Seaweed Production and Processing in Connecticut: A Guide to Understanding and Controlling Potential Food Safety Hazards



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## Note to Users:

This document was developed by Connecticut Sea Grant in partnership with the Connecticut Department of Agriculture Bureau of Aquaculture and provides recommended guidelines on food safety practices to minimize hazards (biological, chemical, and physical) associated with the production, storing, handling, processing and transportation of seaweed in Connecticut. It is the responsibility of the user of this document to verify that these guidelines are appropriate for their operation and that their own procedures meet with the current requirements.

This guidance document represents the Connecticut Department of Agriculture, Bureau of Aquaculture's (DABA) assessment of hazards, critical control points and critical limits associated with the production of seaweed in Connecticut at this time. It will be modified as additional information becomes available. It is presumed that the reader of this document has completed the nationally standardized seafood HACCP (Hazard Analysis and Critical Control Points) training. In Connecticut, all aquaculture producers are required to be trained in the application of seafood HACCP principles and to apply this knowledge when developing and implementing both a HACCP plan and a sanitation program for their operations. This document is to be used as a companion manual to the 4th edition of the *Food and Drug Administration's (FDA) Fish and Fishery Products Hazards and Controls Guidance*, hereafter referenced as the FDA Hazards Guide. Throughout this document (hereafter referenced as the Seaweed Guide), the reader will be directed to specific sections of the FDA Hazards Guide which go into further detail regarding the topic or hazard in question. Unless otherwise stated, please assume information regarding significance, Critical Control Points (CCPs), Critical Limits (CLs), and recommendations provided in the FDA Hazards Guide FDA Hazards Guide are applicable to **Connecticut** seaweed production, processing, and sale. Some chapters of the 2011 FDA Hazards Guide have been updated and should be reviewed.

For information about <u>seafood HACCP training courses</u> offered by Connecticut Sea Grant, email <u>nancy.balcom@uconn.edu</u>.

For more information about production techniques for seaweed, please refer to the <u>New England</u> <u>Seaweed Culture Handbook: Nursery Systems</u>. Companion <u>videos</u> are also available. Another useful resource is the Ocean Approved <u>Kelp Farming Manual</u>.

The consumption of seaweed as a sea vegetable is an emerging trend in the United States and its production does not currently fall under any species-specific federal regulation. As new data related to the safety of seaweed for human consumption emerge, it is anticipated that regulatory oversight may ultimately fall under either the 1997 FDA Seafood HACCP regulation (21 CFR Part 123) or the FDA Food Safety Modernization Act (FSMA) – Preventive Controls rules.

Cover photo: Culinary instructor and chef Jeff Trombetta holds up raw and packaged sugar kelp grown in Long Island Sound. Credit: Anoushka Concepcion

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# Introduction

Seaweeds are multi-cellular macroalgae found in both marine and freshwater environments. They come in a wide variety of shapes and sizes and are found in almost all oceans. There are three (3) types of seaweeds: Brown (Phaeophyta), Red (Rhodophyta), and Green (Chlorophyta). The majority of brown and red seaweeds are strictly marine and most are edible. Green seaweeds are mostly freshwater and generally not consumed as a food. Seaweed and components derived from seaweed have many applications in addition to food and food products and are utilized by a variety of industries. As a source of hydrocolloids (agar, alginate, and carrageenan), seaweeds can be used as fertilizer, animal and fish feed, biofuels, pharmaceuticals and cosmetics (McHugh 2003; Sahoo and Yarish 2005; Johnson et. al. 2014).

Seaweed is utilized in dishes such as sushi, salads and dried snacks. Seaweed provides a wide range of nutritional and health benefits and have been marketed as a "super food" containing dietary fiber, omega-3 fatty acids, protein, essential amino acids, calcium, iodine, magnesium and vitamins A, B, C and E (Fleurence 1999; Fujiwara-Arasaki et. al. 1984; MacArtain et. al. 2007; Rajapakse and Kim 2011).

Global seaweed production has an estimated value between \$8 and \$10 million (USD) (Grand View Research 2016) with the majority of aquaculture occurring in Asia (FAO 2018). U.S. demand for seaweed is estimated at more than \$35 million and supplied through imports. Although domestic production has traditionally been a very small scale, wild-harvest industry, interest in the cultivation of seaweed is growing.

# Need for Guidance

Safe handling and processing of seafood is regulated by the U.S. Food and Drug Administration (FDA) which also provides food safety guidance for the seafood industry through the Seafood HACCP Alliance and the FDA Hazards Guide. Production and processing of seaweed are not covered by this guidance. FDA currently regulates seaweed as a GRAS (generally recognized as safe) food under the category of spices (FDA 2001, 2003), however there is no guidance related to the consumption of seaweed in larger amounts as a sea vegetable. In the absence of federal regulatory oversight of domestic seaweed production and processing for human consumption, the Connecticut Department of Agriculture, Bureau of Aquaculture (DABA)—the lead state regulatory agency for aquaculture—requires all seaweed producers to be trained in the development of a food safety management program that includes sanitation and the application of HACCP principles to seafood processing.

This training can then be applied to seaweed production and processing. As with any seafood product, critical control points and critical limits must be determined and corrective action, verification, monitoring and record-keeping procedures developed to support the control of any identified hazards throughout their process, from harvest to sale to the consumer. Seaweed producers in Connecticut are required to submit a HACCP plan to DABA prior to being licensed as an Aquaculture Seaweed Producer. This plan should build upon a strong sanitation program. They must also be inspected and obtain a Wholesale License to Manufacture Food from the Connecticut Department of Consumer Protection.

Connecticut Sea Grant and DABA have developed this Seaweed Guide to help growers produce and process seaweed safely. The content of this document is based upon key resources used in seafood and general food safety, which will be referenced throughout. In addition, this Seaweed Guide follows the

format of the FDA Hazards Guide in presenting species- and process-related hazards that should be considered by the producer.

Until federal guidance specific to seaweed production and processing in the U.S. is developed, the State will continue to require all seaweed producers and processors in Connecticut to develop seaweed HACCP plans based on the requirements outlined in this Seaweed Guide.

# Section I – Sanitation Standard Operating Procedures

As with seafood HACCP, it is important to develop and implement an effective sanitation program for your operation with standard operating procedures. These procedures should address the relevant eight key sanitation conditions or areas called out in the 1997 FDA seafood regulation. As a reminder, these are:

- 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 conditions
- 8. Exclusion of pests

For guidance on developing sanitation standard operating procedures (SSOPs), please refer to Chapter 2 in the 6<sup>th</sup> edition (2017) of the <u>Hazard Analysis and Critical Control Point Training Curriculum</u>. Other resources include the <u>Sanitation Control Procedures for Processing Fish and Fishery Products</u> manual, and the following new appendices in the FDA Hazards Guide, <u>Appendix 8 – Procedures for Safe and</u> <u>Sanitary Processing and Importing of Fish and Fishery Products</u>, <u>Appendix 9 – Allergen Cross-Contact</u> <u>Prevention</u> and <u>Appendix 10 – Cleaning and Sanitation for the Control of Allergens</u>.

# Section II – Analyzing Hazards

To get started, as taught in the seafood HACCP training courses, it is important to develop a process description and process flow diagram for seaweed production and process. By taking these steps, information needed to conduct a hazard analysis and complete a HACCP plan will be easily accessible.

A review of preliminary steps in developing a HACCP plan is found in Chapter 4 of the <u>Hazard Analysis</u> <u>and Critical Control Point Training Curriculum</u>. Hazard analysis is covered in Chapter 5.

Following the guidance contained in the FDA Hazards Guide and <u>21 CFR 117 Good Manufacturing</u> <u>Practices</u>, a hazard analysis approach has been undertaken by DABA to identify potential significant food safety hazards associated with seaweed produced and processed with the intention of being sold as an "approved" food source for human consumption. The general supply chain for seaweed intended as an "approved" food source is described in Figure 1.

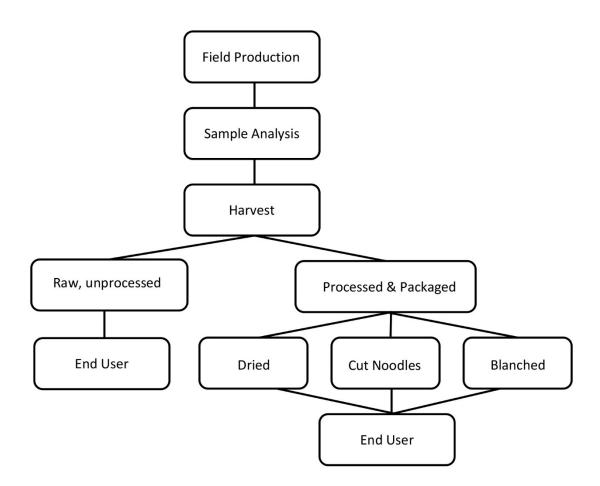


Figure 1. General supply chain for seaweed intended as an "approved" food source

Species of seaweed currently approved for cultivation and sale in Connecticut are the sugar kelp (*Saccharina latissima*) and the red algae *Gracilaria tikvahiae*. As in the FDA Hazards Guide, hazards in this Seaweed Guide have been categorized as *species-related hazards* or *process-related hazards*, with further classification as to whether they are biological, chemical or physical hazards. These hazards could potentially affect the safety of seaweed (sea vegetable) food products in the absence of controls.

Each seaweed producer or processor must conduct a hazard analysis. Potential significant hazards neither covered currently in this Seaweed Guide nor the FDA Hazards Guide may be relevant to certain sea vegetable products under specific circumstances. Producers and processors should be alert to new or emerging problems (e.g., the occurrence of natural toxins in seaweed not previously associated with those toxins), and address them accordingly.

The following state agencies are involved in assessing aquaculture food safety hazards by adhering to existing federal standard parameters tested in food:

1) **Connecticut Department of Public Health** – conducts analyses for the presence of microbial pathogens of concern including *Vibrio, Salmonella, E.coli O157:H7, Shigella* and total and fecal coliform count.

2) **Connecticut Agricultural Experiment Station** – conducts analyses for amount of pesticides; PCBs; and heavy metals - arsenic (As), cadmium (Cd), chromium (Cr), copper (Cu), mercury (Hg), nickel (Ni), lead (Pb), zinc (Zn) and Nicotine found in food.

3) **Connecticut Department of Agriculture, Bureau of Aquaculture (DABA)** – reviews the analyses and issues licenses for seaweed cultivation and sale based on the results.

Chemical and microbiological analyses of seaweed cultivated for human consumption in Connecticut are currently required by the DABA prior to marketing and sale of seaweed each growing season. These testing services are currently provided by state regulatory agency laboratories, however the required analyses may also be performed by a private environmental laboratory certified by the State of Connecticut to provide environmental testing services, or an equivalently certified food laboratory approved for this testing by DABA. The <u>Connecticut Department of Public Health Environmental</u> <u>Laboratory Certification Program</u> website provides information on which private labs are currently certified.

DABA requires testing results to be submitted for review **at least one month prior** to the desired sale of seaweed. If a private laboratory is used for testing, be sure to discuss the turn-around time involved for the testing and analysis of seaweed samples in order to receive and submit the results in a timely manner as required. Producers utilizing the state laboratories for testing services must request analysis of seaweed or seaweed products six to eight (6 to 8) weeks prior to the desired first date of harvest.

## A. Species-Related Hazards

This section covers known potential significant hazards associated with the species of seaweed currently being cultivated in Connecticut. While for seafood, potential species-related hazards may be related to feeding habits, physiology or the harvest environment, for seaweed, potential species-related hazards are closely tied to the grow-out waters. For *Gracilaria*, grow-out could take place on longlines in Long Island Sound or in a recirculating tank.

Although national standards for shellfish production require shellfish growing areas to meet certain water quality standards to be used for direct market harvest of shellfish, at this time there is no equivalent national standard for seaweed growing areas for direct market harvest. Therefore, in Connecticut, the <u>shellfish growing area classification system</u> is applied to aquaculture food production in Long Island Sound intended for direct consumption, including seaweed production.

DABA requires that seaweed production for food be conducted in waters classified for shellfish as Approved or Conditionally Approved (Open Status). As for shellfish, water quality of the harvest waters will "prevent, eliminate or reduce to an acceptable level" any potential biological or chemical hazards. Waters classified as Prohibited or Restricted Growing Areas may be utilized for growing seaweed for non-food uses such as biofuels or fertilizers, or if the seaweed will be subsequently processed in a way that eliminates any pathogen hazard (e.g., validated study). The determination and approval of appropriate growing areas for production will be made on a case-by-case basis; additional validation testing may be required in order to evaluate effectiveness of post-harvest processing used to reduce or eliminate microbial contamination. Table 1. Potential Significant Species-related Hazards

	Potential Species-related Hazards			
	Biological Chemi		nical	
Species Market Name	Pathogens from Harvest Area Section III	Environmental Contaminants from the Harvest Area Section IV	Natural Toxins from the Harvest Area Section V	
Sugar kelp (Saccharina				
<i>latissimi)</i> – longline	$\checkmark$	✓		
culture				
<i>Gracilaria tikvahiae</i> – Iongline culture	~	~	~	
Gracilaria tikvahiae — tank culture		~		

## B. Process-related Hazards

Currently, the same FDA definition for "processing" applied to seafood can be applied to seaweed or sea vegetable culture. Processing includes handling, storing, preparing, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading or holding.

In Connecticut, seaweed for human consumption can be sold as a raw commodity, dried product, or blanched (blades, stipes or cut noodles) and put under cold temperature control. "Blanching" is a process in which seaweed blades, stipes or noodles are placed in boiling water, removed after a brief amount of time and put into ice water or under cold running water to stop the cooking process. The purpose of blanching is to retain quality over time. It should NOT be considered a kill step for pathogens.

Potential biological, chemical and physical hazards associated with the handling, storage, and/or processing of seaweed destined for human consumption must be taken into account. They depend on type of processing, final product form, and intended use/consumer. Seaweed processors must be inspected and obtain a <u>Wholesale License to Manufacture Food</u> from the Connecticut Department of Consumer Protection. Wherever Critical Control Points (CCPs) and Critical Limits (CLs) are not included for these potential hazards in this Seaweed Guide, seaweed processors are encouraged to work with the Connecticut Department of Consumer Protection, Food & Standards division, to determine appropriate critical control points, control measures and critical limits.

Potential significant process-related hazards are provided in Table 2. Note that as in seafood HACCP, the hazards depend not only on the finished product form but also the packaging type. This table will be updated as new product forms are developed.

Table 2. Potential	Significant	Process-rel	ated Hazards
	olonnoante	1100000101	ated mazarao

				ential Process	s-relate	ed Hazards		
			Biolo	ogical		Chemical	Phy	sical
Finished Product Form	Package Type	Pathogenic Bacterial Growth due to Temperature Abuse	C. botulinum Toxin	Pathogenic Bacterial Growth & Toxin Formation due to Temperature Abuse	Mold, Yeast, Fungi	Allergens	Metal	Glass
	Section:	VI	VII	VIII	IX	Х	XI	XII
Raw agricultural seaweed commodity	Unsealed bag or box	•				•		
Uncooked whole seaweed	Reduced oxygen packaged (e.g., mechanical vacuum, hermetically sealed)	~	V			~		
Uncooked whole seaweed, frozen	Reduced oxygen packaged (e.g., mechanical vacuum, hermetically sealed)	•	v			~		
Dried	All			•	✓	>		•
Blanched sugar kelp blades	Reduced oxygen packaged (e.g., mechanical vacuum, hermetically sealed)	•	•			~		
Blanched sugar kelp blades	Other than reduced oxygen packaged	•				~		
Blanched sugar kelp noodles or stipes	Reduced oxygen packaged (e.g., mechanical vacuum, hermetically sealed)	~	•			~	>	
Blanched sugar kelp noodles or stipes	Other than reduced oxygen packaged	~				~	>	
Blanched <i>Gracilaria</i>	Reduced oxygen packaged (e.g., mechanical vacuum, hermetically sealed)	~	•			~		
Blanched <i>Gracilaria</i>	Other than reduced oxygen packaged	•				~		

Information about species-related and process-related hazards are provided in subsequent sections, including information on critical control points, control strategies and critical limits.

# Section III - Pathogens from the Harvest Area

Pathogens from the harvest area are a biological hazard (<u>Chapter 4 in the FDA Hazards Guide</u>). As with shellfish, pathogens from the harvest area are considered to be potentially SIGNIFICANT because the seaweed may be intended for use as a raw product for human consumption, without any additional processing step that could serve as a kill step. The two control strategies provided for shellstock in Chapter 4, Source Control (primary processor) and Shellstock temperature control (both primary and secondary processors), can serve as models on which control strategies for seaweed source control and temperature control can be built.

The quality of the harvest (source) waters of the seaweed is therefore critically important, and is why in Connecticut, the <u>shellfish growing area classification system</u> is applied to seaweed production intended for direct consumption. DABA requires that seaweed production for human consumption be conducted in waters classified as Approved or Conditionally Approved (Open Status) for shellfish. This hazard is controlled through the Seaweed Producer Licensing Process whereby seaweed licenses will only be designated in an Approved or Conditionally Approved (Open Status) area. This prohibits market harvest from waters that may be subjected to bacterial and viral contamination of animal or human fecal origin, from sources such as sewage and storm water. Once harvested, time/temperature control of the seaweed product will prevent the growth of pathogens to problematic levels, addressing potentially seasonal hazards associated with naturally occurring pathogenic bacteria, such as *Vibrio*<sup>1</sup>.

As previously discussed, DABA requires samples of seaweed produced for food in Connecticut to be analyzed for standard microbial parameters prior to market harvest. Pathogens of concern include *Vibrio, Salmonella, E.coli* O157:H7 and *Shigella, Norovirus,* and Hepatitis A. Total and fecal coliform count are also used as indicators of microbial contamination of the product. Negative results for the pathogens are required for the seaweed product to be sold as an "approved" food source in Connecticut. Screening indicators (total and fecal coliform) may be positive; these results will be evaluated on a case-by-case basis. DABA-proposed edible seaweed limits and reference levels for microbial pathogens are listed in <u>Appendix 2</u>.

## Critical Control Point (CCP) 1: Seaweed Source Control

Pathogens from the harvest area are controlled at the source by identifying growing areas that have been shown to have minimal presence of microbial pathogens (i.e., reduced to an acceptable level) in accordance with the <u>shellfish growing area classification system</u>. Access to Approved or Conditionally Approved (Open Status) growing areas is required for the licensing of seaweed for food in Connecticut via the Seaweed Producer licensing process.

**Critical Limit (CL):** All seaweed must be harvested from Approved or Conditionally Approved Growing Areas (Open Status).

## Critical Control Point (CCP) 2: Seaweed Temperature Control

Due to the natural occurrence of potential pathogens (biological hazard) present in approved or conditionally approved growing areas, inadequate handling and storage of seaweed harvested from

these growing areas could promote pathogen growth. In the absence of time/temperature control, minimal levels of pathogens can multiply to levels that may increase the risk of foodborne illness in products consumed raw. For example, *Vibrio* sp. will grow at temperatures that are 50°F or higher. Seaweed should be quickly placed under temperature control (ice or mechanical refrigeration) to maintain food safety upon harvest.

**Critical Limits (CL):** Harvested seaweed must be placed under temperature control (ice\*/gel packs\*\* or mechanical refrigeration set at  $\leq$  41°F) within two (2) hours of when harvest began.

\*If ice is used to control temperature, a barrier should be used between the seaweed and the ice (e.g., plastic bag) to prevent fresh water ice melt from adversely affecting the quality of the seaweed. \*\*If gel packs (clean and sanitized) are used as cooling media, a sufficient quantity should be used to ensure the seaweed is adequately chilled.

# Section IV - Environmental Contaminants from the Harvest Area

Environmental contaminants (PCBs, heavy metals, pesticides) are chemical hazards (<u>Chapter 9 in the</u> <u>FDA Hazards Guide</u>). Until our understanding of environmental chemical concerns related to seaweed improves, seaweed produced in Connecticut for human consumption will be sampled for levels of deleterious environmental chemicals including heavy metals, PCBs and pesticides. While these contaminants are generally not associated with food-borne illness outbreaks, they can cause health risks such as carcinogenic and mutagenic effects that are associated with long-term exposure.

Three relevant control strategies from Chapter 9 that could serve as models are Results of testing and monitoring (primary processor), Chemical contaminant testing (primary processor) and Source control for molluscan shellfish (primary and secondary processors). These strategies should incorporate the following DABA requirements when developing control strategies for environmental contaminants in seaweed for human consumption.

# A. Heavy metals

Food standard codes in other countries and regions, including those of France, Australia and New Zealand, have established limits for certain heavy metals (i.e. toxic minerals, including arsenic, lead, cadmium, tin, mercury and iodine) specific to seaweed. In the absence of U.S. guidance for seaweed, the limits established in the France Food Code are being used to assess the heavy metal levels contained in seaweed produced in the Connecticut growing waters. DABA-proposed edible seaweed limits and reference levels for heavy metals are listed in <u>Appendix 3</u>.

# B. Pesticides

The <u>Code of Federal Regulations, Title 40: Protection of Environment PART 180—TOLERANCES AND</u> <u>EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD Subpart C—Specific Tolerances</u> is used to provide tolerance levels for pesticide chemical residues allowed in food commodities. Based on this guidance, tolerance levels for pesticides have been adopted for seaweed produced in Connecticut pesticide levels should be non-detectable. However, DABA will make recommendations on a case-bycase basis if seaweed samples contain detectable levels of pesticides. DABA-proposed edible seaweed limits and reference levels for pesticides are listed in <u>Appendix 4</u>.

## C. PCBs

PCBs or polychlorinated biphenyls are a group of compounds used in industrial products and chemicals. Determined to be hazardous to human and environmental health, their use was banned in 1979. However, they remain widespread and persistent in the environment. DABA-proposed edible seaweed limits and reference levels for PBCs are listed in <u>Appendix 5</u>.

Environmental contaminants are considered potentially SIGNIFICANT chemical hazards because certain species of seaweeds exhibit a high affinity for accumulating heavy metals and other contaminants in their tissues. *Gracilaria* may be grown on longlines in Long Island Sound but also in land-based recirculating tanks containing water that may be treated with fertilizer. There are no additional processing steps that could prevent or eliminate this hazard. The best option is to minimize exposure to environmental contaminants, reducing the potential hazard to acceptable levels.

## Critical Control Point (CCP): Source Control for Seaweed

Environmental contaminants including heavy metals, pesticides and PCBs from the harvest area are controlled at the source by identifying growing areas that have been shown to have minimally-acceptable levels of chemicals (<u>shellfish growing area classification system</u>). Just as for potential pathogenic hazards from the harvest areas, DABA requires that growers have access to Approved or Conditionally Approved (Open Status) growing areas for the licensing of seaweed for food in Connecticut via the Seaweed Producer licensing process. This reduces the potential hazard of chemical contaminants from the environment to an acceptable level.

**Critical Limit (CL):** All seaweed must be harvested from Approved or Conditionally Approved Growing Areas (Open Status).

# Section V - Natural Toxins from the Harvest Area

Other countries and other states in the U.S. have reported food-borne disease outbreaks associated with naturally occurring seaweed toxins, including outbreaks related to the consumption of several *Gracilaria* species<sup>2</sup>. These toxins are often heat-stable and even if seaweed is cooked sufficiently to kill pathogens, the toxin may remain stable. These toxins have the ability to cause severe illness or even death.

Plankton and shellfish tissue monitoring for toxins in Long Island Sound is ongoing, as required by the Connecticut DABA biotoxin contingency plan which is in place for shellfish growing areas. The potentially significant hazard of natural toxins is just beginning to be investigated in Long Island Sound. Although preliminary investigations into the presence of the blue-green algae *Lyngbya* in *Gracilaria* in Long Island Sound have not identified the toxin-producing species of concern, there is insufficient data available currently to eliminate this hazard completely. There may be additional toxins associated with either the seaweed tissue itself, or with hazardous algal blooms impacting Long Island Sound harvest waters. Further research is needed to determine if natural toxins are a concern in seaweed production in Long Island Sound.

With respect to the hazard of natural toxins (<u>Chapter 6 in the FDA Hazards Guide</u>), the hazard MAY be potentially SIGNIFICANT for *Gracilaria* cultivated in coastal waters of Connecticut, warranting further

investigation. The control strategy in Chapter 6 that could serve as a model for developing a control strategy for *Graciliaria* and natural toxins (primary processors) is Source control for molluscan shellfish.

# Critical Control Point (CCP): Source Control for Seaweed

Until sufficient information is collected to make a final determination on the significance of this hazard, natural toxins from the harvest area will be controlled through source water classification in the same manner as for pathogens and environmental contaminants. *Gracilaria* must be cultivated in waters classified as Approved or Conditionally Approved to reduce the potential hazard (<u>shellfish growing area</u> <u>classification system</u>). This is required for the licensing of seaweed for food in Connecticut via the Seaweed Producer licensing process.

**Critical Limit (CL):** All seaweed must be harvested from Approved or Conditionally Approved Growing Areas (Open Status).

# Section VI – Pathogenic Bacterial Growth due to Temperature Abuse

Pathogenic bacteria are naturally occurring in the environment. Recommendations have been provided to mitigate the potentially significant effects of biological hazards (pathogens) through source control related to harvest waters and time/temperature control immediately post-harvest. If proper time/temperature critical limits are not maintained through all subsequent critical processing and storage control points, pathogens could begin to multiply, creating a potentially SIGNIFICANT hazard, particularly if the seaweed will be consumed raw (<u>Chapter 12 in the FDA Hazards Guide</u>).

Control strategies included in Chapter 12 that may serve as useful models for producers/processors developing control strategies for seaweed to prevent pathogenic bacterial growth due to temperature abuse are Transit control (secondary processor), Refrigerated storage and refrigerated processing control (primary and secondary processors), Cooling after cooking control (primary and secondary processor) and Unrefrigerated processing control (primary and secondary processor).

Critical Control Point (CCP): Seaweed Temperature Control

Temperature control must be maintained during processing and storage to prevent the growth of pathogens. Mechanical refrigeration at  $\leq$  41°F, ice\* or gel packs\*\* may be used to maintain food safety.

**Critical Limits (CL) 1:** Harvested seaweed must be maintained under temperature control (ice\*/gel packs or mechanical refrigeration set at  $\leq 41^{\circ}$ F).

\*If ice is used to control temperature, a barrier should be used between the seaweed and the ice (e.g., plastic bag) to prevent fresh water ice melt from adversely affecting the quality of the seaweed. \*\*If gel packs (clean and sanitized) are used as cooling media, a sufficient quantity should be used to ensure the seaweed is adequately chilled.

Critical Limits (CL) 2: Harvested seaweed must not be exposed to temperatures >40°F for more than 2 hours.

# Section VII - Clostridium botulinum Toxin Formation

Spores of the pathogenic bacteria, *Clostridium botulinum*, are naturally occurring in the marine and estuarine environment. It is a spore-forming bacteria that requires anaerobic conditions to grow (reduced oxygen packaging, for example). This hazard (<u>Chapter 13 in the FDA Hazards Guide</u>) could be considered potentially SIGNIFICANT for seaweed products that are raw or blanched and then packaged in a modified or reduced atmosphere package (e.g., vacuum packed). Typically multiple controls or barriers are required to prevent the formation of the *C. botulinum* toxin. Control strategies included in Chapter 13 that could serve as relevant models include Refrigeration with TTI or Frozen with labeling.

# Section VIII – Pathogenic Bacteria Growth and Toxin Formation due to Inadequate Drying

Many seaweed products are processed to be marketed as a dried, shelf-stable product. Properly dried products are usually considered shelf-stable and are often stored and distributed unrefrigerated. Water activity levels of 0.85 or lower will prevent the growth and toxin formation of all pathogenic bacteria, including *Staphylococcus aureus* and *Clostridium botulinum*. For dried products, Staph is considered the pathogen to target, as it can grow at a lower water activity than other pathogenic bacteria (<u>Chapter 14</u> in the FDA Hazards Guide). Packaging type and final water activity level have bearing on whether a dried product is considered shelf stable or requires storage under refrigerated conditions. This hazard is considered potentially SIGNIFICANT for dried seaweed products. The control strategy in Chapter 12 that could serve as a relevant model for developing a control strategy for a dried seaweed product is Control by drying (primary and secondary processors).

## Critical Control Point (CCP): Seaweed drying step

# Critical Limit (CL): A water activity (W<sub>a</sub>) level of 0.85 or below\*

\*Rather than trying to directly measure water activity, a series of critical limits more easily measured could collectively demonstrate that the dried product achieves a W<sub>a</sub> of 0.85 or lower. These critical limits include drying time, input/output air temperature, humidity, velocity, and thickness of the seaweed. Determination of the necessary critical limits would require a validated study. See model example #2 in Section

# Section IX - Contamination and Growth of Molds, Yeast and Fungi

For dried shelf-stable products, a heat treatment, addition of chemical additives, further drying or other treatment may be necessary to inhibit or eliminate spoilage organisms such as mold (<u>USDA's</u> <u>Introduction to the Microbiology of Food Processing</u>). It may be appropriate for seaweed processors to perform end-product testing of processed seaweed to enumerate molds and yeasts.

The risk of pathogenic bacteria proliferation is highly dependent on the process that is used to prepare and package the seaweed. This hazard is considered potentially SIGNIFICANT for shelf-stable seaweed products. It is recommended producers conduct or commission food processing validation testing to evaluate the specific hazards that may be associated with the process under consideration. Please contact the <u>Connecticut Department of Consumer Protection Food Standards Division</u> for more information.

# Section X – Allergens

Seaweed of itself is not considered an allergen. However, seaweed cultivated on longlines in Long Island Sound could be exposed to fouling organisms, including crustacean shellfish, one of the top eight allergens (*Chapter 19 in the FDA Hazards Guide*). Fouling crustaceans may contain the protein tropomyosin which is known to cause ingestion-related allergic reactions; this potential "hidden" crustacean shellfish allergen hazard could be present in raw or dried seaweed products (Motoyama et. al 2007). For this reason, the crustacean shellfish allergen is considered a potentially SIGNIFICANT chemical hazard for seaweed.

## Critical Control Point (CCP): Seaweed Product Labeling

**Critical Limit (CL):** All finished product packages must bear a label declaring contents may contain an allergen commonly found in crustacean shellfish

## Section XI – Metal

Some processing of sugar kelp can include a mechanical cutting operation (i.e., stipe removal from kelp or kelp noodle processing). Metal, a physical hazard, is considered potentially SIGNIFICANT for such processed seaweed products (*Chapter 20 in the FDA Hazards Guide*).

## Critical Control Point (CCP): Cutting step for seaweed

Critical Limit (CL): Perform routine maintenance on knives or kelp noodle cutting machine

## Section XII – Glass

Glass can be used for storage and/or packaging of dried powdered sugar kelp or *Gracilaria*. Use of glass for packaging or storage is considered a potentially SIGNIFICANT physical hazard (<u>*Chapter 21 in the FDA</u>* <u>*Hazards Guide*</u>).</u>

## Critical Control Point (CCP): Packing step

Critical Limit (CL): Perform routine visual inspection of all individual glass containers

# Section XIII – Seaweed Production Licenses and Associated Requirements

Applications are available on the CT Department of Agriculture Bureau of Aquaculture's website.

## 1. Raw Agricultural Seaweed Commodity

Raw Agricultural Seaweed Commodity, or fresh seaweed, is an approved species, in its raw, whole and unprocessed form. It is sold by the agricultural unit (i.e. sold by the blade), not by weight or volume and in an unsealed bag or box. The intended use of raw seaweed is to be eaten as is or cooked or processed by the end-user.

In Connecticut, a local seaweed seed source is defined as originating from a Connecticut hatchery and utilizing reproductive tissue harvested from the waters of Long Island Sound. In order to offer a Raw

Agriculture Seaweed Commodity for sale in Connecticut, a producer must apply for and obtain an Aquaculture Seaweed Producer License.

## Aquaculture Seaweed Producer License

A. The following documents must be submitted with the Aquaculture Seaweed Producer License application:

- Process document and flow chart outlining steps from harvest to sale (refer to Figure 2, Figure 3, and Figure 4 in Section XIV)
- Fertilizer/type and ingredients if used in tank cultivation (provide copy or photo of label)
- Well water test results if well water is used for processing (well water must be tested twice a year; testing requirement does not apply to public water supply)
- Detailed facility diagram/plan/schematic (for land-based facilities)
- HACCP plan for seaweed production and/or processing
- Sanitation Standard Operating Procedures (SSOPs) and/or Best Management Practices (BMPs) for seaweed production
- Written recall plan: Allows product to be traced back and recalled in case of illness or potential risk
- Example of label/tag/identification for seaweed product

B. Additional requirements for obtaining an Aquaculture Seaweed Producer License

Seaweed producers are required to provide analytical results for food safety analyses of seaweed, including testing for chemical and microbiological contaminants and bacterial indicators, to DABA prior to the sale of any seaweed product intended for human consumption. A producer has two options for conducting these sample analyses, utilizing a) the state laboratory services for testing or b) a state-certified private environmental laboratory.

<u>If utilizing state laboratory services for testing</u>: Prior to harvest of seaweed product, sample collection and analyses for microbiological and chemical analysis must be scheduled by contacting DABA. Samples should be scheduled six to eight (6 to 8) weeks in advance of anticipated first date of harvest.

*If utilizing a state-certified private environmental laboratory:* Prior to harvest of seaweed product, DABA shall review the certification status of the private laboratory and evaluate the analytical results of the testing prior to allowing the product to be offered for sale.

DABA should be notified at least six (6) weeks in advance of the anticipated first date of harvest. It is the producer's responsibility to confirm that the turn-around time for the analyses will allow for DABA review prior to the anticipated first date of harvest. Producers should be aware of the potential delays in laboratory reporting and plan accordingly to allow adequate time for review.

## 2. Processed Seaweed Commodity

Processed Seaweed Commodity is defined as seaweed that is an approved species in a processed form (cut, blanched, cooked, dried, frozen), may be sold packaged in a sealed bag, and may be sold by weight or volume (e.g., by the ounce). In consideration of the regulatory structure in Connecticut, raw seaweed

that has been packaged in any way other than what is allowed for a Raw Agricultural Commodity is considered to be a processed seaweed commodity and is subject to additional Connecticut Department of Consumer Protection (CT DCP) licensing.

Local seaweed seed source is defined as originating from a Connecticut hatchery and utilizing reproductive tissue harvested from the waters of Long Island Sound.

Processed seaweed must meet all requirements of a raw agricultural seaweed commodity in addition to the requirements below.

Additional analytical testing may be required by the regulatory agencies depending on the type of processing that the seaweed will undergo.

Each operation that intends to produce seaweed to be sold as a Processed Seaweed Commodity must obtain a Seaweed Producer License from DABA as well as a Food Manufacturing Establishment License (FME) from the CT DCP.

Food Manufacturing Establishment License (FME)

<u>Requirements for Manufacturing Retail and Wholesale Food Products</u> must be followed:

Zoning approval or equivalent town approval

If using a shared facility, operator must provide documentation granting permission to use that facility from owner of the shared kitchen, including days and times facility will be used (e.g., lease agreement)

Water source – if utilizing a private well, an annual water analysis will be required, maintained as record on file and presented upon request

Food safety training certification

If the operation or facility is solely a seaweed processor and subject to <u>Subparts A, B and F for 21</u> <u>CFR 117</u>, food safety training is required. If the processor and subject to <u>Subpart C in CFR 117</u>, training in Preventive Controls Qualified Individual (PCQI) certification may be required. If processing a seaweed product that is subject to Seafood HACCP under <u>21 CFR 123</u>, but NOT subject to Subpart C in CFR 117, Seafood HACCP training would be adequate to fill the training requirements.

Local health department approval may be required depending on if the food manufacturer is a retail or wholesale firm; contact the local health department or health district for town specific regulations

Wholesale Food Manufacturers shall also register with the FDA in accordance with the Food Safety Modernization Act (FSMA) registration requirements

Additional Requirements to Manufacture Wholesale Food Products

An FME license is required for the production of prepared wholesale food products. "Prepared" means a process of canning, cooking, freezing, dehydrating, milling, repacking or cutting.

#### Food Labeling

Under Connecticut law, packaged food sold in the state must be labeled in accordance with the Federal Food Drug and Cosmetic Act, the Federal Fair Packaging and Labeling Act, and the Uniform Packaging and Labeling Regulation as adopted by the National Conference of Weights and Measures.

Food labeling shall include but not be limited to the following items:

- common name of the product;
- list of ingredients in order of predominance;
- net weight or volume;
- name and address or phone number of producer or distributor.

# Section XIV. Process Description and Flow Diagrams

1. Raw Agricultural Commodity

Description: A seaweed species, in its raw, whole and unprocessed form, sold by the agricultural unit, not by weight or volume (i.e. sold by the blade), and in an unsealed bag or box.

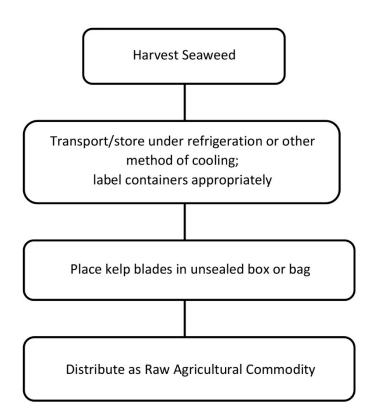


Figure 2. Example process flow diagram for seaweed as a Raw Agricultural Commodity

#### 2. Kelp noodles

Description: A kelp species, washed in fresh water to remove debris, blanched, then cut into strips (noodles) using a cutting machine. Strips are then packaged, sealed, and labeled. Ready for sale.

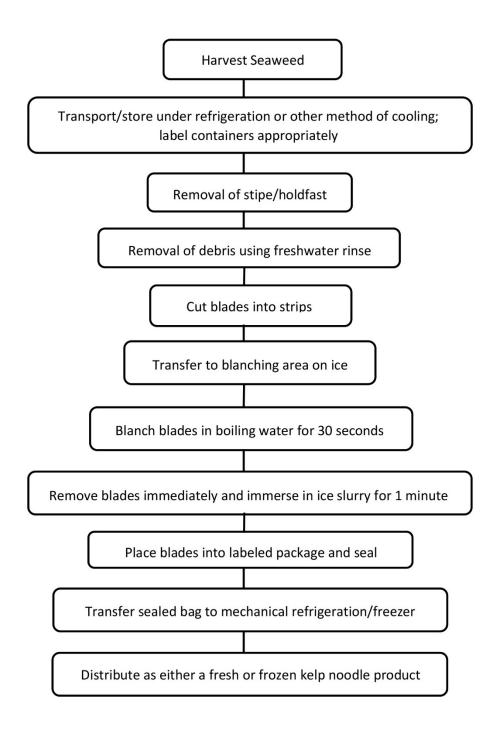


Figure 3. Example process flow diagram for kelp noodles

#### 3. Dehydrated/Dried Seaweed Product

Description: A seaweed species, washed in fresh water to remove debris, placed in a commercial food dehydrator for 12 to 24 hours, and packaged (sealed) with label.

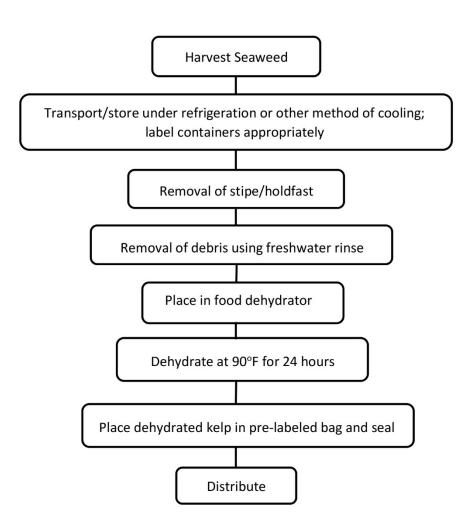


Figure 4. Example process flow diagram for a dehydrated/dried seaweed product

## Section XV - References

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## Section XVI - Special Thanks and Acknowledgments

The Connecticut seaweed aquaculture industry Connecticut Department of Public Health Connecticut Department of Consumer Protection Connecticut Agricultural Experiment Station Tasty Kale, LLC Marrakech, Inc.

# Section XVII – Footnotes

<sup>1</sup>*Vibrio* bacteria are naturally occurring in the marine and estuarine environment, and if present will multiply to harmful levels in the growing area or post-harvest under the right conditions. Outbreaks of food-borne disease associated with *Vibrio parahaemolyticus* contamination of seaweed have occurred in Japan, and along with *V. vulnificus*, is the topic of active research in Japan and elsewhere. Both *V. parahaemolyticus* and *V. vulnificus* have been isolated from seaweeds in Japan with the recommendation that seaweed not be consumed during the summer months in Japan, due to contamination by *V. vulnificus*.

Food-borne disease outbreaks of *V. parahaemolyticus* have occurred in association with oysters and clams harvested in New York and Connecticut waters. Due to these findings and under current environmental conditions, continued efforts to monitor the presence or absence of *Vibrio* in cultivated seaweed species must be conducted to determine whether or not specific pathogens from the harvest area are considered a significant hazard.

<sup>2</sup>Outbreak of Gastrointestinal Illness Associated with Consumption of Seaweed-Hawaii, 1994. Centers for Disease Control Morbidity and Mortality Weekly Report, 44(39): 724-7. Downloaded on 12/11/12.

# Section XVIII - Appendices

Appendix 1. Model Hazard Analysis and HACCP Plan for sugar kelp, raw and unprocessed (Raw Agricultural Seaweed Commodity)

Product Description and Market Name: Raw, unprocessed sugar kelp (Saccharina latissima)

Source of Product: Harvester

Methods of Packaging, Distribution & Storage: Open container, stored and distributed on ice

Intended Use and Consumer: Raw, unprocessed; general public

#### **Process Flow Chart**

a. Harvest

- b. Dockside Unloading/Transport
- c. Cooler Storage
- d. Distribution

#### **Process Description**

**Harvest** – Fresh sugar kelp (*Saccharina latissima*) is harvested from longlines in growing area(s) and placed in totes on deck. Product in totes is labeled by growing area and adequately cooled with ice or gel packs within two hours of harvest. If ice is used, a barrier is placed between ice and product.

**Dockside Unloading/Transport** – Totes of sugar kelp are unloaded and kept cool during transport with ice/gel packs or placed into refrigerated truck pre-chilled to  $\leq$ 41°F.

**Cooler Storage** – Sugar kelp are placed in open containers, separated and labeled with harvest area and date, and stored under mechanical refrigeration set at  $\leq$ 41°F.

**Distribution** – Raw, unprocessed kelp is kept chilled (mechanical refrigeration/ice/gel packs) and sold by blade. Purchasers are informed in writing of potential "hidden" hazard of a crustacean shellfish allergen.

Note: The Product Description Form on Page 228 of the <u>Hazard Analysis and Critical Control Point</u> <u>Training Curriculum</u> can be used to help develop the Product Description.

Identify Species and Process-related Hazards (see Table 1 and Table 2 this document):

Species-related Hazards:	Pathogens from Harvest Area
	Environmental Contaminants from the Harvest Area
	Natural Toxins from the Harvest Area
Process-related Hazards:	Pathogenic Bacterial growth due to Temperature Abuse
	Allergens (crustacean shellfish)

Hazard Analysis	Worksheet					
Firm Name:				Product Description: S	ugar kelp, raw and unprocessed	
Firm Address:				Method of Storage & D	Distribution: Open container, stored/dis	tributed on ice
				Intended Use & Consu	mer: Raw and unprocessed; general pub	olic
(1) Processing Step	(2) List all potential biological, chemical, and physical food safety hazards associated with this product and process.	(3) Are any potential food safety hazards significant (introduced, enhanced or eliminated) at this step? (Yes or No)		(4) <b>the decision</b> that you ade in column 3	(5) What <b>control measure(s)</b> can be applied to prevent this significant hazard?	(6) Is this step a Critical Control Point? (Yes or No)
Harvest (source waters)	Pathogens from harvest area Environmental Contaminants from harvest area Natural toxins from harvest area	Yes Yes Yes	Sugar kel and unpr	p will be consumed raw ocessed	Licensed Aquaculture Seaweed Producer; harvest from Approved or Conditionally Approved Growing Area (Open Status); pre-harvest samples collected for DABA/certified lab; approval from DABA for sale received	YES YES YES
Harvest (kelp)	Pathogenic Bacteria Growth due to Temperature Abuse Allergen	Yes Yes	pathogen be consul unproces Exposure crustacea poses sig	ne/temp abuse, is will grow; product to med raw and sed to potential hidden in shellfish allergen nificant health hazard consumers	Control time and temperature exposure* Inform buyer in writing of potential allergen hazard during distribution	YES NO

Hazard Analysis (see page 229 of the Hazard Analysis and Critical Control Point Training Curriculum).

\*While for public health purposes, raw kelp could remain unrefrigerated for up to 8 hours before pathogen growth could become a potential food safety hazard, the *quality* of raw kelp as a raw, unprocessed commodity diminishes rapidly and significantly (becomes very slimy) if kept out of temperature control for more than 2 hours after harvest.

(1)	(2)	(3)	(4)	(5)	(6)
Processing Step	List all potential biological, chemical, and physical food safety hazards associated with this product and process.	Are any potential food safety hazards significant (introduced, enhanced or eliminated) at this step? (Yes or No)	(+) Justify the decision that you made in column 3	(3) What <b>control measure(s)</b> can be applied to prevent this significant hazard?	ls this step a Critical Control Point? (Yes or No)
Dockside Unloading and Transport	Pathogenic Bacteria Growth due to Temperature Abuse	Yes	Under time/temp abuse, pathogens will grow; product to be consumed raw and unprocessed	Control time and temperature exposure during unloading and transport	YES
Cooler Storage	Pathogenic Bacteria Growth due to Temperature Abuse	Yes	Under time/temp abuse, pathogens will grow; product to be consumed raw and unprocessed	Control product temperature during storage	YES
Distribution	Pathogenic Bacteria Growth due to Temperature Abuse Allergen	Yes Yes	Under time/temp abuse, pathogens will grow; product to be consumed raw and unprocessed Exposure to potential hidden crustacean shellfish allergen poses significant health hazard to some consumers	Control product temperature during distribution Inform buyer in writing of potential allergen hazard during distribution	YES YES

# HACCP Plan for Sugar Kelp, raw and unprocessed

# CCP 1: Harvest (Source waters)

Significant Hazards:	Pathogens from harvest area; Environmental Contaminants from harvest area; Natural Toxins from harvest area
<b>Critical Limits:</b>	a. Licensed Aquaculture Seaweed Producer
	b. Pre-harvest samples collected for DABA/certified lab; approval from DABA for sale as an "approved" food source received
	c. Harvest from Approved or Conditionally Approved Growing Area (Open Status)
Monitoring:	
What:	a. License
	b. Approval from DABA for sale based on analyses of pre-harvest samples
	c. Status of growing waters by lot
How:	a. & b. Visual
	c. Phone call
Frequency:	Before start of harvest on each lot (all)
Who:	Designee (all)
Corrective Actions:	
	IF harvester does not hold a valid seaweed producer license, THEN kelp cannot be legally harvested until a valid license is obtained. Divert any harvested kelp to a non- food use or compost appropriately on land AND review and modify harvest procedures/training as necessary. Kelp cannot be discarded in the water as its decomposition adversely affects water quality.
	IF pre-harvest samples were not been collected for analysis prior to harvest OR the analyses came back testing positive for pathogens OR the analyses were not reviewed by DABA and the approval to harvest kelp as an approved food source issued; THEN harvest of sugar kelp as a Raw Agricultural Seaweed Commodity cannot commence until samples have been collected, analyzed by DABA and approval for sale issued AND harvest procedures/training reviewed and modified as necessary.
	IF kelp has been harvested in the absence of DABA approval, THEN divert any harvested kelp to a non-food use or composted appropriately on land AND review and modify harvest procedures/training as necessary. Kelp cannot be discarded in the water as its decomposition adversely affects water quality.
	<b>IF kelp is harvested from wrong growing area;</b> THEN harvest must cease. Divert any harvested kelp to a non-food use or compost on land appropriately AND review and modify harvest procedures/training as necessary. Kelp cannot be discarded in the water as its decomposition adversely affects water quality.

	IF the status of the growing areas was not checked prior to commencement of harvest; THEN status must be checked and documented immediately. IF status is Approved or Conditionally Approved (Open Status) THEN harvested kelp can be retained AND pre-harvest procedures/training must be reviewed and modified as necessary. IF status is not Approved or Conditionally Approved (Open Status), THEN harvest must cease. Divert any harvested kelp to a non-food use or compost on land appropriately AND review and modify harvest procedures/training as necessary. Kelp cannot be discarded in the water as its decomposition adversely affects water quality.
Verification:	Review CCP and corrective action records within one week of generation. Annual renewal of Aquaculture Seaweed Producer license
Records:	Harvest log; Aquaculture Seaweed Producer license; results of pre-harvest analyses; DABA approval to harvest

CCP 2: Harvest (Kelp)	
Significant Hazards:	Pathogenic bacterial growth due to temperature abuse
Critical Limits:	Harvested kelp must be put on ice (with barrier between ice and product) or cooled with adequate gel packs or placed into mechanical refrigeration at $\leq$ 41°F within $\leq$ 2* hours of time harvest began. Each container of harvested kelp must be tagged with harvest location/lot number, time harvest began time onto ice/gel packs or into mechanical refrigeration.
Monitoring: What:	a. Tag with required information
	b. Temperature of mechanical refrigeration
How:	a. Visual
	b. Continuous temperature recorder
Frequency:	a. Every harvest, every lot
	b. Continuous, with visual check once per day
Who:	Designee (all)
Corrective Actions:	<ul> <li>IF tag is missing record of time since harvest began, THEN kelp should be immediately placed under temperature control and the time recorded AND an evaluation of time/temperature exposure undertaken AND pre-harvest procedures/training reviewed and modified as necessary. IF evaluation indicates potential safety problem, THEN divert harvested kelp to process as blanched, frozen product or dried product OR divert kelp to a non-food use or compost on land appropriately. Kelp cannot be discarded in the water as its decomposition adversely affects water quality.</li> <li>IF harvester does not place harvested kelp under temperature control within 2 hours of when harvest began, THEN kelp should be immediately placed under temperature</li> </ul>
	control and the time recorded AND an evaluation of time/temperature exposure undertaken AND pre-harvest procedures/training reviewed and modified as necessary. IF evaluation indicates potential safety problem, THEN divert harvested kelp to process as blanched, frozen product or dried product OR divert to a non-food use or compost on land appropriately. Kelp cannot be discarded in the water as its decomposition adversely affects water quality.
	IF mechanical refrigeration is >41°F, then adjust temperature or cool product with ice or adequate gel packs AND fix cooler AND review and modify harvest procedures/training as necessary. IF time/temperature evaluation indicates potential safety problem, THEN divert harvested kelp to process as blanched, frozen product or dried product OR divert to a non-food use or compost on land appropriately. Kelp cannot be discarded in the water as its decomposition adversely affects water quality.
Verification:	Review CCP and corrective action records within one week of generation.

Calibrate continuous temperature recorder per manufacturer's instruction

Conduct accuracy check on mechanical refrigeration once daily prior to harvest beginning using NIST thermometer in ice slurry in refrigeration unit

Records:Temperature control log, including amount of product, amount of ice or gel packs used,<br/>or temperature of mechanical refrigeration; corrective action records; calibration<br/>records, accuracy check records

\*Although no published studies exist, raw seaweed starts to decompose (feel slimy) rapidly once harvested. For this reason and not necessarily for public health protection, the critical limits for cooling harvested seaweed with ice, gel packs or mechanical refrigeration at  $\leq$ 41°F within 2 hours of when harvest began is set for product intended to be sold as a Raw Agricultural Commodity (raw consumption). For public health reasons, it technically could be held un-iced for up to 8 hours, however the resulting quality would be so poor that the product would no longer be viable for sale for raw consumption.

# CCP 3: Dockside Unloading and Transport

Significant Hazards:	Pathogenic bacterial growth due to temperature abuse
Critical Limits:	Harvested kelp must be kept on adequate ice (with barrier between ice and product) or kept cooled with adequate gel packs or maintained under mechanical refrigeration at <a>41°F.</a>
Monitoring: What:	Adequacy of ice or gel packs OR refrigeration at <41°F
How:	Visual or thermometer depending on cooling medium
Frequency:	Every harvest lot
Who:	Designee (all)
<b>Corrective Actions:</b>	
	IF ice or gel packs are inadequate to cool harvested kelp, THEN add more ice or additional gel packs to ensure kelp continues to cool and remains cool during dockside unloading and/or transport AND review and modify cooling procedures/training as necessary. IF time/temperature evaluation indicates potential safety problem, THEN divert harvested kelp to process as blanched, frozen product or dried product OR divert to a non-food use or compost on land appropriately. Kelp cannot be discarded in the water as its decomposition adversely affects water quality.
	IF mechanical refrigeration is >41°F, then adjust temperature or cool product with ice or adequate gel packs AND fix cooler AND review and modify transport procedures/training as necessary, including truck pre-chilling. IF time/temperature evaluation indicates potential safety problem, THEN divert harvested kelp to process as blanched, frozen product or dried product OR divert kelp to a non-food use or compost on land appropriately. Kelp cannot be discarded in the water as its decomposition adversely affects water quality.
Verification:	Review CCP and corrective action records within one week of generation.
	Calibrate continuous temperature recorder per manufacturer's instruction
	Conduct accuracy check on truck mechanical refrigeration once daily prior to loading product using NIST thermometer in ice slurry in refrigeration unit.
Records:	Transport log, including amount of product, amount of ice or gel packs used, or temperature of mechanical refrigeration

CCP 4: Cooler Storage	
Significant Hazards:	Pathogenic bacterial growth due to temperature abuse
Critical Limits:	Harvested kelp must maintained under mechanical refrigeration at <41°F.
Monitoring: What:	Cooler temperature
How:	Visual, thermometer
Frequency:	Continuous, with visual checks twice per day
Who:	Designee (all)
Corrective Actions: Verification:	IF mechanical refrigeration is >41°F, then adjust temperature or cool product with ice or adequate gel packs or divert to functioning cooler AND fix cooler AND review and modify cooler storage procedures/training as necessary. IF time/temperature evaluation indicates potential safety problem, THEN divert harvested kelp to process as blanched, frozen product or dried product OR divert kelp to a non-food use or compost on land appropriately. Review CCP and corrective action records within one week of generation. Calibrate continuous temperature recorder per manufacturer's instruction
Records:	Conduct accuracy check on mechanical refrigeration once daily using NIST thermometer in ice slurry in refrigeration unit. Cooler storage log, including # of containers of product

CCP 5: Distribution	
Significant Hazards:	Pathogenic bacterial growth due to temperature abuse; crustacean shellfish allergen
Critical Limits:	Harvested kelp must maintained under refrigeration at <41°F; purchasers must be provided written warning of potential hidden crustacean shellfish allergen
Monitoring: What:	a. Cooler temperature b. Allergen warning label
How:	<b>a.</b> Visual, thermometer b. Visual
Frequency:	a. Continuous, with visual checks twice per day b. Every Raw Agricultural Commodity purchase
Who:	Designee (all)
Corrective Actions:	IF mechanical refrigeration is >41°F, then adjust temperature or cool product with ice or adequate gel packs or divert to functioning cooler AND fix cooler AND review and modify cooler storage procedures/training as necessary. IF time/temperature evaluation indicates potential safety problem, THEN divert harvested kelp to process as blanched, frozen product or dried product OR divert kelp to a non-food use or compost on land appropriately.
	IF written crustacean shellfish allergen warning is not provided with purchase, THEN ensure all purchasers receive a copy AND review and modify labeling procedures as necessary.
Verification:	Review CCP and corrective action records within one week of generation.
	Calibrate continuous temperature recorder per manufacturer's instruction
	Conduct accuracy check on mechanical refrigeration once daily using NIST thermometer in ice slurry in refrigeration unit.
Records:	Distribution log

Appendix 2. DABA proposed limits and reference levels for microbial parameters for raw agricultural seaweed commodity.

Parameter	Units	Reference Level/Tolerance Level	Source
Microbiological Food Testing			
Salmonella Screen	NA	ND	Code of Federal Regulations Title 21 Part 117
<i>E. coli</i> O157:H7	NA	ND	<u>Code of Federal Regulations</u> <u>Title 21 Part 117</u>
<i>Listeria</i> Screen	NA	ND	<u>Code of Federal Regulations</u> <u>Title 21 Part 117</u>
Shigella	NA	ND	<u>Code of Federal Regulations</u> <u>Title 21 Part 117</u>
Total Coliform	MPN/mL	Screening indicator	<u>Code of Federal Regulations</u> <u>Title 21 Part 117</u>
Fecal Coliform	MPN/mL	Screening indicator	<u>Code of Federal Regulations</u> <u>Title 21 Part 117</u>

Note: ND is abbreviation for "Non-Detectable". NA is abbreviation for "Not Applicable".

Appendix 3. Criteria and limits proposed by DABA for PCBs in raw agricultural seaweed commodity.

Parameter	Units	Recommended Limit	Source
Total PCBs	ppm	ND	Code of Federal Regulations Title 21 Part 109.30

Appendix 4. Criteria and limits proposed by DABA for heavy metals in raw agricultural seaweed commodity.

Parameter	Units	Recommended Limit	Source
Arsenic (As, inorganic)	mg/kg dry weight	<3.0	<u>French Agency for Food,</u> <u>Environmental and Occupational</u> <u>Health &amp; Safety</u>
Lead (Pb)	mg/kg dry weight	<5.0	<u>French Agency for Food,</u> <u>Environmental and Occupational</u> <u>Health &amp; Safety</u>
Cadmium (Cd)	mg/kg dry weight	<0.5	<u>French Agency for Food,</u> <u>Environmental and Occupational</u> <u>Health &amp; Safety</u>
Mercury (Hg)	mg/kg dry weight	<0.1	<u>French Agency for Food,</u> <u>Environmental and Occupational</u> <u>Health &amp; Safety</u>
lodine (I)	mg/kg dry weight	<2000.0	<u>French Agency for Food,</u> Environmental and Occupational <u>Health &amp; Safety</u>

Appendix 5. Criteria and limits proposed by DABA for pesticide residues in raw agricultural seaweed commodity.

Parameter	Units	Recommended Limit	Source
			Title 40: Protection of Environment
Pesticide Chemical Residues	ppm	ND	PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD Subpart C-Specific Tolerances

Appendix 6. Contact Information for Relevant Regulatory Agencies

Kristin DeRosia-Banick Connecticut Department of Agriculture, <u>Bureau of Aquaculture</u> P.O. Box 97, Milford, CT 06460 (203) 874-0696 / fax (203) 783-9976 Email: <u>Kristin.DeRosia-Banick@ct.gov</u>

Jenna Nicol MFRPS Coordinator Connecticut Department of Consumer Protection, <u>Food and Standards Division</u> 450 Columbus Boulevard, Suite 901 Harford, CT 06103 (860) 713-6163 jenna.nicol@ct.gov

Appendix 7. Contact Information for Seafood HACCP Training and Extension Services

Nancy Balcom Seafood Safety/HACCP training courses Connecticut Sea Grant/UConn Extension 1080 Shennecossett Road, Groton, CT 06340 (860) 405-9107 nancy.balcom@uconn.edu

Anoushka Concepcion Seaweed Extension Connecticut Sea Grant/UConn Extension 1080 Shennecossett Road, Groton, CT 06340 (860) 405-9105 anoushka.concepcion@uconn.edu

Appendix 8. Other Resources

<u>CFR Title 21 Part 117 - Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive</u> <u>Controls for Human Food</u>

CFR Title 21 Part 109.30 - Tolerances for polychlorinated biphenyls (PCB's)

Title 40: Protection of Environment - PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD Subpart C-Specific Tolerances

French Agency for Food, Environmental and Occupational Health & Safety on the risk of excess iodine intake from the consumption of seaweed in foodstuffs

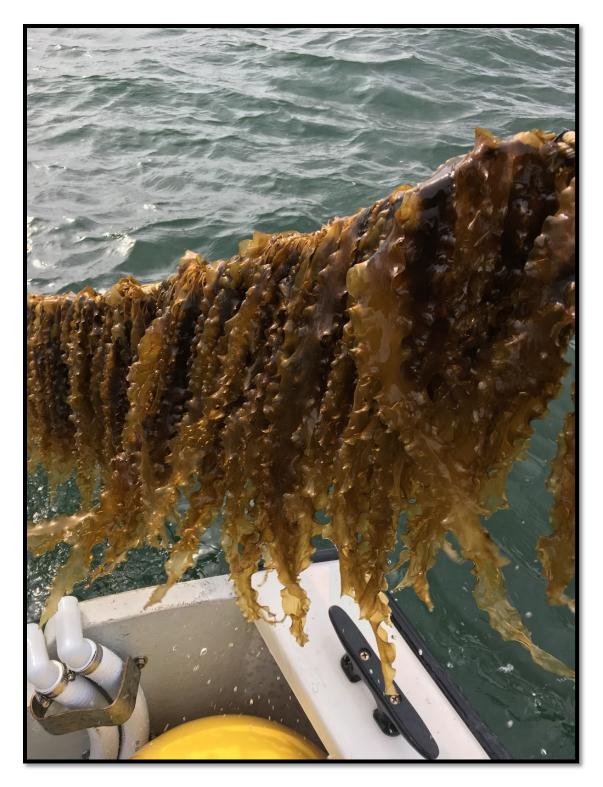


Photo: Sugar kelp growing on longline in waters off Groton, CT. Credit: J.P. Velotti