned to prevent cross-contamination with environmental pathogens or those present on other foods or raw ingredients*"

Frequency of cleaning

- Daily, before production and any time you transition between products or when sanitation is warranted.

Who will Implement the Sanitation Control

- Sanitation personnel or any other trained individual designated to carry out the sanitation control procedures.

Procedure

- Outline the sanitation procedures for the specific equipment or area of the facility to be cleaned, following the applicable written Sanitation Standard Operating Procedure (SSOP).

Monitoring – What, How, How Often, Who

- What will be monitored?
  - Adequacy of sanitation practices on relevant equipment and food contact surfaces used at a given processing step. Reference to SSOP.
- How will monitoring be done?
  - Visual observation of equipment cleanliness **AND/OR** ATP swabs (to assess for presence of organic matter indicative of potential microbial contamination).
- How often will monitoring be done (frequency)?
  - After sanitation is completed and before production begins.
- Who will do the monitoring?
  - An individual with an understanding of the control and trained to carry out the required monitoring procedures.

Corrections

- If inadequate sanitation is observed **OR** testing indicates that biological materials are present, then stop production, if applicable, and re-clean all food contact surfaces before retesting or assessing cleanliness.

AND address the root cause to prevent future occurrence.

- Retrain staff to address issues in sanitation practices and revise SSOPs as needed to address the root cause and prevent recurrence of sanitation deficiencies.

Verification

- Review of monitoring and correction records within one week of preparation to ensure they were completed appropriately.

AND

- Written sanitation procedures or SSOPs should be evaluated to ensure they are effective to prevent cross-contamination before implementation.
    - For high risk and hard to clean equipment or areas of a facility, validation of cleaning procedures can be conducted to ensure pathogens are effectively controlled. For more information on cleaning process validation, review the USFDA's *Guide to Inspections Validation of Cleaning Procedures*.

OR

- Environmental testing for pathogens of concern to assess the effectiveness of the cleaning procedures. Refer to the Food Safety Preventive Controls Alliance PCHF training for more information on environmental monitoring.
    - More information on environmental monitoring can be found in FDA's 2017 Control of Listeria monocytogenes in Ready-To-Eat Foods: guidance for Industry *Draft Guidance* (PDF) or the National Fisheries Institute's *Ready-To-Eat Seafood Pathogen Control Guidance Manual (Listeria monocytogenes and Salmonella species)* (PDF).

Records

- **Monitoring Records:** Maintain a sanitation log that records when each sanitation step was performed and who performed it. It is considered good practice to also reference the specific SSOP used for the task.
    - Written SSOPs are required for foods regulated under the Preventive Controls for Human Foods (PCHF) rule.
- **Correction Records:** Document any corrections made to address conditions or practices that required attention, including a description of the issue, the action taken, and the date and person responsible for the correction.
- **Verification Records:** Include record reviews, cleaning procedure validations, or ATP testing results, and environmental monitoring results, as applicable.
- **Recall Plan:** A written recall plan is required for any product with significant hazards when regulated under Preventive Controls for Human Foods (PCHF).
- **Training Records:** Training records for the preventive controls qualified individual (PCQI) must be maintained if regulated under Preventive Controls for Human Foods (PCHF).

Example Food Safety Plan for Sanitation Preventive Control

Below is an example showing what a food safety plan could look like. It is intended for illustrative purposes only. Each producer must develop a plan tailored to their unique products, production and processing methods, and regulatory requirements. **This example should not be copied and used without modification to fit your specific operation.**

Control Strategy: Sanitation Preventive Control

Purpose (Sanitation Preventive Control): To prevent cross-contamination of seaweed granola bars after cooking and prior to packaging. This sanitation control applies specifically to the processing table used in pre-packaging operations.

Frequency of Cleaning: Daily, before production begins and at any time there is a transition between products or batches.

Responsible Personnel: Sanitation personnel or any other trained individual designated to carry out sanitation control procedures.

Procedure: Sanitation will follow the established Sanitation Standard Operating Procedure (SSOP) for the packaging table and associated equipment, which includes: 1) Removal of visible debris; 2) Rinsing with potable water; 3) Application of an approved cleaning agent ensuring full surface contact and adequate exposure time; 4) Rinse and sanitize with food-safe sanitizer following manufacturer instructions; and 5) Allow surfaces to air dry.

This example is continued on the next page.

Example HACCP/Food Safety Plan for Sanitation Preventive Control (continued)

Criterion	Monitoring				Corrective Action	Verification	Records
	What	How	When	Who			
The table used for packaging seaweed granola bars is cleaned and sanitized before use. Personnel practice good hygiene and wear gloves when handling cooked bars.	Cleanliness of packing table. Personnel are wearing gloves when packaging cooked bars.	Visually	Prior to packaging **AND** Between production changes.	QA Staff	If table(s) are visibly unclean, then all surfaces will be re-cleaned in accordance with appropriate SSOP If personnel are not wearing gloves, then cooked bars handled since the last acceptable check will be discarded **OR** recooked. **AND** Personnel will be retrained to prevent future violations.	Annual review of SSOP efficacy to ensure effective cleaning. Weekly review of sanitation monitoring records.	Sanitation monitoring records including checks of table cleanliness and personnel glove use. Correction/ Corrective Action records, if necessary Verification records - Environmental monitoring plan and results on monitoring PCQI training records (PCHF only)

Table 11-4: *Process-related hazards based on type of processing applied and storage conditions. Under the Details column, "**ROP**" stands for reduced oxygen packaging, "**MAP**" stands for modified atmosphere packaging, and "**NA**" stands for not applicable. Cells with "**X**" indicate a potential hazard, and cells with a blank box (☐) indicate that there is no evidence to date that associates this pathogen with this process.*

Process Applied	Details	Storage	*Bacillus cereus*	*Clostridium botulinum*	*Clostridium perfringens*	Pathogenic *E. coli*	*Salmonella*	*Listeria monocytogenes*	*Staphylococcus aureus*	*Vibrio* species	Viruses
None (whole / shredded	Oxygen Not Excluded	Refrigerated	X	☐	X	X	☐	X	☐	X	X
None (whole / shredded)	ROP, Vacuum, or MAP	Refrigerated	X	X	X	X	☐	X	☐	X	X
None (whole / shredded)	*NA*	Frozen	☐	☐	☐	☐	☐	X	☐	☐	X
Heat Treated	Oxygen Not Excluded	Refrigerated	X	X	X	X	X	X	☐	☐	☐
Heat Treated	ROP, Vacuum, or MAP	Refrigerated	X	X	X	☐	☐	☐	☐	☐	☐
Heat Treated	*NA*	Frozen	☐	☐	☐	☐	☐	X	☐	☐	☐
Salted	*NA*	Ambient	☐	☐	☐	X	X	X	X	☐	☐
Salted	*NA*	Refrigerated	☐	☐	☐	X	X	X	X	☐	☐
Dried / Dehydrated	Oxygen Not Excluded	Ambient	X	☐	☐	☐	X	X	☐	☐	☐
Dried / Dehydrated	ROP, Vacuum, or MAP	Ambient	X	X	X	☐	X	X	☐	☐	☐
Fermented	pH ≤ 4.5	Ambient	☐	☐	☐	X	X	X	☐	☐	☐
Fermented	*NA*	Refrigerated	☐	☐	☐	X	X	X	☐	☐	☐

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Chapter 12 Clostridium botulinum Toxin

General Background: Understanding the Potential Hazard

Although there are no documented cases of botulism linked to seaweed consumption, processors who use oxygen-free (anaerobic) packaging should evaluate the risk of Clostridium botulinum growth and neurotoxin production during their hazard analysis. If the risk is determined to be significant—either "reasonably likely to occur" (HACCP) or "hazard requiring a preventive control" (PCHF)—appropriate controls should be implemented to destroy or inhibit growth, as described in Chapter 13 of the FDA's *Fish and Fishery Products Hazards and Controls Guide* (USFDA, 2022). In addition, appropriate sanitation controls should be applied to reduce the potential for contamination, as outlined in Chapter 11 of this guide.

Botulism Food Poisoning

Botulism is a foodborne illness caused by ingesting the botulinum neurotoxin. In the U.S. approximately ten outbreaks of foodborne botulism occur annually, from a variety of food sources, including seafood products (Iwamoto et al., 2010; Roy et al., 2024). Symptoms of botulism appear 18–36 hours after consumption of contaminated food and include weakness, vertigo, double vision, difficulty speaking, swallowing and breathing, abdominal swelling, constipation, and paralysis (CDC, 2021). Even a few micrograms of the neurotoxin can cause illness in a healthy adult, and infants are especially vulnerable (CDC, 2021). Without antitoxin treatment and respiratory support, botulism can be fatal.

Clostridium botulinum

Clostridium botulinum is the bacterium that produces botulinum neurotoxin. This bacterium grows in environments without oxygen (strictly anaerobic conditions) and can form highly resistant endospores. These endospores can survive many heat-based control methods, including blanching and pasteurization.

No studies to date have successfully detected *Clostridium botulinum* in raw seaweeds (see Chapter 5); however, few studies have directly tested raw seaweed for this bacterium. *Clostridium botulinum* has been found in marine sediments and seawater, indicating it could be a potential biological hazard associated with the harvest area (Venkateswaran et al., 1989; Dodds, 2018). For raw seaweed products packaged in reduced oxygen environments (e.g., vacuum packaging) without additional processing and/or strict temperature controls to prevent spore germination and bacterial growth, botulinum neurotoxin formation should be considered a potential hazard.

Clostridium botulinum can also enter products during processing, and if the product is later exposed to improper temperature control, the bacteria may grow and produce neurotoxin under anaerobic conditions. Although no studies in the U.S. have documented *Clostridium botulinum* on processed seaweed, botulinum neurotoxin formation should also be considered a potential hazard for processed seaweed products when oxygen-free conditions occur. Various control measures used in seafood products as presented in Chapter 13 of the FDA's *Fish and Fishery Products Hazards and Controls Guide* (USFDA, 2022) can be used as guidelines for controlling Clostridium botulinum in seaweed food products.

Controlling Botulinum Neurotoxin Production

Vacuum-sealing, modified atmosphere packaging, and packing in hermetically-sealed containers (e.g., double-seamed cans, glass jars with sealed lids, and heat-sealed plastic containers) are all control measures that reduce or halt the growth of many aerobic bacteria and fungi by limiting the amount of oxygen available to support their growth (see Chapter 11). However, these processes also create anaerobic conditions that favor *Clostridium botulinum* spore germination and cell growth unless retort processing—a method of preserving food in sealed containers by heating it to high temperatures under pressure to destroy bacteria, including heat-resistant spores—has been used to inactivate both *Clostridium botulinum* cells and endospores.

Thermal Processing

High temperature treatments kill many bacterial pathogens that may be associated with seaweed products. While temperatures above 113°F (45°C) are necessary to prevent the growth of both proteolytic (strains that can break down proteins and typically grow at warmer temperatures) and non-proteolytic (strains that do not break down proteins and can grow at colder temperatures) *Clostridium botulinum*, significantly higher temperatures—such as those achieved through retort processing in cans or jars—are required to inactivate endospores. Specific processing times and temperatures for endospore inactivation are provided in Appendix 4 Table A-4 of the FDA's *Fish and Fishery Products Hazards and Controls Guide* (USFDA, 2022).

Refrigeration and Freezing

Temperatures below 38°F (3.3°C) prevents or significantly slows the growth of many foodborne bacteria, including Clostridium botulinum. In reduced oxygen environments, temperatures below 38°F inhibit germination of *Clostridium botulinum* endospores (USFDA, 2022). Freezing at 0°F (-18°C) or lower offers an additional layer of safety (Huss, 2004).

Reducing Water Activity (a_W)

This is accomplished by adding salt and humectants (e.g., sugar or other water-binding ingredients) or by drying the product to inhibit bacterial growth (see Chapter 11). A minimum of 10% water-phase salt (WPS)—the amount of salt when compared to the moisture in the seafood—corresponds to a water activity (a_w) of 0.95 and prevents growth of proteolytic *Clostridium botulinum* strains. A lower level of 5% WPS (a_w = 0.97) is sufficient to control non-proteolytic strains (Sperber, 1983).

Reducing pH

Natural acids such as vinegar and lemon juice are commonly used in seafood preservation to inhibit bacterial growth (Huss, 2004). Seafood products with a pH less than 4.6 inhibits growth and neurotoxin production by *Clostridium botulinum* (Peck, 2014).

Oxygen-Permeable Packaging

These packaging materials allow oxygen to pass through, reducing the risk of *Clostridium botulinum* neurotoxin formation. According to FDA guidelines for raw fishery products, packaging with an oxygen transmission rate of at least 10,000 cc $O_2/m^2/24$ hours at 75.2°F (24°C) is considered oxygen-permeable (USFDA, 2022).

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Chapter 13 Pathogen Survival Through Cooking or Pasteurization

The potential microbial pathogens associated with seaweed, and their characteristics, are discussed in detail in Chapters 5, 6, 10, 11 and 12 and will not be repeated here. Instead, this chapter focuses on heat-based processes—such as cooking, pasteurization, and commercial sterilization—used to control vegetative bacterial pathogens in seaweed products.

Blanching, Pasteurization, and Commercial Sterilization

Blanching

Blanching is a short heat treatment (e.g., hot water immersion or steam) typically used for quality purposes, such as extending shelf life by reducing spoilage organisms; enzyme inactivation; and color stabilization. The term is less precisely defined than other processes like pasteurization, and typically not designed to eliminate pathogens.

Pasteurization

Pasteurization is a heat treatment designed to target the most heat-resistant pathogens of public health concern that are associated with a specific food product.

Commercial Sterilization

Commercial sterilization is more commonly called retorting. It is a more intense process that drastically reduces the population of all viable microbes—beyond the reductions affected by pasteurization—making food shelf-stable. Retorting parameters depend heavily on the acidity of the food because of the anaerobic conditions created in hermetically sealed (airtight) packaging used in the process. Low-acid canned foods are at higher risk for *Clostridium botulinum* spore germination and subsequent toxin production, and require significantly more stringent processing, such as retorting, as outlined in 21 CFR Part 113 (see Chapter 11 for more detail).

Identifying the Appropriate Target Pathogen for Seaweed(s)

The determination of the appropriate target pathogen for seaweed products depends on several factors, including:

- Water quality of the harvest site (see Chapter 5)
- Handling and processing facility conditions
- Specific processing steps subsequently applied to the seaweed

- Intended shelf life and storage conditions of the final product
- Intended consumer preparation practices

There are several variables affecting the efficacy of pasteurization processes for which adequate species-specific information for seaweeds is not currently available. Reliable information regarding pathogen loads on harvested seaweeds are also not widely available. Due to these data gaps, the FDA recommends a target of six orders of magnitude reduction of pathogens for consumer safety (USFDA, 2024). However, suggested time/temperature treatment combinations specific to pathogens on seaweeds have not been established. When the specific pathogen is not known, food safety measures can focus on Listeria monocytogenes in air packed products, and Clostridium botulinum for vacuum-sealed or reduced oxygen packaged foods. General guidelines for inactivation of *Listeria monocytogenes* and *Clostridium botulinum* can be found in the FDA's *Fish and Fishery Products Hazards and Controls Guide*, Appendix 4 (USFDA, 2022).

Heat Resistance and D-values

The heat resistance of an organism is usually expressed as D-values (decimal reduction). This is the time (in minutes) required to inactivate 90%, (1-log) of a bacterial population at a specific temperature, in a specific food (USFDA, 2024). Higher temperatures result in lower D-values because bacteria are killed more quickly. Certain types of bacteria are inherently more heat resistant than others. For example:

- *Bacillus cereus* spores range in thermal resistance but researchers determined that the D_{90} values—the time it takes to inactivate 90% of spores at 194°F (90°C)—range from 1 to 52 minutes (Jovanovic et al., 2021).
- Vegetative pathogens such as *Salmonella* and *E. coli* O157 are not considered to be heat resistant. Their D_{145}—the time it takes to inactivate 90% of spores at 145°F (62.7°C)—values are under one minute in ground beef, a system in which protein and fat should protect cells from heat (Goodfellow & Brown, 1978; Line et al., 1991).
- *Listeria monocytogenes* is more heat resistant than *Salmonella* or *E. coli* and is often recommended as the target pathogen for pasteurization because of its persistence in processing environments (see Chapter 11).

Pasteurization in Seaweed Processing

Pasteurization processes must be properly validated for each product form using inoculation studies, (see ICMSF, 2011). Once validated, processing must be consistently monitored to ensure the critical limits determined through the inoculation studies are met. Guidance on developing and applying heat treatment as a process control is available in the FDA's *Draft*

Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food, Chapter 6 (USFDA, 2024).

In seaweed processing, pasteurization may be applied:

- **Before further processing** (e.g., prior to drying), which can also reduce drying time (Del Rosario & Mateo, 2019).
- **As a final processing step** for products sold under refrigeration.

In instances where pasteurization is not the final processing step applied; it is of particular importance to prevent subsequent re-contamination of the product (see Chapter 11).

Proper and prompt cooling of heat-treated products is essential to prevent pathogen growth and toxin formation. Some pathogens, such as *Clostridium perfringens*, can produce spores that survive heat treatments designed to kill active (vegetative) cells. If cooling takes too long, these spores may germinate and multiply. At 110°F (43.3°C), *Clostridium perfringens* populations can double in number in less than ten minutes (Todd, 2014). Similar risks occur if finishing ingredients, such as seasonings, are added after heat treatments, since they may introduce pathogens or other contaminants.

Determining if the Hazard is Significant

It is reasonably likely that raw seaweed may carry one or more pathogens of public health concern at the time of harvest (see Chapter 5). Additional pathogens may also be introduced during postharvest handling and processing steps (see Chapter 11). Although adherence to prerequisite programs helps reduce overall risk, the use of heat treatments introduces a significant hazard—either "reasonably likely to occur" (HACCP) or "hazard requiring a preventive control" (PCHF)—that requires a validated control measure to ensure the thermal process is effectively executed to achieve the intended microbial reduction.

Hazard Controls and Critical Control Points

Table 13-1*: Control Strategies for Clostridium botulinum toxin*

Control Strategy	Primary Processor	Secondary Processor
Processing Control	✓	✓

Control Strategy – Processing Control

Critical Limit(s)/Parameter(s) and Value(s)

- Critical limits for pasteurization or cooking (time and temperature) should be established based on a replicated validation study. Although target time and temperature (to be applied to the particular product being pasteurized or cooked) are consistent based on product and pathogen combination, the specifics of the process applied will depend on:
    - The initial temperature of the product
    - The size and shape of the product package
    - The temperature of the heating medium (e.g., water or steam)

Monitoring – What, How, How Often, Who

- What will be monitored?
    - Particular variables to be monitored will depend on the outcome of the validation study, but may include (for example):
        - Visual observation of boiling and time held at boiling
        - Temperature of oven (at coldest point) and time at temperature for thermal treatment
- How will monitoring be done?
    - Depending on the process, monitoring procedures could include:
        - Temperature, ideally a continuous recording thermometer, installed at experimentally determined cold spot (for ovens)
        - Visual observation of boiling and time held at boiling
- How often will monitoring be done (frequency)?
    - Every batch or continuously during processing of every batch
- Who will do the monitoring?
    - An individual with an understanding and knowledge of the controls and monitoring procedures.

Corrective Action/Corrections

- If treatment time is not achieved, then wait until the required processing time is met.
- If target temperature is not achieved, then reprocess the affected product **OR** divert to non-food use **OR** dispose of the product.

AND address the root cause to prevent future occurrence.

- Address the root cause of the process failure to future deviations from the critical limit(s) (e.g., inadequately trained staff, equipment malfunction, thermometer calibration, etc.).

Verification

- Validation study to demonstrate process effectiveness for pathogen reduction.
- Periodic random testing of finished products for indicator organism or pathogen (like *Listeria monocytogenes*) presence by an accredited third-party laboratory.
- Review or monitoring and corrective action records within one week of preparation to ensure they were completed appropriately.
- Others, dependent on specific processes applied and parameters determined through the validation study.
- Accuracy and calibration checks of measuring devices used.

Records

- **Monitoring Records:** Including temperature logs indicating processing time and temperature.
- **Corrective Action Records:** Any records indicating what was done to address potential deviations from parameters, values, or critical limits.
- **Verification Records:** Including a validation study on file, accuracy and calibration checks of temperature measuring/recording and other measuring devices used, and results of any product testing on file.
- **Recall Plan:** A written recall plan is required for any products with significant hazards if regulated under preventive controls for human foods.
- **Training Records:** Training records for the preventive controls qualified individual (PCQI) must be maintained if regulated under preventive controls for human foods. While the

HACCP rule requires a HACCP trained individual, records of that training are not explicitly required (federally, may vary by state).

Example HACCP/Food Safety Plan for Processing Control

Below is an example showing what a food safety plan could look like. It is intended for illustrative purposes only. Each producer must develop a plan tailored to their unique products, production and processing methods, and regulatory requirements**. This example should not be copied and used without modification to fit your specific operation.**

NOTE: The time and temperature profiles listed here are fictional, specific critical limits should be identified through the process validation study.

Control Strategy: Processing Control
Critical Control Point/Process Preventive Control: Steam Pasteurization
Hazard: Pathogen Survival Through Cooking or Pasteurization

Parameters, Values, Critical Limits	Monitoring				Corrective Action	Verification	Records
	What	How	When	Who			
Steam Temperature ≥212°F (100°C) Exposure time of 4 minutes	Temperature Time	Continuous temperature recording device Timer	Every Batch	Manufacturing Associate	If the system fails to reach and maintain ≥212°F, then, reprocess product **OR** dispose of product **AND** Address the root cause of the process failure to prevent future occurrence. If the 4-minute exposure time is not reached, then, hold product till exposure time is reached **OR** dispose of product **AND** Address the root cause of the process failure to prevent future occurrence (e.g. retrain staff).	Validation study reviewed at least annually or as needed and reevaluated as needed Weekly review of monitoring and corrective action records Annual external laboratory pathogen testing of product Temperature recording device accuracy checks daily before use and calibration as needed and at least once a year	Batch log including treatment time and temperature Corrective action records, as necessary Lab analysis reports Validated study on file PCQI training records (PCHF only)

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Chapter 14 Allergens and Food Intolerance Substances

General Background: Understanding the Potential Hazard

In the United States, nine specific foods account for over 90% of serious allergic reactions and are classified as major food allergens. Food producers selling products in the U.S. must properly manage these allergens to help prevent severe allergic reactions in consumers.

The U.S. Food and Drug Administration (FDA) is responsible for enforcing food allergen regulations, including the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), which originally identified eight major food allergens. In January 2023, the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act added sesame as the ninth major allergen.

The nine major food allergens in the United States are:

Milk | Eggs | Fish | Crustacean Shellfish |Peanuts | Tree Nuts |Wheat | Soybeans | Sesame

Seaweeds themselves are not recognized as major food allergens in the U.S., but some individuals may still have allergic reactions to them (Afsan & Mather, 2023). A greater concern is that seaweeds are often harvested from coastal waters where small crustaceans—such as shrimp-like amphipods—commonly inhabit and attach to them (Banach et al., 2024; Duffy, 1990; Gutow et al., 2020).

Research by Motoyama et al. (2007) and Bito et al. (2017) found that amphipods and amphipod tropomyosin—the allergenic protein in crustacean shellfish—can be present on red seaweed such as nori. This can potentially trigger allergic reactions in sensitive individuals. Crustacean allergens have also been detected on *Saccharina latissima* grown in integrated multitrophic aquaculture (IMTA) systems, where crustaceans are occasionally observed during handling or intentionally included as part of the system (Mildenberger et al., 2022).

Tropomyosin has also been detected in blanched and fermented sugar kelp harvested in Norway (Banach et al., 2024). Although the detected levels of allergens were likely below thresholds that typically cause allergic reactions, further research is needed to assess seasonal, geographic, and product-based variability (Mildenberger et al., 2022).

Current literature indicates that small crustacean species are common in seaweeds harvested from marine environments. As a result, tropomyosin—a known allergen in crustacean shellfish—may be present and could trigger allergic reactions in sensitive individuals. Since crustaceans are a major food allergen that must be declared on food labels under U.S.

regulations, producers may be responsible for including shellfish allergen labeling on seaweed products likely to contain these residues.

Producers should carefully assess the likelihood of crustacean allergen presence in their products and determine whether allergen labeling is necessary. Advisory statements such as "*May contain shellfish*" can help alert highly allergic consumers, but they must not replace proper Good Manufacturing Practices (GMPs), including sanitation protocols and allergen control plans aimed at minimizing allergen risks.

Certain consumers may also experience hypersensitivity or intolerance to specific food substances and color additives, such as sulfiting agents and FD&C Yellow No. 5. These additives can trigger adverse, allergy-like responses upon ingestion, making accurate labeling essential to protect sensitive individuals.

Sulfites have been detected in various commercially available microalgae species worldwide, raising public health concerns (Ashworth, 2021). If introduced during production of seaweed-based products, they must be properly declared on the label to inform consumers of potential intolerance-inducing substances.

All advisory labeling must be truthful, not misleading, and used in accordance with applicable FDA guidance and regulations (21 U.S.C. 343(i)). For more information on food intolerance substances, refer to Chapter 19 of the FDA's *Fish and Fishery Products Hazards and Controls Guide* (USFDA, 2019).

Controls

Food allergen labeling is mandatory for major allergens and enforced by federal and state regulatory agencies to help reduce the risk of severe allergic reactions. When allergens or intolerance substances are present in foods, facilities must prevent consumers from unknowingly being exposed by:

- **Labeling products** properly with market names of all allergenic ingredients and intolerance substances on consumer-packaged foods
- **Implementing allergen** control measures to prevent cross-contact

Allergen cross-contact occurs when an allergen from one food comes into contact with another food, resulting in unintended allergen presence. For example, processing finfish and crustacean shellfish on the same bench without proper cleaning between products can transfer allergenic proteins between products.

Facilities operating under Seafood HACCP (21 CFR 123) can address cross-contact risks through pre-requisite programs such as sanitation control procedures (SCP) or allergen control plans. These controls do not have to be part of the HACCP plan itself.

In contrast, facilities regulated under Preventive Controls for Human Foods (PCHF) (21 CFR Part 117 Subpart C) must include appropriate allergen and sanitation preventive controls directly in their written food safety plan.

As with allergens, the most effective way to control food intolerance substances in products is through clear, accurate labeling, allowing consumers to avoid products that may cause adverse reactions.

Determining if the Hazard is Significant

If a major food allergen or intolerance substance is present, it is considered a significant hazard—either "reasonably likely to occur" (HACCP) or "a hazard requiring a preventive control" (PCHF)—and must be controlled at some point in the production process. While seaweeds are not major food allergens, facilities should closely monitor products for signs of crustacean contamination and take steps to reduce their presence.

If crustaceans are consistently found—especially if in high numbers—appropriate controls should be included in either the HACCP plan or the PCHF food safety plan to ensure the hazard is effectively managed.

Hazard Controls and Critical Control Points

To properly manage major food allergens and intolerance substances:

- Label products accurately with the correct market or common name of the allergen or food intolerance substance.
- Identify the labeling step as a critical control point or preventive control for allergens and food intolerance substances.
- Apply sanitation controls where cross-contact risk is high, especially when multiple allergens are present in a facility. Sanitation controls should be applied to any step where there is a high risk of cross-contact occurring.

Producers who routinely observe low levels of crustaceans on seaweed products may consider using advisory statements such as "*May contain shellfish*" to inform and protect highly sensitive individuals. These individuals could experience allergic reactions, even from trace amounts of allergenic proteins. However, these statements must not replace crustacean removal or reduction measures—such as rinsing or manual removal.

Allergens can be controlled either through a specific CCP in a food safety plan, or through a separate Allergen Control Plan.

Table 14-1: *Control Strategies for Allergens and Food Intolerance Substances*

Control Strategy	Primary Processor	Secondary Processor
Receiving Control	✓	✓
Labeling Control	✓	✓
Sanitation Preventive Control*	✓	✓

* Sanitation controls are not required as Critical Control Points (CCPs) in seafood HACCP plans but can be included or managed through pre-requisite programs (see Chapter 3).

NOTE: Under PCHF regulations, food safety plans must include food allergen preventive controls and/or sanitation preventive controls necessary to prevent allergen hazards.

Control Strategy 1 – Receiving Control for Pre-Printed Labels

This control strategy can be incorporated into a HACCP Plan or Food Safety Plan (under Preventive Controls for Human Foods) and implemented at the receiving step for pre-printed labels. **However, this control alone is not sufficient to manage allergens and food intolerance substances.** This would be considered a label content control that ensures the information on the label received is accurate. A second Critical Control Point (CCP) or label management control is needed at the labeling step to ensure that the correct labels are applied to the appropriate product(s) before they leave the facility.

Critical Limit(s)/Criterion

Check a representative sample of incoming pre-printed labels, boxes, or bags to verify that all required allergens and food intolerance substances are properly declared.

Monitoring – What, How, How Often, Who

- What will be monitored?
    - The presence of the market or common name of any allergen or food intolerance substance on incoming pre-printed labels, boxes, or bags.
- How will monitoring be done?

    - Through visual inspection of a representative sample of the pre-printed labels or packaging materials.
- How often will monitoring be done (frequency)?
    - Upon receipt of each shipment of labels, boxes, or bags.
- Who will do the monitoring?
    - An individual with an understanding of the control and trained to carry out the required monitoring procedures.

Corrective Action/Corrections

- If labels or packaging received are missing allergen market or common name or food intolerance substance declaration, then reject the shipment and return to the supplier **OR** discard.

AND address the root cause to prevent future occurrence.

- Discontinue use of supplier(s) until the root cause of the labeling error is identified and corrected to prevent recurrence.

Verification

- Review of monitoring and corrective action records within one week of preparation to ensure they were completed appropriately.
- Annual product specifications assessment to ensure all ingredients are accurately listed, all allergens and food intolerance substances are properly declared, and no changes have occurred that would affect labeling requirements.

Records

- **Monitoring Records:** Labeling log indicating visual inspection was conducted, the date it was conducted, the result of the inspection, and who completed the inspection. Include space for weekly reviews and initials.
- **Corrective Action Records:** When corrective actions are taken, document the issue, the steps implemented to ensure product safety, and the measures put in place to prevent recurrence.
- **Verification Records:** Record of annual product specifications verification. Monitoring records indicating review within one week.

- **Recall Plan:** A written recall plan is required for any product with significant hazards when regulated under Preventive Controls for Human Foods (PCHF).
- **Training Records:** Training records for the preventive controls qualified individual (PCQI) must be maintained if regulated under preventive controls for human foods. While the Seafood HACCP regulation requires a HACCP trained individual to conduct certain activities, training records are not explicitly mandated under the regulation.

Example HACCP/Food Safety Plan for Receiving Control

Below is an example showing what a food safety plan could look like. It is intended for illustrative purposes only. Each producer must develop a plan tailored to their unique products, production and processing methods, and regulatory requirements. **This example should not be copied and used without modification to fit your specific operation.**

Control Strategy: Receiving Control
Critical Control Point (HACCP) / Allergen Preventive Control (PCHF): Receiving Step
Hazard: Allergens

Parameters, Values, Critical Limits	Monitoring				Corrective Action	Verification	Records
	What	How	When	Who			
Shellfish allergen declared on the pre-printed food packages received.	Presence of crustacean shellfish allergen on pre-printed package	Visually	At Receipt	QA Staff	If shellfish are not declared on the label, then, reject the shipment and return to supplier **AND** Discontinue use of supplier until the root cause of the labeling error is identified and corrected to prevent recurrence.	Weekly review of records Annual product specifications assessment to ensure all ingredients are accurately listed, all allergens and food intolerance substances are properly declared, and no changes have occurred that would affect labeling requirements.	Monitoring Records: Labeling log including results of package checks Corrective Action Records, as needed Verification Records: Annual product specifications verification PCQI training records (PCHF only)

Control Strategy 2 – Labeling Control

Proper labeling of products leaving a facility is the most effective measure for managing allergens and food intolerance substances. It is essential to inspect a representative sample of finished product labels to ensure that accurate labels are applied and that allergen and food intolerance warnings are clearly present.

Because labeling practices can vary significantly between facilities, producers should tailor their procedures to reflect the specific practices in place. The primary goal is to establish controls that minimize the risk of products leaving the facility without proper labeling of any allergens or food intolerance substances present.

Critical Limit(s)/Criterion

- A label that clearly declares all major food allergens and/or food intolerance substances present in the product must be affixed to the finished product packaging.

Monitoring – What, How, How Often, Who

- What will be monitored?
    - The presence of a label that clearly identifies the appropriate market or common name of any allergen(s) and/or food intolerance substances.
- How will monitoring be done?
    - Labels will be visually inspected to verify the correct identification of allergens and food intolerance substances.
- How often will monitoring be done (frequency)?
    - Label inspections will be performed at the start of label application and periodically throughout production. Checks should occur at least once every two hours during the labeling process.
- Who will do the monitoring?
    - A trained individual who understands the control measures and is qualified to perform the required monitoring procedures.

Corrective Action/Corrections

- If the label is missing or incorrect during inspection, then stop production to prevent further labeling errors **AND** check all packages since the last verified accurate check to ensure proper labeling **AND** relabel all affected products with the correct label.

AND address the root cause to prevent future occurrence.

- Identify the cause of the mislabeling and correct the issue to prevent re-occurrence.

Verification

- Review of monitoring and corrective action records within one week of preparation to ensure they were completed appropriately.
- Annual product specifications assessment to ensure all ingredients are accurate and allergens/food intolerance substances are appropriately listed on the labels.

Records

- **Monitoring Records:** Labeling log indicating visual inspection was conducted, the date and time it was conducted, the result of the inspection, and who completed the inspection. Include space for weekly review and initials.
- **Corrective Action Records:** When corrective actions are taken, document the issue, the steps implemented to ensure product safety, and the measures put in place to prevent recurrence.
- **Verification Records:** Record of annual product specifications verification. Monitoring records indicating review within one week.
- **Recall Plan:** A written recall plan is required for any product with significant hazards when regulated under Preventive Controls for Human Foods (PCHF).
- **Training Records:** Training records for the preventive controls qualified individual (PCQI) must be maintained if regulated under preventive controls for human foods. While the Seafood HACCP regulation requires a HACCP trained individual to conduct certain activities, training records are not explicitly mandated under the regulation.

Example HACCP/Food Safety Plan for Labeling Control

Below is an example showing what a food safety plan could look like. It is intended for illustrative purposes only. Each producer must develop a plan tailored to their unique products, production and processing methods, and regulatory requirements. **This example should not be copied and used without modification to fit your specific operation.**

Control Strategy: Labeling Control
Critical Control Point (HACCP) / Allergen Preventive Control (PCHF): Labeling Step
Hazard: Allergens

Parameters, Values, Critical Limits	Monitoring				Corrective Action	Verification	Records
	What	How	When	Who			
Finished product label contains: Shellfish	Presence of crustacean shellfish allergen listed on product label	Visual inspection of label	At the start of production and at least every two hours	Packing Manager	If the label is not present or is inaccurate, then stop labeling and recheck all products since the last correct check. Relabel all incorrectly labeled products. **AND** Determine the cause of the labeling error and make corrections to prevent future errors.	Weekly review of label monitoring records. Annual review of product specifications to verify accuracy of labels.	Monitoring Record: Label Log with results of visual inspections Corrective Action Records: When needed Verification Records: Annual product specifications assessment. PCQI training records (PCHF only)

Control Strategy 3 – Sanitation Control

NOTE: Facilities regulated under Seafood HACCP are not required to identify sanitation controls as Critical Control Points (CCPs) in their HACCP plans. Instead, these controls can be addressed through pre-requisite programs, such as Sanitation Control Procedures (SCPs).

In contrast, facilities regulated under the Preventive Controls for Human Foods (PCHF) rule must include any sanitation preventive controls necessary to prevent hazards directly in their written food safety plan.

Whether regulated under HACCP or PCHF, facilities should ensure that allergenic and non-allergenic ingredients—including different major food allergens—are processed with adequate separation by time or space to prevent cross-contact.

Sanitation controls should be implemented at any processing step—such as drying, milling, or fermenting—where there is a risk of allergen cross-contact and where proper sanitation can effectively prevent it. This is especially critical in facilities handling multiple major allergens or both allergenic and non-allergenic products, to protect consumers and ensure regulatory compliance.

Purpose (Sanitation Preventive Control)

- Clearly define the purpose of each sanitation control and specify the equipment or area of the facility to which it applies. **For example**: "*To ensure the processing table is thoroughly cleaned to prevent cross-contact between products that contain major food allergens and those that do not.*"

Frequency of Cleaning

- Daily, before production and any time you transition between different allergens, or between allergenic and non-allergenic ingredients.

Who Will Implement the Sanitation Control

- Sanitation personnel or any other trained individual designated to carry out the sanitation control procedures.

Procedure

- Outline the sanitation procedures for the specific equipment or area of the facility to be cleaned, following the applicable Sanitation Standard Operating Procedure (SSOP).

Monitoring – What, How, How Often, Who

- What will be monitored?
  - Cleanliness of surface or equipment.
- How will monitoring be done?
  - Visual observation of cleanliness **AND/OR** allergen testing (test strips).
- How often will monitoring be done (frequency)?
  - At least once daily, after sanitation is completed and before production begins.
- Who will do the monitoring?
  - A trained individual who understands the control measures and is qualified to perform the required monitoring procedures.

Corrections

- If inadequate sanitation is observed **OR** testing indicates that allergens are present, then stop production, if applicable, and re-clean all surfaces or equipment before retesting or assessing cleanliness.

AND address the root cause to prevent future occurrence.

- Retrain staff to address issues in sanitation practices and revise SSOPs as needed to address the root cause and prevent recurrence of sanitation deficiencies.

Verification

- Review of monitoring and correction records within one week of preparation to ensure they were completed appropriately.

AND

- Written sanitation procedures or SSOPs should be evaluated to ensure they are effective at removing potential allergens to effectively prevent cross-contact before implementation.
  - For high risk and hard to clean equipment or areas of a facility validation of cleaning procedures can be conducted to ensure allergens are effectively controlled through sanitation procedures. For more information on cleaning process validation, review the *FDA's Guide to Inspections Validation of Cleaning*

Procedures or Appendix 10: *Cleaning and Sanitation for the Control of Allergens* (PDF) in the FDA's *Fish and Fishery Products Hazards and Controls Guide*.

OR

- Allergen testing to periodically assess the effectiveness of the cleaning procedures.

Records

- **Monitoring Records:** Maintain a sanitation log that documents when each sanitation step is performed, who completed the task, and the results of the sanitation check. It is considered good practice to also reference the specific Sanitation Standard Operating Procedure (SSOP) used for each task.
- Written SSOPs are required for foods regulated under the Preventive Controls for Human Foods (PCHF) rule.
- **Correction Records:** Document any corrections made to address conditions or practices that required attention, including a description of the issue, the action taken, and the date and person responsible for the correction.
- **Verification Records:** Including record reviews, documentation of monitoring record review, cleaning procedure validations, or allergen testing results as applicable.
- **Recall Plan:** A written recall plan is required for any product with significant hazards when regulated under Preventive Controls for Human Foods (PCHF).
- **Training Records:** Training records for the preventive controls qualified individual (PCQI) must be maintained if regulated under preventive controls for human foods. While the Seafood HACCP regulation requires a HACCP trained individual to conduct certain activities, training records are not explicitly mandated under the regulation.

Example Food Safety Plan for Sanitation Preventive Control

Below is an example showing what a Sanitation Preventive Control could look like. It is intended for illustrative purposes only. Each producer must develop a plan tailored to their unique products, production and processing methods, and regulatory requirements. **This example should not be copied and used without modification to fit your specific operation.**

Control Strategy: Sanitation Preventive Control

Purpose: To ensure that the processing table and equipment is thoroughly cleaned to prevent cross-contact between products that contain major food allergens and those that do not. This sanitation control applies specifically to the processing table used in pre-packaging operations.

Frequency of Cleaning: Daily, before production begins and at any time there is a transition between different allergens or between allergenic and non-allergenic products

Responsible Personnel: Sanitation personnel or any other trained individual designated to carry out sanitation control procedures.

Procedure: Sanitation will follow the established written Sanitation Standard Operating Procedure (SSOP) for the processing table and associated equipment, which includes: 1) Removal of visible debris; 2) Rinsing with potable water; 3) Application of an approved cleaning agent ensuring full surface contact and adequate exposure time; 4) Rinse and sanitize with food-safe sanitizer following manufacturer instructions; and 5) Allow surfaces to air dry.

This example is continued on the next page.

Example Food Safety Plan for Sanitation Preventive Control (continued)

Criterion	Monitoring				Corrective Action	Verification	Records
	What	How	When	Who			
The bench, cutting board, and knives used for seaweed salad preparation are visibly clean and free of debris.	Cleanliness of surfaces	Visually	Prior to packaging **AND** Between production changes.	QA Staff	If surfaces are visibly unclean, then all surfaces will be re-cleaned in accordance with appropriate SSOP **AND** The root cause will be determined and corrected to prevent future violations.	Records of annual allergen testing to verify cleaning practices are effective. Weekly review of sanitation monitoring and correction records.	Sanitation monitoring records Correction records, if necessary Verification records - Annual allergen test results and record reviews PCQI training records (PCHF only)

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Chapter 15 Physical Hazards

General Background: Understanding the Potential Hazard

The FDA's Health Hazard Evaluation Board identifies physical fragments between 0.3 inches (7 mm) and 1 inch (25 mm) in length to be of most concern, warranting regulatory action for all consumable products including seaweed (USFDA, 2015a). Fragments smaller than 0.3 inches, though less visible, can also pose risks—especially to vulnerable consumers such as small children. Producers/processors should consider their target consumers when developing controls for physical fragments within their facility.

Physical hazards in seaweed products occur when foreign materials inadvertently enter the product during growing, harvesting, processing, packaging, or distribution. These materials can pose significant risks to consumer safety, including choking, digestive tract injuries, or dental damage. Common physical hazards identified in seaweed production include metal, glass, plastic, rope fibers, seeding twine, and other physical contaminants like stones or shells (FAO & WHO, 2022; Turner et al., 2021).

Metal

Sources

Metal fragments can pose significant safety risks and must be controlled when they are reasonably likely or foreseeable in a product (Codex Alimentarius, 2019; USFDA, 2015a). Metal can be unintentionally introduced into seaweed products through damaged equipment, cutting tools, or storage containers. Automated processing procedures, such as mechanical cutting for kelp stipes or noodle production, present particular risks. Small parts—e.g., screws, bolts, washers, and nuts—may fall into/find their way into seaweed products if processing machines are not properly maintained or inspected, or when these intact parts are misplaced during equipment maintenance and reassembly.

Controls

- **Prevention:** Metal contamination can be prevented by performing routine maintenance, inventory, and inspection of equipment and tools used for processing. This will help to prevent and address wear and tear. Training personnel to identify and report potential risks of metal contamination will also be crucial when relying on prevention alone (FAO & WHO, 2022).
- **Detection:** Detection is achieved through the use of metal detectors or X-ray systems designed to detect metal fragments in processed and packaged products.

- **Removal:** Removal of metal fragments from seaweeds largely applies to blended products that can be passed through a sieve to remove potentially hazardous metal fragments.

Glass

Sources

Whenever glass is used for packaging or storage in a facility, it should be considered a significant physical hazard. In general, glass should never be used or present in a food processing facility, unless used for final product packaging. Shatterproof glass or plastic covers should be considered when glass is needed for certain fixtures and equipment. Processors manufacturing sauces, spices, and fermented products that are typically packaged in glass containers should develop procedures to prevent breakage and glass fragment contamination.

Controls

Control of glass contamination within a facility requires procedures in place designed to prevent and detect potential contamination:

- Use shatterproof glass or protective covers on fixtures and equipment.
- Make it a routine practice to visually inspect glass containers, equipment, and light fixtures at receipt, before use, and regularly thereafter (Turner et al., 2021).
- Routinely inspect the facility for signs of broken glass that could indicate potential contamination of the food.
- Establish breakage protocols, including isolating affected products, inspecting for contamination, and through cleaning of affected areas.

Plastic

Sources

The use of plastic is common in most processing facilities and kitchens. When consumed, plastic fragments in foods can pose a similar risk of physical harm as glass and metal. Plastic fragments can enter products from damaged packaging materials, worn processing equipment, or debris in the seaweed harvest environment.

Controls

To prevent plastic fragments from entering foods:

- Ensure proper maintenance of packaging and processing equipment to prevent plastic breakage.

- Replace plastic equipment and parts when they begin to show signs of wear or brittleness.
- Primary processors should work with producers to minimize the risk of external plastic contamination during harvest.
- Conduct visual inspections and implement quality control checks for breakage of equipment and packaging materials during processing (Smith et al., 2022).

Other Physical Contaminants

Sources

Additional physical contaminants, such as stones, shells, or other debris, can enter seaweed during growing and harvesting. These contaminants are particularly relevant in wild-harvested seaweed operations (FAO & WHO, 2022). In farmed seaweed, seed string is the most commonly reported physical contaminant. This material can enter the crop when seaweed is cut too close to the holdfast during harvest. Although not lethal, seed string is considered a contaminant and is generally regarded as undesirable by consumers.

Controls

To prevent foreign materials from entering seaweeds at harvest or processing plant
s:

- Visually inspect and manually remove debris.
- Rinse or wash the product.
- Environmental assessments of harvest areas can help identify and mitigate sources of contamination. Primary processors should either conduct these assessments themselves or verify that producers have done so to ensure product safety.
- Primary processors can educate producers on the importance of maintaining harvesting equipment and implementing harvesting practices to help reduce this hazard (Codex Alimentarius, 2019).

Determining if the Hazard is Significant

Physical hazards, primarily metal, glass, and plastic, become significant—either "reasonably likely to occur" (HACCP) or "hazard requiring a preventive control" (PCHF)—when the likelihood of contamination is high or when the potential for injury is severe. Examples include, but are not limited to:

- Highly automated equipment used to process and package products increases the risk of **metal** or **plastic** shards from equipment breakage or general wear. This warrants proper controls in place to prevent this significant hazard.
- When **glass** jars are used as packaging material, glass should be considered a significant hazard, and controls should be implemented to prevent breakage and product contamination.
- Although **stones** and **shells** may be less common, they can still pose a significant hazard due to risk of injury (Turner et al., 2021). If a harvest area has a history of physical contamination, it should be considered a significant hazard warranting controls.

NOTE: It is also important to establish standard operating procedures (SOPs) regarding employee personal belongings—such as phones, jewelry, and earbuds—to prevent these items from falling into or contaminating food products.

Hazard Controls and Critical Control Points

Three primary strategies can be used to control physical hazards in food: metal detection, visual inspection, and processing controls. While metal detectors are effective, they can be costly and may not always be necessary. Where appropriate, visual inspection can serve as a practical control measure for detecting metal hazards.

Table 15-1: *Control Strategies for Physical Hazards*

Control Strategy	Primary Processor	Secondary Processor
Metal Detection*	✓	✓
Visual Inspection	✓	✓
Processing Control	✓	✓

*Applies to metal hazard only

Control Strategy 1 – Metal Detection

Critical Limit(s)/Parameter(s) and Value(s)

- All product passes through an operating metal detection device AND no metal is detected in product.

Monitoring – What, How, How Often, Who

- What will be monitored?

    - The presence of a metal detection device

  AND

    - The presence of metal fragments.

- How will monitoring be done?
    - Visual observation

  AND

    - Metal detector itself

- How often will monitoring be done (frequency)?
    - At the start of every production shift

  AND

    - Continuously by the metal detection device itself

- Who will do the monitoring?
    - The metal detection device and an individual with an understanding of the control and trained to carry out the required monitoring procedures.

Corrective Action/Corrections

- If a metal detection device is not operating or present upon inspection, then halt production (if applicable) **AND** hold all product produced since last acceptable check and rerun through the working metal detection device **OR** divert all product to a non-food use **OR** discard all product since last acceptable inspection.
- If metal is detected, then rework the product to remove metal fragments **OR** divert to non-food use **OR** discard product.

AND address the root cause to prevent future occurrence.

- Repair or replace metal detection device(s) **OR** investigate and resolve the source of contamination to prevent future occurrences.

Verification

- Review or monitoring and corrective action records within one week of preparation to ensure they were completed appropriately.

- Conduct a validation study to determine appropriate settings and sensitivity for the metal detection device and the product(s) being tested.
- Develop sensitivity standards for the metal detection device and test device against these standards daily before use and throughout production. See Chapter 20: Metal Inclusion of the FDA hazards guide for more details (USFDA, 2015a).
- Conduct a periodic review—at least annually—of consumer complaints to identify any evidence of physical hazards.

Records

- **Monitoring Records:** Including metal detection logs confirming visual inspection for the functioning device.
- **Corrective Action Records:** When corrective actions are taken, document the issue, the steps implemented to ensure product safety, and the measures put in place to prevent recurrence.
- **Verification Records:** Monitoring records indicating review within one week, records of metal detector sensitivity checks and consumer complaint report(s).
- **Recall Plan:** A written recall plan is required for any product with significant hazards when regulated under Preventive Controls for Human Foods (PCHF).
- **Training Records:** Training records for the preventive controls qualified individual (PCQI) must be maintained if regulated under preventive controls for human foods. While the Seafood HACCP regulation requires a HACCP trained individual to conduct certain activities, training records are not explicitly mandated under the regulation.

NOTE: X-ray detection systems can also be used to detect both metallic and non-metallic contaminants, such systems are referred to as "separation systems” (USFDA, 2022). For this chapter, we focused on metal detection systems, but the user is encouraged to consider other appropriate separation systems as they see fit for their operation.

Example HACCP/Food Safety Plan for Metal Detection

Below is an example showing what a food safety plan could look like. It is intended for illustrative purposes only. Each producer must develop a plan tailored to their unique products, production and processing methods, and regulatory requirements. **This example should not be copied and used without modification to fit your specific operation.**

Control Strategy: Metal Detection
Critical Control Point (HACCP) / Allergen Preventive Control (PCHF): Metal Detection
Hazard: Metal Fragments

This example is continued on the next page.

Parameters, Values, Critical Limits	Monitoring				Corrective Action	Verification	Records
	What	How	When	Who			
All product passes through an operating metal detection device **AND** no metal is detected in product	The presence of a metal detection device and the presence of metal fragments	Visual observation and the device itself	At start of production and continuously by the device	QA Staff and the device itself	If a metal detection device is not operating or present upon inspection, then, halt production (if applicable) **AND** Hold all product produced since last acceptable inspection to rerun through the working metal detection device **OR** divert all product to a non-food use **OR** discard all product since last acceptable inspection **AND** Fix or replace the metal detection device before restarting production. If metal is detected, then, isolate product produced since last acceptable inspection to evaluate for safety **OR** rework the product to remove metal fragments **OR** divert to non-food use **OR** discard product **AND** Investigate and resolve the source of contamination to prevent future occurrences **OR** repair or replace the metal detection device, if applicable.	Review of monitoring and corrective action records within one week. Conduct a validation study to determine settings for the metal detection device. Develop sensitivity standards and test the device at the start of production and at least every four hours during production and wherever changes occur in the process. Conduct a periodic review—at least annually—of consumer complaints to identify any evidence of physical hazards.	Monitoring Records including metal detection logs confirming the visual inspection for the metal detector and that it is functioning. Corrective Action Records, if needed Verification records including sensitivity testing, functionality of metal detection devices and consumer complaint report(s) PCQI training records (PCHF only)

Control Strategy 2 – Visual Inspection

Critical Limit(s)/Parameter(s) and Value(s)

- For metal or plastic, equipment is in good working order with limited wear and no visible damage or breakage.
- For glass, there are no visible signs of broken glass in, on, or around production lines and equipment.

Monitoring – What, How, How Often, Who

- What will be monitored?
    - The condition of processing and packaging equipment.
    - The presence of or evidence of broken glass.
- How will monitoring be done?
    - Visual inspection
- How often will monitoring be done (frequency)?
    - Before and after each production run and at least every four hours during production.
- Who will do the monitoring?
    - An individual with an understanding of the control and trained to carry out the required monitoring procedures.

Corrective Action/Corrections

- If visible signs of damage or missing pieces are observed during equipment inspection, then stop production (if applicable) inspect all product processed since the last acceptable check for missing components or contamination **OR** discard all product processed since the last acceptable check **OR** divert all product processed since the last acceptable check to non-food use.
- If visible damage or broken glass is observed during inspection, then stop production (if applicable) and check all product processed since last acceptable check for glass contamination **OR** discard product since last acceptable check **OR** divert all product produced since last acceptable check to non-food use **AND** thoroughly clean affected equipment and area to ensure all glass fragments are removed.

AND address the root cause to prevent future occurrence.

- Identify the source and cause of the breakage or contamination and implement corrective measures to prevent recurrence before resuming production **OR** repair or replace the defective equipment prior to restarting operations.

Verification

- Review of monitoring and corrective action records within one week of preparation to ensure they were completed appropriately.
- Conduct a periodic review—at least annually—of consumer complaints to identify any evidence of physical hazards.

Records

- **Monitoring Records:** Including inspection logs and maintenance logs, the date and time they were conducted, the result of the inspection, and who completed the inspection. Include space for weekly review and initials.
- **Corrective Action Records:** When corrective actions are taken, document the issue, the steps implemented to ensure product safety, and the measures put in place to prevent recurrence.
- **Verification Records:** Monitoring records indicating review within one week and periodic consumer complaint report(s).
- **Recall Plan:** A written recall plan is required for any product with significant hazards when regulated under Preventive Controls for Human Foods (PCHF).
- **Training Records:** Training records for the preventive controls qualified individual (PCQI) must be maintained if regulated under preventive controls for human foods. While the Seafood HACCP regulation requires a HACCP trained individual to conduct certain activities, training records are not explicitly mandated under the regulation.

Example HACCP/Food Safety Plan for Equipment Checks

Below is an example showing what a food safety plan could look like. It is intended for illustrative purposes only. Each producer must develop a plan tailored to their unique products, production and processing methods, and regulatory requirements. **This example should not be copied and used without modification to fit your specific operation.**

Control Strategy: Equipment Checks
Critical Control Point (HACCP) / Allergen Preventive Control (PCHF): Processing Line
Hazard: Physical Hazards (Metal and Plastic, Glass)

Parameters, Values, Critical Limits	Monitoring				Corrective Action	Verification	Records
	What	How	When	Who			
Equipment is in good working order with limited wear and no visible damage or breakage.	Condition of processing and packaging equipment.	Visual Inspection	Before and after each production run and at least every four hours during production.	Production Line Staff	If visible signs of damage or missing pieces are observed during equipment inspection, then stop production (if applicable) and inspect all product processed since the last acceptable check for missing components or contamination **OR** discard all product processed since the last acceptable check **OR** divert all product processed since the last acceptable check to non-food use. **AND** Identify the source and cause of the breakage or contamination and implement corrective measures to prevent recurrence before resuming production.	Weekly review of monitoring and corrective action records Conduct a periodic review—at least annually—of consumer complaints to identify any evidence of physical hazards.	Processing log indicating time and status of facilities and equipment during visual inspection Verification Records including equipment inspection log and consumer complaint report(s) PCQI training records (PCHF only)

Control Strategy 3 – Processing Control

Critical Limit(s)/Parameter(s) and Value(s)

- Product passes through a filter excluding all foreign material greater than 0.3 inches (7mm).

Monitoring – What, How, How Often, Who

- What will be monitored?
  - Functionality of the filtering device, including screen integrity or sieve clogging.
- How will monitoring be done?
  - Visual inspection of the product filtration process
- How often will monitoring be done (frequency)?
  - At the start of production, at least every two hours during production and at the end of production.
- Who will do the monitoring?
  - An individual with an understanding of the control and trained to carry out the required monitoring procedures.

Corrective Action/Corrections

- If any product fails to pass through the filtration system, or if the filter is found to be clogged or broken, then rework the product through a properly functioning filter **OR** discard the affected product **OR** divert the product to a non-food use.

AND address the root cause to prevent future occurrence.

- Retrain staff to ensure proper understanding and execution of filtration procedures **OR** correct the production line to ensure all product consistently passes through the filtration system **OR** repair or replace the filter to restore functionality and prevent future failures.

Verification

- Review of monitoring and corrective action records within one week of preparation to ensure they were completed appropriately.

- Regular inspection of filtration equipment for signs of wear and damage that may result in contamination of products.
- Conduct a periodic review—at least annually—of consumer complaints to identify any evidence of physical hazards.

Records

- **Monitoring Records:** Demonstrating that filtration is being observed and enforced and equipment is properly maintained.
- **Corrective Action Records:** When corrective actions are taken, document the issue, the steps implemented to ensure product safety, and the measures put in place to prevent reoccurrence.
- **Verification Records:** Monitoring records indicating review within one week and periodic consumer complaint report(s).
- **Recall Plan:** A written recall plan is required for any product with significant hazards when regulated under Preventive Controls for Human Foods (PCHF).
- **Training Records:** Training records for the preventive controls qualified individual (PCQI) must be maintained if regulated under preventive controls for human foods. While the Seafood HACCP regulation requires a HACCP trained individual to conduct certain activities, training records are not explicitly mandated under the regulation.

Example HACCP/Food Safety Plan for Processing Control

Below is an example showing what a food safety plan could look like. It is intended for illustrative purposes only. Each producer must develop a plan tailored to their unique products, production and processing methods, and regulatory requirements. **This example should not be copied and used without modification to fit your specific operation.**

Control Strategy: Processing Control
Critical Control Point (HACCP) / Allergen Preventive Control (PCHF): Filtration Step
Hazard: Physical Hazards (Metal and Plastic, Glass)

Parameters, Values, Critical Limits	Monitoring				Corrective Action	Verification	Records
	What	How	When	Who			
Product passes through a filter excluding all foreign material greater than 0.3 inches (7mm).	Filtration	Visual Inspection	At the start of production, at least every two hours during production, and at the end of production.	QA Manager	If any product does not pass through filtration, then, rework product through the filter **OR** discard product **AND** Identify and address the root cause of the deviation to prevent future occurrences.	Review of monitoring and corrective action records within one week. Regular inspection of filtration equipment for signs of wear and damage that may result in contamination of products. Conduct a periodic review—at least annually—of consumer complaints to identify any evidence of physical hazards.	Monitoring Records demonstrating that filtration is being observed and enforced. Corrective Action Records, if necessary Verification Records including filtration inspection log and consumer complaint report(s) PCQI training records (PCHF only)

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Chapter 16 Knowledge Gaps and Summary

Summary

Seaweeds—like all food products—have potential food safety hazards. To protect consumers, it is essential that producers understand these hazards and implement effective control measures. This guide is designed to help seaweed producers assess the safety risks associated with their products and develop appropriate food safety programs. State agencies may also use this guide as a reference when reviewing seaweed food safety practices. However, it is the responsibility of each producer to ensure that these guidelines are suitable for their specific operations and that their procedures comply with current local, state, and federal regulations.

This guidance was developed to support the continued growth of the seaweed industry and to help ensure ongoing access to this highly nutritious food in U.S. markets. But limited knowledge and understanding of many seaweed-specific food safety hazards hinders the creation of comprehensive, product-specific guidance. This chapter outlines the major knowledge gaps identified during the development of this guide.

Knowledge Gaps and Areas for Future Research

Pathogens

A clear knowledge gap is a thorough and detailed understanding of the pathogens that are associated with seaweed. Thus, the inherent risk is associated with consumption of raw seaweed and the effect a pathogen load has on downstream processes. The load may be pathogen-specific within a given harvest site and may change seasonally, yearly, and/or with changing water quality. Additionally, there may be species-specific interactions between seaweeds and various bacterial and viral pathogens, but there is a lack of scientific data to fully assess these interactions. Finally, for the *Vibrio* pathogens especially, documentation of how warming ocean conditions may impact pathogen attachment and survival on various seaweeds is imperative given the continued global increase in water temperatures and their prevalence in the marine environment.

A better and more nuanced understanding of the pathogen load attached to harvested seaweed will aid in understanding the short-term and long-term risks associated with the consumption of raw seaweeds, which can then be communicated to producers and consumers. Additionally, a better understanding of the pathogen load of harvested seaweeds will aid in validation studies meant to develop critical limits and procedures for safe drying, storage, transport, and processing. While proper drying can inhibit pathogen growth, the low temperatures typically used do not serve as a kill step. As a result, any high initial microbial loads present on the raw product may persist in the finished dried product.

To accurately understand the risk of harmful pathogens on raw seaweeds, the following types of studies would need to be conducted:

- **Large-scale Surveys:** These studies measure how many pathogens are naturally present on different seaweed species at the time of harvest. This helps establish the starting level (initial load) of contamination that might be expected.
- **Challenge Studies:** In these experiments, pathogens—sourced from the environment or past foodborne illness outbreaks—are deliberately added (or "inoculated") onto various seaweed species. The inoculated seaweed is then stored under different temperature and packaging conditions to observe whether the bacteria can grow.

While there have been several studies of this kind conducted in recent years, the available data is still limited. Factors such as the effect of different seasons, the maturity of the seaweed at harvest, and differences between species—have not been fully studied. In addition, most available data comes from just one species, *Saccharina latissima*. Given the large variety of seaweed species being grown and harvested, future research will need to focus on expanding studies to include other species that are important to farmers and producers.

Chemical Contaminants

Research on the uptake and accumulation of environmental chemical contaminants, including heavy metals, persistent organic pollutants (POPs), and per- and poly-fluoroalkyl substances (PFAS), across different seaweed species is limited. Bioaccumulation patterns vary among species due to differences in morphology, metabolism, and interactions with the environment, but a complete understanding of species-specific differences in contaminant uptake is still lacking. The issue of PFAS contamination in seaweed has not been extensively studied, although they are well documented in water. Determining the prevalence of these chemicals in various seaweed species and geographic locations is necessary due to their persistent and bioaccumulative nature.

Standardized and reliable methods for testing chemical contaminants in seaweed have not yet been developed. This lack of testing capability makes it difficult to accurately assess health risks and establish safety thresholds for specific contaminants. Setting appropriate limits for heavy metals and other substances in seaweed requires a nuanced understanding of toxicology—not just the concentration of a contaminant, but also how much and how often it is consumed. A simplistic, one-size-fits-all approach to setting standards fails to account for consumption patterns.

Environmental factors such as water temperature, salinity, and proximity to industrial or agricultural discharge points likely influence contaminant levels in seaweed. These variations indicate that contamination risks are highly location-specific, further complicating efforts to establish broad food safety guidelines. A systematic assessment of contamination risks in different growing environments is lacking. Additionally, water testing is not suggested as a control measure for environmental chemical contaminants in this guidance, as the correlation between waterborne environmental chemical contaminants and their absorption and accumulation in seaweed remains poorly understood. To advance our understanding, future research efforts should focus on identifying key factors that influence heavy metal uptake by different seaweed species, developing predictive models for contamination risk, and exploring mitigation strategies to reduce accumulation.

Further compounding these concerns is the absence of validated processing methods to mitigate contaminant levels in harvested seaweed. Unlike bacteria or parasites, which can be controlled through processing (e.g. cooking and freezing), chemical contaminants are not easily removed. Research on potential remediation strategies, such as washing techniques, fermentation, or adsorption-based treatments, is minimal. Therefore, in this guidance, processing control is not suggested as a control strategy for reducing the environmental chemical contaminants to acceptable levels.

Other Gaps

While some processing techniques for seaweeds are available, there are few studies evaluating the safety of these processes. Validation studies for common processing techniques are critical to fully support growth in this emerging industry.

Other major gaps identified include:

- There is limited understanding of how chemical and microbial water quality correlates with the presence and concentration of contaminants in or on seaweeds harvested from those waters.
- Inconsistent methods for measuring iodine concentrations in seaweed, leading to variability in reported values.
- Uncertainty around long-term health risks associated with chronic high iodine intake from seaweed consumption.
- Limited understanding of heavy metal bioavailability across different seaweed species and how it affects human exposure.

Appendix A Pathogens in Harvest Area Reference Table

Table A-1: *Potential bacterial pathogens and fecal indicator bacteria detected on pre-harvest seaweed species.*

Bacterial Pathogen	Seaweed Species	Reference(s)
Bacillus cereus	*Codium fragile* *Euchema cottonii* *Saccharina latissima*	Indraningrat et al., 2023 Lytou et al., 2021 Picon et al., 2021 Wiese et al., 2009
Bacillus licheniformis	*Alaria esculenta* *Codium fragile* *Saccharina latissima* *Ulva lactuca*	Blikra et al., 2019 Picon et al., 2021 Wiese et al., 2009
Bacillus pumilus	*Alaria esculenta* *Saccharina latissima*	Blikra et al., 2019 Wiese et al., 2009
Citrobacter freundii	*Fucus* species	Kreisseg et al., 2023
Clostridium perfringens	Unspecified brown seaweed	Kim et al., 2006
Coliform bacteria	*Alaria esculenta* *Fucus* species *Porphyra yezoensis* *Saccharina latissima*	Kreisseg et al., 2023 Skonberg et al., 2021 Son et al., 2014 Wang et al., 2023
Enterobacter cloacae	*Fucus* species Gracilaria foliifera	Kreisseg et al., 2023 Ezhilarasi et al., 2023
Escherichia coli (non-toxigenic strains)	*Fucus* species *Fucus spiralis* *Macrocystis pyrifera* *Saccharina latissima*	Barberi et al., 2020 Kreisseg et al., 2023 Quero et al., 2015 Quilliam et al., 2013

Bacterial Pathogen	Seaweed Species	Reference(s)
	Sargassum muticum *Ulva* species *Ulva pinnatifida* *Ulva reticulata*	Russell et al., 2013 Vairappan et al., 2000
Escherichia coli (toxigenic strains)	*Saccharina latissima*	Barberi et al., 2020
Klebsiella oxytoca	*Fucus* species	Kreisseg et al., 2023
Klebsiella variicola	*Fucus* species	Kreisseg et al., 2023
Listeria monocytogenes	*Alaria esculenta* *Caulerpa lentillifera* *Padina* species *Sargassum* species *Turbellaria* species	Beleneva et al., 2011 Lytou et al., 2021
Salmonella enterica	*Saccharina latissima*	Barberi et al., 2020
Serratia liquefaciens	*Fucus* species	Kreisseg et al., 2023
Staphylococcus aureus	*Caulerpa lentillifera* *Laminaria japonica* *Padina* species *Sargassum* species *Sargassum pallidum* *Turbullaria* species	Beleneva et al., 2011
Vibrio alginolyticus	*Alaria esculenta* *Caulerpa racemosa* *Gracilariopsis heteroclada* *Kappaphycus striatus* *Saccharina latissima*	Banach et al., 2024 Barberi et al., 2020 Faassen et al., 2024 Lytou et al., 2021 Martinez & Padilla, 2016

Bacterial Pathogen	Seaweed Species	Reference(s)
	Sargassum species *Ulva reticulata*	Mincer et al., 2023 Setyati et al., 2023 Tahiluddin et al., 2021 Vairappan et al., 2020
Vibrio cholerae	*Ascophyllum nodosum* *Gracilaria corticate* *Sargassum turbinaroides* *Ulva lactuca*	Chan & McManus, 1969 Haley et al., 2012 Haley et al., 2012 Murthy et al., 2013
Vibrio parahaemolyticus	*Caulerpa lentillifera* Fucus species *Gracilaria vermiculophylla* *Gracilariopsis heteroclada* *Kappaphycus striatus* *Laminaria* species *Porphyra* species *Saccharina latissima* *Ulva lactuca* *Ulva reticulata* *Ulva* species	Barberi et al., 2020 Gonzalez et al., 2014 Mahmud et al., 2006 Mahmud et al., 2007 Martinez & Padilla, 2016 Mincer et al., 2023 Murthy et al., 2023 Tahiluddin et al., 2021 Vairappan et al., 2000
Vibrio vulnificus	*Fucus* species *Gracilaria vermiculophylla* *Laminaria* species *Porphyra* species *Undaria* species	Gonzalez et al., 2014 Mahmud et al., 2008
Yersinia intermedia	*Fucus* species	Kreisseg et al., 2023

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Appendix B Environmental Chemical Contaminants Reference Tables

Table B-1: *Potential heavy metal contaminants identified in seaweeds.*

Heavy Metal	Seaweed Species	Reference(s)
Cadmium (Cd)	*Enteromorpha intestinalis; Enteromorpha linza; Ulva lactuca; Corrallina mediterranea; Pterocladia capillacea*	Mohammed & Khaled, 2005
Cadmium (Cd)	*Sargassum* species	Davis et al., 2000
Cadmium (Cd)	*Undaria pinnatifida; Himanthalia elongata; Laminaria ochroleuca;* Seaweed Salad (a mix of *Undaria pinnatifida*, *Laminaria ochroleuca*, and *Himanthalia elongata*)	Paz et al., 2019
Cadmium (Cd)	*Saccharina; Himanthalia*; *Laminaria*; *Ascophyllum; Undaria*; *Porphyra*; *Palmaria*; *Ulva* species; Mixed samples (combining various seaweed types).	Filippini et al., 2021
Cadmium (Cd)	*Gracilaria chouae*; *Ulva fasciata*; *Pelvetia siliguosa*	Sun et al., 2019
Cadmium (Cd)	*Fucus vesiculosus*	Guisti et al., 2001
Cadmium (Cd)	*Ulva* species; *Durvillaea incurvate*; *Lessonia spicata*; *Lessonia berteroana*; *Lessonia trabeculate*; *Macrocystis pyrifera; Gracilaria chilensis*; *Chondracanthus chamissoi*; *Cryptonemia obovate*; *Sarcodiotheca gaudichaudii*; *Acrosorium* species	Véliz et al., 2023
Cadmium (Cd)	*Eisenia bicyclis*; *Himanthalia elongata; Hizikia fusiforme*; *Laminaria* species; *Undaria pinnatifida*; *Ulva rigida*; *Gelidium* species; *Chondrus crispus*; *Porphyra umbilicalis*	Besada et al., 2009

Heavy Metal	Seaweed Species	Reference(s)
	Mixed seaweed products: Seaweed salad (mixtures of wakame, nori, and sea lettuce) and Algae salad (mixtures of wakame, ogonori, kombu, agar, and akamodoki).	
Cadmium (Cd)	*Saccharina latissima; Alaria esculenta; Palmaria palmata*	Roleda et al., 2019
Cadmium (Cd)	*Ulva lactuca; Agardhiella subulata*	Jarvis et al., 2015
Cadmium (Cd)	*Ulva lactuca; Eisenia bicyclis; Laminaria ochroleuca*; *Undaria pinnatifida*; *Sargassum fusiforme; Himanthalia elongata; Gracilaria*; *Porphyra*; *Mastocarpus stellatus*	Martín-León et al., 2021
Cadmium (Cd)	*Gelidium* species; *Chondrus crispus*; *Lithothamnium calcareum; Palmaria palmata; Porphyra umbilicalis; Ascophyllum nodosum; Fucus vesiculosus; Himanthalia elongata; Laminaria digitata*; *Undaria pinnatifida*; *Chlorella pyrenoidosa; Ulva lactuca; Ulva/Enteromorpha* species	Desideri et al., 2016
Copper (Cu)	*Sargassum* species	Davis et al., 2000
Copper (Cu)	*Ulva lactuca; Agardhiella subulata*	Jarvis et al., 2015
Copper (Cu)	*Enteromorpha intestinalis; Enteromorpha linza; Ulva lactuca; Corrallina mediterranea; Pterocladia capillacea; Sargassum* species	Mohammed & Khaled, 2005
Lead (Pb)	*Saccharina; Himanthalia; Laminaria; Ascophyllum; Undaria; Porphyra*; *Palmaria*; *Ulva* species; Mixed samples (combining various seaweed types).	Filippini et al., 2021
Lead (Pb)	*Fucus vesiculosus*	Guisti et al., 2001
Lead (Pb)	*Ulva lactuca; Agardhiella subulata*	Jarvis et al., 2015

Heavy Metal	Seaweed Species	Reference(s)
Lead (Pb)	*Ulva lactuca*; *Eisenia bicyclis*; *Laminaria ochroleuca*; *Undaria pinnatifida;* *Sargassum fusiforme*; *Himanthalia elongata*; *Gracilaria*; *Porphyra*; *Mastocarpus stellatus*	Martín-León et al., 2021
Lead (Pb)	*Enteromorpha intestinalis*; *Enteromorpha linza*; *Ulva lactuca*; *Corrallina mediterranea*; *Pterocladia capillacea*; *Porphyra* species; *Ecklonia radiata*; *Macrocystis pyrifera*; *Undaria pinnatifida*	Mohammed & Khaled, 2005; Smitha et al., 2010
Lead (Pb)	*Undaria pinnatifida; Himanthalia elongata; Laminaria ochroleuca*; Seaweed Salad (a mix of *Undaria pinnatifida*, *Laminaria ochroleuca*, and *Himanthalia elongata*)	Paz et al. 2019
Lead (Pb)	*Gracilaria lemaneiformis; Gracilaria chouae*; *Ulva fasciata; Sargassum thunbergii; Sargassum fusiforme; Sargassum horneri; Pelvetia siliguosa; Laminaria japonica*	Sun et al., 2019
Lead (Pb)	*Ulva* species; *Durvillaea incurvate; Lessonia spicata; Lessonia berteroana; Lessonia trabeculate; Macrocystis pyrifera; Gracilaria chilensis; Chondracanthus chamissoi; Cryptonemia obovate; Sarcodiotheca gaudichaudii; Acrosorium* species	Véliz et al., 2023
Mercury/Methylmercury	*Saccharina; Himanthalia; Laminaria; Ascophyllum; Undaria; Porphyra*; *Palmaria*; *Ulva* species; Mixed samples (combining various seaweed types)	Filippini et al., 2021
Mercury/Methylmercury	*Ulva lactuca; Eisenia bicyclis; Laminaria ochroleuca; Undaria pinnatifida; Sargassum fusiforme; Himanthalia elongata; Gracilaria*; *Porphyra*; *Mastocarpus stellatus*	Martín-León et al., 2021
Mercury/Methylmercury	*Enteromorpha intestinalis; Enteromorpha linza; Ulva lactuca; Corrallina mediterranea; Pterocladia capillacea; Porphyra spp.; Ecklonia radiata; Macrocystis pyrifera; Undaria pinnatifida*	Mohammed and Khaled, 2005; Smitha et al., 2010

Heavy Metal	Seaweed Species	Reference(s)
Mercury/Methylmercury	*Undaria pinnatifida; Himanthalia elongata; Laminaria ochroleuca*	Paz et al., 2019
Mercury/Methylmercury	*Ulva* species; *Durvillaea incurvate; Lessonia spicata*; *Lessonia berteroana; Lessonia trabeculate; Macrocystis pyrifera; Gracilaria chilensis; Chondracanthus chamissoi; Cryptonemia obovate*; *Sarcodiotheca gaudichaudii; Acrosorium* species	Véliz et al., 2023

__Table B-2__: Radionuclides identified in seaweeds.

Radionuclide	Seaweed Species	Reference(s)
^{125} Antimony (Sb)	Various Species	Masson et al., 1995
^{7} Beryllium (Be)	*H. virgatum*	Tejera et al., 2019
$^{134 \& 137}$ Caesium (Cs)	*Kappaphycus; Dictyota dichotoma & Laminaria digitata*	Wan Mahmood et al., 2018; Abbasi et al., 2023
$^{127, 129, \& 131}$ Iodine (I)	*Fucus vesiculosus & Fucus distichus;* Various Species	Hou et al., 2000; Chester et al., 2013
^{210} Lead (Pb)	Various Species	Tejera et al., 2019
^{238} Plutonium	*Fucus vesiculosus*	Ryan et al., 1999
^{210} Polonium (Po)	Various Species	Akakçe et al., 2023; Tejera et al., 2019
^{40} Potassium (K)	*Eucheuma Cottoni;* Various Species	Khandaker et al., 2019; Tejera et al., 2019
$^{224, 226 \& 228}$ Radon (RA)	*Eucheuma Cottoni;* Various Species	Khandaker et al., 2019; Tejera et al., 2019
^{99} Technitium (Tc)	Various Species	Masson et al., 1995
$^{228 \& 234}$ Thorium (Th)	Various Species	Tejera et al., 2019
^{238} Uranium (U)	Various Species	Tejera et al., 2019

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Appendix C Natural Toxins Reference Tables

Table C-1: *Natural toxins identified in seaweed species. Cells labeled "not quantified" indicate that the toxin was identified, but concentrations were not quantified in the study. Values labeled with an asterisk (*) were converted to ppm.*

Natural Toxin	Seaweed Level (dry weight unless noted)	Seaweed Species	Reference
Domoic Acid: Amnesic Shellfish Poisoning (ASP)	498.1 ppm*	*Alsidium corallinum*	Impellizzeri et al., 1975
ASP	1.1ppm*	*Amnasia glomerata*	Sato et al., 1996
ASP	<1–37 ppm (wet)	*Amphiroa* species	Noguchi and Arakawa, 1996
ASP	201–928 ppm (wet); 4,300 ppm (dry)	*Chondria armata*	Noguchi and Arakawa, 1996
ASP	1,090 ppm*	*Chondria armata*	Sato et al., 1996
ASP	<1–775 ppm (wet)	*Coelothrix irregularis*	Noguchi and Arakawa, 1996
ASP	20.7–28.2 ppm*	*Digenea simplex*	Sato et al., 1996
ASP	<1 ppm (wet)	*Digenea simplex*	Noguchi and Arakawa, 1996
ASP	38–709 ppm (wet)	*Jania capillacea*	Noguchi and Arakawa, 1996
ASP	0.7 ppm*	*Vidalia obtusiloba*	Sato et al., 1996
Caluerpin	*Not quantified*	*Chondria armata*	Govenkar & Wahidulla, 2000
Caluerpin	0.85% crude yield	*Caulerpa sertularioides*	Doty & Aguilar-Santos, 1970
Caluerpin	*Not quantified*	*Caulerpa lentillifera; Caulerpa lamourouxii*	Doty & Aguilar-Santos, 1970
Caulerpicin	≤400 ppm*	*Caulerpa racemosa*	Doty et al., 1966
Caulerpicin	0.87% crude yield	*Caulerpa sertularioides*	Doty & Aguilar-Santos, 1970

Natural Toxin	Seaweed Level (dry weight unless noted)	Seaweed Species	Reference
Caulerpicin	*Not quantified*	*Caulerpa lentillifera; Caulerpa racemosa Caulerpa lamourouxii*	Doty & Aguilar-Santos, 1970
Cyanobacteria (Aplysiatoxin & Debromoaplysiatoxin)	*Not quantified*	*Gracilaria coronopifolia* (epiphytes)	Nagai et al., 1996; Nagai et al., 1997
Diethyl Peroxide	*Not quantified*	*Sphaerotrichia divaricate; Cladosiphon okamuranus; Analipus japonicus; Gracilariopsis chorda*	Fusetani & Hashimoto, 1981
Kainic Acid	319.8 ppm*	*Centroceras clavulatum*	Impellizzeri et al., 1975
Kainic Acid	21.3–27.6 ppm*	*Digenea simplex*	Sato et al., 1996
Kainic Acid	10.1 ppm*	*Laurencia papillosa*	Sato et al., 1996
Kainic Acid	<7–560 ppm*	*Palmaria palmata*	Jørgensen & Olesen, 2018
Kainic Acid	1.4 ppm*	*Vidalia obtusiloba*	Sato et al., 1996
Polycavernoside A	72–84 nmol/kg	*Gracilaria edulis*	Yotsu-Yamashita et. al., 2004
Prostaglandin E2 (PGE2)	0.05–0.07%	*Gracilaria lichenoides*	Gregson et al., 1979
Prostaglandin E2 (PGE2)	~1–6 ppm[1]	*Gracilaria tenuistipitata*	Hsu et al., 2008
Prostaglandin E2 (PGE2)	4.3–78.6 ppm	*Gracilaria verrucosa*	Noguchi et al., 1994
Prostaglandin E2 (PGE2)	*Not quantified*	*Gracilaria verrucosa*	Fusetani & Hashimoto, 1984

[1] Note: Units were reported as grams/gram in the original publication, which is believed to be an error meant to be the common unit grams/kilogram (ppm).

Table C-2: *Recorded incidences of mycotoxin quantification or isolation of toxigenic-fungi from unprocessed seaweeds (not ready-to-eat products). This table is not exhaustive and focuses only on the current "mycotoxins of focus" as defined by the FDA (USFDA, 2024). Mycotoxins and associated producing fungal species can be found in Table C-3 below.*

Seaweed Species	**Aflatoxin** Action Levels US: 20 ppb EU 4–25 ppb[a]	**Deoxynivalenol** Action Levels US: 1000 ppb[b] EU: 150–1750 ppb[c]	**Fumonisin** Action Levels US: 2000–4000 ppm[d] EU: 200–1000 ppb[e]	**Patulin** Action Levels US: 50 ppb[f] EU: 10–50 ppb[g]	**Ochratoxin** Action Levels US: None established EU: 0.5–10 ppb[b]	**T-2** Action Levels Not Established[h]	**Zeralenone** Action Levels Not Established	**References**
Ahnfeltia plicata	Not detected	Not detected	Not detected	--	Not detected	Not detected	Not detected	Burkin & Kononenko, 2023
Ascophyllum nodosum	Toxin: 0.011	Toxin: 1.39	Toxin: 0.460	--	Toxin: 0.046	Toxin: 0.014	Toxin: 0.150	Burkin & Kononenko, 2023
Ascophyllum nodosum	Toxin: 0.160	Toxin: 1.66	Toxin: 0.765	--	Toxin: 0.115	Toxin: 0.029	Toxin: 0.175	Burkin et al., 2021
Ascophyllum nodosum	Toxin: 0.040	Toxin: 1.05	Toxin: 2.50	--	Toxin: 0.074	Toxin: 0.028	Toxin: 0.478	Kononenko et al., 2022
Ascophyllum nodosum	Toxin: 0.090	Toxin: 2.31	Toxin: 1.66	--	Toxin: 0.120	Toxin: 0.083	Toxin: 0.445	Kononenko et al., 2021
Asparagopsis taxiformis	Not detected	Not detected	Not detected	Not detected	Not detected	Not detected	Not detected	Garzoli et al., 2015
Chorda filum	Not detected	Not detected	Not detected	--	Not detected	Not detected	Not detected	Kononenko et al., 2021

[a] Applies only to certain food categories, coverage of seaweed is unclear.
[b] Advisory level only (no action level defined), applies only to wheat.
[c] Applies only to cereal products, no other foods covered.
[d] Advisory level only (no action level defined), applies only to corn-based foods.
[e] Applies only to corn products, no other foods covered.
[f] Applies only to apple juice, no other foods covered.
[g] Applies only to apple-derived products, no other foods covered.
[h] EU Tolerable Daily Intake (TDI) 0.02 µg/kg body weight (sum of T-2 and HT-2 toxins).

Seaweed Species	**Aflatoxin** Action Levels US: 20 ppb EU 4–25 ppb[a]	**Deoxynivalenol** Action Levels US: 1000 ppb[b] EU: 150–1750 ppb[c]	**Fumonisin** Action Levels US: 2000–4000 ppm[d] EU: 200–1000 ppb[e]	**Patulin** Action Levels US: 50 ppb[f] EU: 10–50 ppb[g]	**Ochratoxin** Action Levels US: None established EU: 0.5–10 ppb[b]	**T-2** Action Levels Not Established[h]	**Zeralenone** Action Levels Not Established	References
Chordaria flagelliformis	Not detected	Toxin: 0.076	Toxin: 0.280	--	Toxin: 0.008	Not detected	Not detected	Kononenko et al., 2021
Fucus distichus	Toxin: 0.385	Toxin: 20.8	Toxin: 5.38	--	Toxin: 0.360	Toxin: 1.55	Toxin: 2.14	Burkin & Kononenko, 2023
Fucus distichus	Toxin: 0.220	Toxin: 6.42	Toxin: 8.51	--	Toxin: 0.358	Toxin: 0.071	Toxin: 1.43	Kononenko et al., 2022
Fucus distichus	Toxin: 0.215	Toxin: 3.68	Toxin: 7.13	--	Toxin: 0.265	Toxin: 0.110	Toxin: 0.890	Kononenko et al., 2021
Fucus serratus	Toxin: 0.410	Toxin: 23.0	Toxin: 8.27	--	Toxin: 0.750	Toxin: 2.98	Toxin: 2.96	Burkin & Kononenko, 2023
Fucus serratus	Toxin: 0.835	Toxin: 31.3	Toxin: 13.4	--	Toxin: 0.605	Toxin: 0.460	Toxin: 2.50	Kononenko et al., 2021
Fucus spiralis	--	--	--	Viable *Penicillium* species	Viable *A. niger, Penicillium* species	--	Viable *F. oxysporum*	Guimarães, 2021
Fucus vesiculosis	Toxin: 0.385	Toxin: 19.4	Toxin: 7.48	--	Toxin: 0.900	Toxin: 2.98	Toxin: 3.44	Burkin & Kononenko, 2023
Fucus vesiculosis	Toxin: 0.497	Toxin: 27.6	Toxin: 9.90	--	Toxin: 0.178	Toxin: 0.328	Toxin: 1.61	Kononenko et al., 2022
Fucus vesiculosis	Toxin: 0.295	Toxin: 12.3	Toxin: 4.43	--	Toxin: 0.180	Toxin: 0.250	Toxin: 0.880	Kononenko et al., 2021
Laminaria digitata	Not detected	Not detected	Not detected	--	Not detected	Not detected	Not detected	Kononenko et al., 2021

Seaweed Species	**Aflatoxin** Action Levels US: 20 ppb EU 4–25 ppb[a]	**Deoxynivalenol** Action Levels US: 1000 ppb[b] EU: 150–1750 ppb[c]	**Fumonisin** Action Levels US: 2000–4000 ppm[d] EU: 200–1000 ppb[e]	**Patulin** Action Levels US: 50 ppb[f] EU: 10–50 ppb[g]	**Ochratoxin** Action Levels US: None established EU: 0.5–10 ppb[b]	**T-2** Action Levels Not Established[h]	**Zeralenone** Action Levels Not Established	**References**
Mastocarpus stellatus	--	Viable *Fusarium* species	Viable *Fusarium* species	Viable *Penicillium* species	Viable *A. carbonarius, A. niger, Penicillium* species	Viable *Fusarium* species	Viable *Fusifarium* species	Guimarães, 2021
Mixture of brown algae: *Cystoseira myrica, Dictyota pinnatifida, Hydroclathrus clathratus, Padina pavonica, Sargassum* species, *Turbinaria decurrens*	Viable *A. flavus*	Viable *Fusarium* species	Viable *Fusarium* species	--	Viable *A. niger*	Viable *Fusarium* species, *Stachybotrys*	Viable *Fusifarium* species	Abdel-Gawad et al., 2014
Mixture of green algae: *Cladophora* species, *Dictyosphaeria cavernosa*, *Ulva lactuca*, *Valonia aegagropila*	Viable *A. flavus*	Viable *Fusarium* species	Viable *Fusarium* species	--	Viable *A. niger*	Viable *Fusarium* species, *Stachybotrys*	Viable *Fusifarium* species	Abdel-Gawad et al., 2014
Mixture of red algae: *Digenea simplex*, *Gracilaria arcuate*, *Heterosiphonia* species, *Hypnea cornuata*, *Jania rubens*, *Laurencia*	Viable *A. flavus*	Viable *Fusarium* species	Viable *Fusarium* species	--	Viable *A. niger*	Viable *Fusarium* species, *Stachybotrys*	Viable *Fusifarium* species	Abdel-Gawad et al., 2014

Seaweed Species	**Aflatoxin** Action Levels US: 20 ppb EU 4–25 ppb[a]	**Deoxynivalenol** Action Levels US: 1000 ppb[b] EU: 150–1750 ppb[c]	**Fumonisin** Action Levels US: 2000–4000 ppm[d] EU: 200–1000 ppb[e]	**Patulin** Action Levels US: 50 ppb[f] EU: 10–50 ppb[g]	**Ochratoxin** Action Levels US: None established EU: 0.5–10 ppb[b]	**T-2** Action Levels Not Established[h]	**Zeralenone** Action Levels Not Established	**References**
species, *Palisada perforate*								
Mixture of algae: *Ascophyllum nodosum, Fucus vesiculosus, Laminaria digitata, Polysiphonia lanosa, Saccharina latissima, Ulva lactuca*	--	--	--	Viable *Penicillium* species	Viable *Penicillium* species	--	--	Miller & Whitney, 1981
Pelvetia canaliculata	Toxin: 0.003	Toxin: 0.735	Toxin: 0.263	--	Toxin: 0.10	Toxin: 0.029	Toxin: 0.074	Burkin & Kononenko, 2023
Pelvetia canaliculata	Toxin: 0.071	Toxin: 1.74	Toxin: 0.790	--	Toxin: 0.130	Toxin: 0.034	Toxin: 0.165	Burkin et al., 2021
Pelvetia canaliculata	Toxin: 0.024	Toxin: 0.490	Toxin: 0.605	--	Toxin: 0.130	Toxin: 0.016	Toxin: 0.180	Kononenko et al., 2021
Saccharina latissima	Not detected	Not detected	Not detected	--	Not detected	Not detected	Not detected	Burkin & Kononenko, 2023
Saccharina latissima	Not detected	Not detected	Not detected	--	Not detected	Not detected	Not detected	Kononenko et al., 2021
Ulva rigida	--	--	--	--	--	--	Viable *F. oxysporum*	Guimarães, 2021

***Table C-3**: Mycotoxins and associated producing fungal species.*

Toxin	Producing Fungal Species
Aflatoxin	*Aspergillus* species: *Aspergillus flavus; Aspergillus parasiticus*
Deoxynivalenol	*Fusarium* species: *Fusarium crookwellense; Fusarium culmorum; Fusarium graminareum; Fusarium pseudograminareum*
Fumonisin	*Aspergillus niger; Fusarium* species: *Fusarium proliferatum; Fusarium verticilloides*
Patulin	*Aspergillus* species; *Byssochlamys* species; *Penicillium* species: *Penicillium expansum*
Ocratoxin A	*Aspergillus* species: *Aspergillus carbonarius; Aspergillus niger; Aspergillus ochraceus; Penicillium* species: *Penicillium nordicum; Penicillium verrucosum*
T-2 Toxin	*Fusarium* species: *Fusarium acuminatum ; Fusarium poae; Fusarium sporotrichioides; Myrothecium* species; *Stachybotrys* species
Zeralenone	*Fusarium* species: *Fusarium acuminatum; Fusarium crookwellense; Fusarium culmorum; Fusarium equiseti; Fusarium graminareum; Fusarium oxysporum; Fusarium poae; Fusarium rosum; Fusarium semitectum; Fusarium solani; Fusarium sporaotrichioides; Fusarium verticilloides*

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Appendix D Iodine Concentrations Reference Tables

Table D-1: *Recommended Dietary Allowances (RDAs) and Upper Limits (UL) for Iodine.*

Age	Female and Male	Pregnancy	Lactation	Upper Limit (UL)
Birth to 6 months	110 µg Adequate Intake (AI)	NA	NA	Not established
7–12 months	130 µg Adequate Intake (AI)	NA	NA	Not established
1–3 years	90 µg	NA	NA	200 µg
4–8 years	90 µg	NA	NA	300 µg
9–13 years	120 µg	NA	NA	600 µg
14–18 years	150 µg	NA	NA	900 µg
Adults 18+	Not established	220 µg	290 µg	1,100 µg
19+ years	150 µg	220 µg	290 µg	NA

Table D-2: *Iodine concentrations measured in various brown seaweed species. "**DW**" stands for Dry Weight. Concentrations measured and reported as mg/kg DW were converted to µg/g DW.*

Common Name	Scientific Name	Iodine Concentration (µg/g DW)	Reference
Arame or Sea Oak	*Eisenia bicyclis*	434	Aakre et al., 2021
Arame or Sea Oak	*Eisenia bicyclis*	706–721	Lee et al., 1994
Arame or Sea Oak	*Eisenia bicyclis*	586	Teas et al., 2004
Arame or Sea Oak	*Eisenia bicyclis*	600	Van Netten et al., 2000
Bladderwrack	*Fucus vesiculosus*	137	Aakre et al., 2021
Bladderwrack	*Fucus vesiculosus*	137.8–451.2	Sá Monteiro et al., 2019
Bladderwrack	*Fucus vesiculosus*	732	Van Netten et al., 2000
Bull Kelp	*Nereocystis luetkeana*	734	Van Netten et al., 2000
Bull Kelp	*Nereocystis luetkeana*	80	Van Netten et al., 2000
Channeled Wrack	*Pelvetia canaliculata*	248	Nitschke & Stengel, 2015
Giant Kelp	*Macrocystis integrifolia*	240	Van Netten et al., 2000
Hijiki	*Sargassum fuciformes*	262	Dawczynski et al., 2007
Hijiki	*Sargassum fuciformes*	391	Lee et al., 1994

Common Name	Scientific Name	Iodine Concentration (µg/g DW)	Reference
Hijiki	*Sargassum fuciformes*	622	Sun et al., 2022
Hijiki	*Sargassum fuciformes*	629	Teas et al., 2004
Hijiki	*Sargassum fuciformes*	436	Van Netten et al., 2000
Kelp	Mixed Species	1,542	Teas et al., 2004
Knotted Wrack	*Ascophyllum nodosum*	168–235	Nitschke & Stengel, 2015
Kombu	*Laminaria japonica*	1,273–3,257	Aakre et al., 2021
Kombu	*Laminaria japonica*	3,040	Hou and Yan, 1998
Kombu	*Laminaria japonica*	2,110	Van Netten et al., 2000
Kombu	*Laminaria ochroleuca*	6,138	Romarís-Hortas et al., 2012
Kombu	*Laminaria* species	2,934	Dawczynski et al., 2007
Kombu	*Laminaria* species	241–4,921	Yeh et al., 2014
Oarweed	*Laminaria digitata*	8,545–8,697	Aakre et al., 2021
Oarweed	*Laminaria digitata*	3,340–10,203	Nitschke & Stengel, 2015
Rainbow Wrack	*Cystoseira tamariscifolia*	165	Nitschke & Stengel, 2015
Rockweed	*Fucus evanescens*	394.16	Sá Monteiro et al., 2019
Sea Spaghetti	*Himanthalia elongata*	12–77	Aakre et al., 2021
Sea Spaghetti	*Himanthalia elongata*	117	Romarís-Hortas et al., 2012
Spiral Wrack	*Fucus spiralis*	190–232	Nitschke & Stengel, 2015
Spiral Wrack	*Fucus spiralis*	209.52	Sá Monteiro et al., 2019
Split Kelp	*Fucus vesiculosis*	99–105	Nitschke & Stengel, 2015
Split Kelp	*Fucus vesiculosis*	1,070	Van Netten et al., 2000
Sugar Kelp	*Saccharina latissima*	836–2,120	Aakre et al., 2021
Sugar Kelp	*Saccharina latissima*	5,580–7,977	Krook et al., 2023
Sugar Kelp	*Saccharina latissima*	420–3,965	Lüning & Mortensen, 2015
Sugar Kelp	*Saccharina latissima*	3,341–6,130	Nitschke & Stengel, 2015
Sugar Kelp	*Saccharina latissima*	1,556–7,208	Roleda et al., 2019
Sugar Kelp	*Saccharina latissima*	333–4,782.2	Sá Monteiro et al., 2019
Sugar Kelp	*Saccharina latissima*	1,600–4,200	Sharma et al., 2018
Sugar Kelp	*Saccharina latissima*	4,898–6,568	Stévant & Braverman, 2014
Sugar Kelp	*Saccharina latissima*	238	Van Netten et al., 2000
Tangle/Cuvie	*Laminaria hyperborea*	1,734–8,976	Nitschke & Stengel, 2015
Toothed Wrack	*Fucus serratus*	221–271	Aakre et al., 2021

Common Name	Scientific Name	Iodine Concentration (µg/g DW)	Reference
Toothed Wrack	*Fucus serratus*	275–320	Nitschke and Stengel, 2015
Toothed Wrack	*Fucus serratus*	105.2–961.4	Sá Monteiro et al., 2019
Wakame	*Undaria pinnatifida*	98–294	Aakre et al., 2021
Wakame	*Undaria pinnatifida*	163	Dawczynski et al., 2007
Wakame	*Undaria pinnatifida*	1,571	Hou & Yan, 1998
Wakame	*Undaria pinnatifida*	104–217	Lee et al., 1994
Wakame	*Undaria pinnatifida*	306	Romarís-Hortas et al., 2012
Wakame	*Undaria pinnatifida*	66	Teas et al., 2004
Wakame	*Undaria pinnatifida*	60–102	Van Netten et al., 2000
Wakame	*Undaria* species	93.9–185.1	Yeh et al., 2014
Winged Kelp	*Alaria esculenta*	245–216	Aakre et al., 2021
Winged Kelp	*Alaria esculenta*	670	Nitschke & Stengel, 2016
Winged Kelp	*Alaria esculenta*	180–1,070	Roleda et al., 2019
Winged Kelp	*Alaria marginata*	151	Van Netten et al., 2000
Wire Weed/Japweed	*Sargassum muticum*	93	Nitschke & Stengel, 2015

Table D-3: *Iodine concentrations measured in various red seaweed species. "**DW**" stand for Dry Weight. Concentrations measured and reported as mg/kg DW were converted to µg/g DW.*

Common/Scientific Name	Scientific Name	Iodine Concentration (µg/g DW)	Reference
Carrageenan Moss	*Mastocarpus stellatus*	174	Nitschke & Stengel, 2015
Ceramium boydenoo	*Ceramium boydenoo*	71.1	Hou & Yan, 1998
Ceramium kondoi	*Ceramium kondoi*	34.1	Hou & Yan, 1998
Gracilaria confervoides	*Gracilaria confervoides*	353	Hou & Yan, 1998
Dulse	*Palmaria palmata*	152	Aakre et al., 2021
Dulse	*Palmaria palmata*	44.1	Lee et al., 1994
Dulse	*Palmaria palmata*	<5–7	Mouritsen et al., 2013
Dulse	*Palmaria palmata*	97	Nitschke and Stengel, 2016
Dulse	*Palmaria palmata*	72–293	Roleda et al., 2019
Dulse	*Palmaria palmata*	77.3	Romarís-Hortas et al., 2012
Dulse	*Palmaria palmata*	72	Teas et al., 2004
Gelidium amansil	*Gelidium amansil*	203.8	Hou & Yan, 1998
Irish Moss	*Chondrus crispus*	56	Nitschke & Stengel, 2015
Laver	*Porphyra umbilicalis*	46	Nitschke & Stengel, 2015
Laver	*Porphyra umbilicalis*	43.2	Romarís-Hortas et al., 2012
Nori	*Porphyra tenera*	4.3–250	Lee et al., 1994
Nori	*Porphyra tenera*	16	Teas et al., 2004
Nori	*Porphyra tenera*	17–185	Van Netten et al., 2000
Nori	*Porphyra* species	19–24	Aakre et al., 2021
Nori	*Porphyra* species	35.8	Hou & Yan, 1998
Nori	*Porphyra* species	42.8	Watanabe et al., 1999
Nori	*Porphyra* species	29.3–45.8	Yeh et al., 2014

Table D-4: *Iodine concentrations measured in various green seaweed species. "**DW**" stands for Dry Weight. Concentrations measured and reported as mg/kg DW were converted to µg/g DW.*

Common/Scientific Name	Scientific Name	Iodine Concentration (µg/g DW)	Reference
***Cladophora* species**	*Cladophora* species	140.27	Sá Monteiro et al., 2019
Enteromorpha intestinalis (Ulva intestinalis)	*Enteromorpha intestinalis (Ulva intestinalis)*	114.8	Hou & Yan, 1998
***Enteromorpha* species**	*Enteromorpha* species	63.5	Watanabe et al., 1999
Monostroma fragile	*Monostroma fragile*	63.6	Hou & Yan, 1998
Dead Man's Fingers	*Codium fragile*	154	Hou & Yan, 1998
Dean Man's Fingers	*Codium fragile*	41	Nitschke & Stengel, 2015
Sea Lettuce	*Ulva intestinalis*	79	Nitschke & Stengel, 2015
Sea Lettuce	*Ulva intestinalis*	92	Nitschke & Stengel, 2016
Sea Lettuce	*Ulva lactuca*	53.8	Hou & Yan, 1998
Sea Lettuce	*Ulva lactuca*	63	Nitschke & Stengel, 2015
Sea Lettuce	*Ulva lactuca*	17.2–20.8	Sá Monteiro et al., 2019
Sea Lettuce	*Ulva pertusa*	12.9–33.2	Hou & Yan, 1998
Sea Lettuce	*Ulva rigida*	65.6	Romarís-Hortas et al., 2012

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Appendix E Foodborne Outbreaks

Introduction to Foodborne Outbreaks

Bacterial pathogens are rarely found in foods that are grown, handled, and processed under sanitary conditions—even in foods that are commonly considered “high risk.” The most recent Global Food Security Index ranked the United States third out of 113 countries for food quality and safety (Economist Impact, 2022). Still, the CDC estimates that about 9 million cases of foodborne illness occur in the U.S. each year (CDC, 2024b).

Public health officials report disease outbreaks to the CDC through the National Outbreak Reporting System (NORS). In 2023, NORS recorded 9,521 reported foodborne illnesses (CDC, 2025)—far fewer than the millions the CDC estimates. This gap is due to several factors that lead to underreporting of foodborne disease.

The leading infectious pathogens in the U.S. are norovirus and *Salmonella* (CDC, 2024b). Consumers who are sickened by these pathogens typically experience vomiting, diarrhea, chills, and other symptoms. Most cases resolve without medical treatment within a few days, so many sick individuals never see a doctor for their symptoms. Even among those who do, about 30% of patients never provide a clinical sample such as stool for laboratory testing (Scallan Walter et al., 2025). In other cases, clinical samples are never tested, or tests fail to identify the disease-causing agent (e.g., due to problems with method sensitivity, and/or analyst error). All of these scenarios are considered cases of **underdiagnosis**, and the extent of underdiagnosis differs depending on the pathogen. For example, *Salmonella illnesses* are estimated to be 14.7 times higher than what is reported through NORS (Scallan Walter et al., 2025).

Underreporting occurs when laboratories fail to report test results to the appropriate public health agency. To address this, the CDC runs the Foodborne Diseases Active Surveillance Network (FoodNet), part of the CDC’s Emerging Infections Program. FoodNet works with state health departments, the FDA and the USDA to gather data directly from clinical laboratories on pathogens such as: *Campylobacter*, *Cyclospora*, *Listeria*, *Salmonella*, *Shigella*, *Vibrio*, *Yersinia* and shigatoxigenic *E. coli* (CDC, 2024a). While underreporting is low for these pathogens, it can be significantly higher for others. For instance, illnesses caused by *Clostridium perfringens* are estimated to be underreported 64-fold (Scallan Walter et al., 2025).

Even when a pathogen is correctly diagnosed—which depends on the ill person seeking medical care, providing a sample, having that sample tested, and the results reported—additional steps are required to link the illness back to the contaminated food. Despite these efforts, in about 36% of outbreaks the specific food (‘food vehicle’) is never identified (White et al., 2022). Reasons include inaccurate reporting by consumers about what foods were eaten, challenges in identifying a single common food item during investigations, incomplete traceability records maintained by vendors or manufacturers, and the inability to test leftover products from suspected batches once they have expired.

Taken together, these and various other factors mean that most foodborne illnesses in the United States are never linked to an outbreak. Nonetheless, outbreaks can still happen. This is why food safety best practices emphasize lowering risk as much as possible, even when the overall likelihood is relatively low.

Measuring Microorganisms in Food

The levels of pathogens commonly present in foods contaminated during production are usually low enough that they are difficult to measure using standard microbiological methods. Bacteria are typically measured in Colony Forming Units (CFU) per gram of food, which indicates the number of viable microbial cells or clumps of cells. For spoilage organisms, 6–7 log CFU/g (1–10 million cells per gram) is typically considered spoiled.

Because naturally contaminated foods often have very low pathogen levels, food microbiology research *usually* takes one of two approaches:

Approach 1: Using "Indicator" Populations

Indicators are groups of microorganisms that signal contamination or poor sanitary conditions. They are more common and usually present in higher numbers than pathogens. While high levels of indicator microorganisms do not necessarily mean the food is unsafe, they can be indicative of pathogen presence and may prompt further testing or stricter sanitation. Expected levels of these groups of organisms vary depending on the specific food and how far into the shelf life (how close to spoiling) a food is. Commonly assessed indicators include:

- **Aerobic Mesophiles**: Bacteria that grow in the presence of oxygen and at temperatures including ambient (~70°F/21.1°C) and body temperature (~98.6°F/ 37°C). Sometimes called "total bacterial count" or similar terminology.
- **Psychrotrophs**: Includes bacteria that can grow at refrigeration temperatures (at or below 40°F/4.4°C) and often spoil refrigerated foods; *Listeria monocytogenes* is an example of a psychrotrophic pathogen.
- **Coliforms:** A group of bacteria with characteristics similar to (and includes) *E. coli* which are found widely in the environment and used to measure sanitary conditions during processing.
- **Fecal Coliforms:** A subset of coliforms that usually originate in the intestines of mammals. These are used as an indication of potential fecal contamination.
- **Generic *E. coli*:** Counts all *E. coli*, both harmless and pathogenic.

- **Fungi (yeasts and molds):** A total count including yeasts and molds, commonly used to indicate the quality of foods with intermediate or low moisture which do not support the growth of bacteria.

Approach 2: Inoculation of Food Samples with Bacterial Pathogen Cultures

Inoculation (or "challenge") studies test how pathogens behave in specific foods under various conditions, such as storage and processing. Researchers deliberately add higher levels of bacteria than would normally occur in a "naturally contaminated" food. This is intentional as bacterial death (or decrease in number of cells) often follows predictable patterns. Studying higher populations allows researchers to model the rate at which bacteria will grow or die over time, meaning that the percentage of the cells expected to die is the same whether you start with 10 million or 10.

These studies help determine whether food safety processes are effective. For example, most lethality processes aim for at least a 5-log CFU/g reduction in pathogens (USFDA, 2024).

Case Study: Salmonella in Almonds

Almonds were linked to salmonellosis outbreaks in 2000–2001 (Isaacs et al., 2005) and 2003–2004 (CDC, 2004). Later studies of thousands of almonds conducted over the course of several years found Salmonella on only 0.87–1.6% of samples (Bansal et al., 2010; Danyluk et al., 2007), at levels ranging from 1.2 to 15.5 cells per 100g of almonds. Still, models estimated a 78% chance of at least one U.S. case of salmonellosis resulting from almonds per year (Danyluk et al., 2006).

In response, the California Almond Marketing Order (USDA AMS, 2007) required implementing a process that achieves at least a 4-log (99.99%) reduction of *Salmonella* on natural almonds grown in California and sold in North America. The Almond Board of California subsequently established detailed validation guidelines to help handlers meet this requirement (Almond Board of California, 2024).

Even though natural contamination levels may be less than one *Salmonella* cell per gram, challenge studies require starting levels of more than 7 log CFU/g (10 million cells/gram) (Almond Board of California Technical Expert Review Panel, 2014). This ensures reliable modeling of pathogen survival and reduction.

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Appendix F Example Seaweed Threshold Calculations

This appendix provides illustrative examples to assist producers and processors in estimating safe consumption thresholds for seaweed products using published tolerable intake values and minimum risk levels. These calculations are intended solely for informational purposes and are not reviewed, approved, or enforced by any local, state, or federal agency. They do not supersede existing regulatory standards or limits.

While such examples may help identify internal safety thresholds, it is the responsibility of each facility to consult with the appropriate regulatory authorities to confirm whether self-calculated contaminant limits will be recognized or accepted. The authors make no representations or warranties regarding the accuracy, applicability, or regulatory acceptance of these calculations and expressly disclaim any liability for decisions or actions taken based on this information.

Calculations Based on Published Tolerable Intakes

The following examples illustrate how seaweed contaminant or metal thresholds can be calculated using cited provisional tolerable weekly or monthly intake values. These calculations are intentionally conservative, assuming daily consumption, a serving size of 15 grams of dried seaweed, and limiting exposure to 25% of the recommended intake to account for the fact that seaweed is not the sole source of dietary exposure. Consumers may also be exposed to contaminants through other foods, so this conservative approach helps ensure overall intake remains within safe limits. The equations can be adjusted to better reflect your specific serving sizes, intended consumer, and known consumption patterns. Adult body weight (84 kg) is based on Centers for Disease Control and Prevention (CDC) averages for U.S. adults, and the provisional tolerable intake for each compound (PTDI/PTWI/PMTDI) is taken from the most authoritative available source for that chemical—e.g., WHO/JECFA, EFSA, or U.S. EPA—and converted to a daily value when only weekly or monthly limits are provided.

$$\frac{PTWI\ (mg) \times\ Body\ Weight\ (kg)}{7} = mg\ consumed\ /\ day$$

$$\frac{max\ mg\ consumed/day}{4} = \frac{1}{4}\ of\ daily\max\ (mg)$$

$$\frac{\frac{1}{4}\ of\ daily\max(mg)}{serving\ size\ (kg)} = \boldsymbol{mg/kg\ threshold\ for\ ingredient\ or\ final\ product}$$

Cadmium (Cd)

1. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has established a provisional tolerable weekly intake (PTWI) for cadmium of 0.007 mg/kg body weight.
2. According to the CDC, the average American adult weighs approximately [(199.8lbs (M) +170.8lbs (F))/2] = ~185lbs (84kg).
3. Based on this, the average American should not consume more than (0.007 * 84) = 0.588mg of Cd in a week, which comes out to 0.084mg per day.
4. Applying the conservative limit of 25% of daily intake from seaweed, the maximum cadmium from one serving of seaweed should be: 0.084mg/day ÷ 4 = 0.021mg/day.
5. According to the USDA Food Central Database, 1 cup or 15g of seaweed constitutes a serving. With a serving size of 15g dried seaweed (0.015kg), the maximum cadmium concentration in seaweed should be set to 0.021mg/day ÷ 0.015kg = 1.4mg/kg.

So, the threshold for maximum amount of cadmium in dried seaweed based on these assumptions would be 1.4mg/kg.

Dioxins

1. The WHO has set the provisional tolerable monthly intake (PTMI) of Dioxin and Dioxin-like compounds to 70 pg/kg body weight per month which is a PTWI of 17.5 pg/kg.
2. According to the CDC the average American weighs approximately [(199.8lbs (M) +170.8lbs (F)) ÷ 2] = ~185lbs (84kg).
3. Based on this, the average American should not consume more than (17.5 * 84) = 1,470pg of Dioxin/Dioxin like compounds in a week, which comes out to 210pg/day.
4. Applying the conservative limit of 25% of daily intake from seaweed, the maximum Dioxin/Dioxin like compound exposure from one serving of seaweed should be: 210pg/day ÷ 4 = 52.5pg/day.
5. With a serving size of 15 g dried seaweed (0.015kg), the maximum dioxin/dioxin like compound concentration in seaweed should be set to 52.5pg/day ÷ 0.015kg = 3,500pg/kg dry weight.

So, the threshold for maximum amount of dioxin/dioxin like compounds in dried seaweed based on these assumptions would be 3,500pg/kg.

Calculations Based on Minimal Risk Level (MRL)

The following examples demonstrate how seaweed contaminant thresholds can be calculated using cited Minimum Risk Levels (MRLs). These calculations are intentionally conservative, assuming daily consumption of 15 grams of dried seaweed and limiting exposure to 25% of the recommended intake. The exposure limit of 25% the daily recommended intake was chosen to account for the fact that seaweed is not the sole source of dietary exposure. Consumers may also be exposed to contaminants through other foods, so this conservative approach helps ensure overall intake remains within safe limits. The equations can be adjusted to more accurately reflect your intended serving sizes, intended consumer, and actual consumption patterns. Adult body weight (84 kg) is based on Centers for Disease Control and Prevention (CDC) averages for U.S. adults, and the MRL for each compound is taken from the most authoritative available source for that chemical—e.g., CDC.

$$\frac{MRL\ (mg) \times\ Body\,Weight\ (kg)}{7} = mg\ consumed\ /\ day$$

$$\frac{max\,mg\ consumed/day}{4} = \frac{1}{4}\ of\ daily \max\ (mg)$$

$$\frac{\frac{1}{4}\ of\ daily \max(mg)}{serving\ size\ (kg)} = \boldsymbol{mg/kg\ threshold\ for\ ingredient\ or\ final\ product}$$

Polyfluoroalkyl Substances (PFAS)

1. This calculation was based on perfluorooctane sulfonic acid (PFOS) specifically since it had the lowest MRL of 2x10-6mg/kg/day.
2. The CDC has calculated a MRL of 2x10-6mg/kg/day (0.000002mg/kg/day) for PFOS, which is the lowest of all PFAS assessed.
3. According to the CDC the average American weighs approximately 84kg [(199.8lbs (M) +170.8lbs (F))/2] = ~185lbs (84kg).
4. Based on this the average American should not consume more than (84 * 0.000002 mg) = 0.000168mg per day.
5. Applying the conservative limit of 25% of daily intake from seaweed, the maximum PFOS exposure from one serving of seaweed should be (0.000168mg/day ÷ 4) = 0.000042mg/day.

6. With a serving size of 15 g dried seaweed (0.015kg), the maximum PFOS concentration in seaweed should be set to (0.000042mg ÷ 0.015kg) = 0.0028mg/kg dry weight.

So, the threshold for maximum amount of PFOS in dried seaweed based on these assumptions would be 0.0028mg/kg or 2.8x10-3mg/kg.