

Regulatory Guide to Processing and Marketing Seaweed in New York



Photo Credit: The Moore Foundation-Lazy Point Farms

This regulatory guide was created by New York Sea Grant with assistance from members of the NY Seaweed Processing and Marketing Task Force with representation from Federal, State County and City agencies as well as industry partners. This document is for educational and informational purposes only. This is a living document that may be updated over time to reflect current requirements for selling/marketing New York seaweed. For the most up to date regulations, refer to codes, rules, and regulations that are linked throughout this resource and relevant agency websites. The information provided should not be used as a substitute for legal advice.

Individuals and businesses are encouraged to consult with legal counsel if starting new initiatives.

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Document Navigation

Introduction

New York Sea Grant created the Seaweed Processing and Marketing Task force in January of 2021 to develop a series of resources to assist NY seaweed producers in understanding the regulations governing the sale and marketing of seaweed products in New York. The task force was made up of various industry, academic, and regulatory agency representatives with control over seaweed production, processing, and sales. All resources created are meant to assist in getting seaweed products to market. The resources include a regulatory guide that outlines the regulations applicable to different avenues of sale and topical guides that provide more detailed information on the various requirements mentioned throughout the regulatory guide.



Photo Credit: The Moore Foundation-Lazy Pont Farms

Interactive Buttons

Throughout this document you will find a variety of buttons that will allow you to interact with the contents and navigate the document. Interactive features can be identified by scrolling the mouse cursor over the buttons and images. The color of the image will change indicating you can click to view the interactive content or navigate to a new page of the document. Some of the most commonly used buttons are explained below.

Regulations Buttons

The regulations buttons depicted above will turn from yellow to blue when you hover over them. When clicked they will pull up the regulations specific to that step in the process flow chart. Each time you click one of these numbered buttons a new set of regulations will appear.

Regulatory Guides Navigation Buttons

Each of the blue buttons on the flowchart that indicate the buyer will turn white when scrolled over as depicted below.

If you are interested in jumping to a regulatory guide specific to a particular buyer for the product you are selling, for example: raw unprocessed seaweed to consumers at a farm or fish stand, you can simply click on the "Farm/Fish Stand" button under "Raw/ Unprocessed" and you will be brought to the page of the guide that outlines all regulatory requirements for selling your seaweed to that buyer.

Returning to Flowchart and Table of Contents

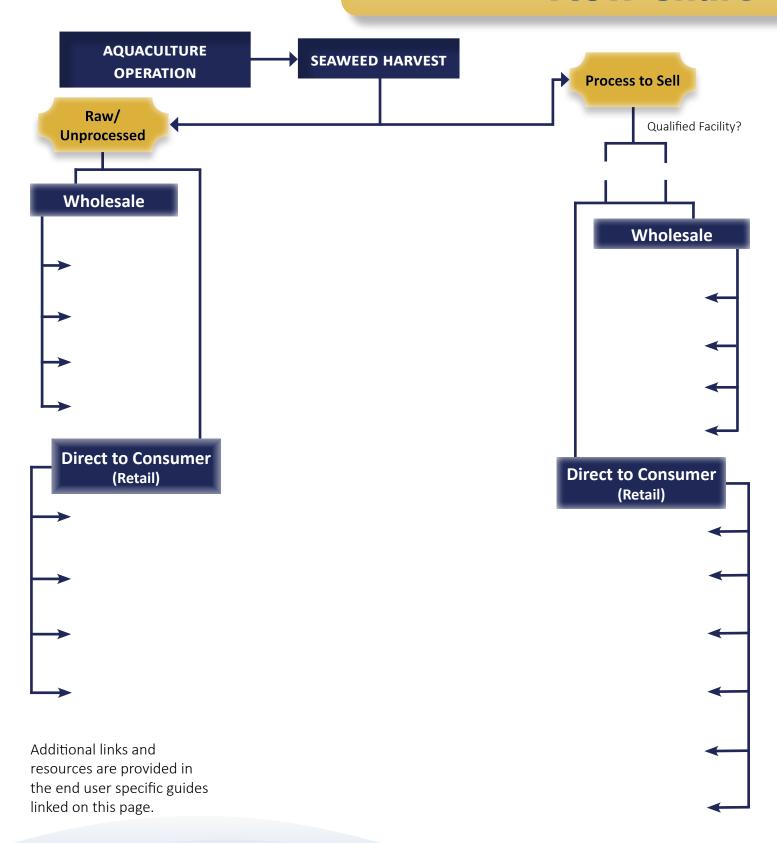
Throughout the document you will see the "Flowchart" and "Table of Contents" buttons depicted below. Click on them to quickly navigate back to the flowchart or table of contents, respectively.

Flowchart

Table of Contents



Seaweed Regulatory Flow Chart





Selling Raw Unprocessed Seaweed Wholesale in NY

This guide covers the requirements for selling raw unprocessed farmed seaweed to a variety of wholesale buyers in NY. Wholesale buyers include:

Processors

» Selling directly to other seaweed processors.

Restaurants

» Selling directly to restaurants and other food service establishments where foods are prepared, portioned for consumption, and sold.

Retailers

» Selling directly to seaweed retail outlets.

Wholesalers

» Selling directly to wholesale buyers or distributors.

Institutions

» Selling directly to institutions (schools, hospitals, senior living etc.).

Aquaculture

- 1. Aquaculture operations (growers) in NY State that have or have applied for an off-bottom lease/license from the appropriate township or County must obtain Aquaculture Permits /Licenses from the Department of Environmental Conservation (DEC), Army Corps of Engineers, and NY State Department of State.

 Aquaculture Licenses/Permits issued by DEC permit growers to grow and sell their products, no additional dealers permits are required unless growing molluscan shellfish species (See molluscan shellfish regulatory guide).
 - **1.1.** Marine aquaculture of seaweeds are permitted through the Bureau of Marine Resources (631-444-0481). Note that not all leasing programs allow seaweed cultivation.

Harvesting Seaweed

- 2. Seaweed Harvested for food must meet minimum food safety requirements including temperature and source controls. Your buyers will likely have specific requirements outlined in their food safety plans that must be met, as they are responsible for ensuring they are sourcing safe foods.
 - **2.1.** Temperature Controls: Mechanical refrigeration (40°F or below) or ice should be used to control temperature and maintain seaweed safely. Seaweed should be chilled as soon as possible after harvest to avoid quality deterioration and pathogen growth.
 - 2.2. Source Controls: Seaweed intended for human consumption should be grown in certified waters (visit the <u>Department of Environmental Conservation's Shellfish Closures Website</u> to identify certified waters in NY). If a farm is operating in uncertified waters, adequate testing prior to harvest should indicate chemical contaminants, heavy metals, and pathogens are not present at levels that pose a potential health risk to consumers. For more information on hazards associated with seaweed refer to <u>CT Sea Grant's</u> Seaweed Hazards Guide.
 - 2.3. Raw seaweed has a short shelf-life and deteriorates quickly after harvest, it will be important to educate your buyers on the stability of your product. Consider using expiration dates to prevent deterioration and growth of pathogens before consumption. The shelf-life and stability of processed products will vary depending on the facility and processes used, producers should evaluate the stability of their products and educate buyers on appropriate handling and storage practices. Consider labeling raw products "Raw Cook Before Consuming" when selling direct to consumers.



Wholesale Sales

3. Selling seaweed wholesale to other processors/ wholesalers, restaurants and foodservice establishments, retail outlets, or institutions (schools, hospitals, senior living etc.) are not subject to any additional food safety regulations.

Checklist for Unprocessed Seaweed

- O Aquaculture Permit
 - O Temperature Controls
 - O Source Controls
- Compliance with labeling requirements



Photo Credit: The Moore Foundation - Lazy Point Farms



Selling Processed Seaweed Wholesale in NY

This guide covers the requirements for selling processed seaweed to a variety of wholesale buyers in NY. Wholesale buyers include:

Processors

» Selling directly to other seaweed processors.

Restaurants

» Selling directly to restaurants and other food service establishments where foods are prepared, portioned for consumption, and sold.

Retailers

» Selling directly to seaweed retail outlets.

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Seaweed Harvest

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 - consumers.



Seaweed Processing

Growers/processors interested in selling seaweed that is processed in any way (dried, blanched, etc.) must possess a <u>20-C Food Processing License</u> from the Department of Agriculture and Markets (AGM) and meet the requirements outlined below.

- **3.** Processors must be compliant with the current Good Manufacturing Practices (GMP) in <u>Title 21</u> <u>CFR117 Subpart B</u>. For more detailed information on GMP's, review <u>NYSG Seafood Guide #4 on Good Manufacturing Practices</u>.
 - **3.1.** The <u>Institute for Food Safety at Cornell</u> manages an online GMP training program.
- **4.** Processors must develop and implement Sanitation Control Procedures or Standard Sanitation Operating Procedures (SSOP's) for their facility to ensure that the facility, products, and packaging are maintained safely. See NYSG Seafood Guide #5 for more information on sanitation.
- **5.** Processors must have a scheduled process (detailed outline of process/procedures) developed by a recognized processing authority. NY State recognized processing authorities can be found on the <u>Department of Agriculture and Markets website</u>. A scheduled process should outline the temperature and source control parameters necessary at harvest, which the processor is responsible for ensuring are met when received. The scheduled process should also indicate any additional controls necessary for hazards specific to the processing procedures used.
- **6.** State and federal labeling requirements are applicable to all avenues of commercial sale, see NYSG Seafood Guide #1 for more information on labeling.
 - **6.1.** Note that fouling crustaceans often grow on seaweeds and should be labeled as an allergen on all seaweed products.



Photo Credit: The Moore Foundation - Lazy Point Farms

Qualified Facility Exemptions

- 7. To accurately determine what additional regulatory requirements are necessary, processors must determine whether or not they meet the definition of a qualified facility according to the Food Safety and Modernization Act Preventive Controls for Human Foods (FSMA PC) regulation outlined in part 117.5. Refer to FDA's "Guidance for Industry: Determination of Status as a Qualified Facility" for detailed guidance on determining if your business is a qualified facility, definitions of terminology, and guidance on sales and value calculations.
 - **7.1.** A qualified facility is either:
 - » A very small business which averages, over the last three year period, <\$1,000,000 in annual sales of human foods. This calculation should include sales of affiliates or subsidiaries, OR
 - » A facility in which the average value of food manufactured, processed, packed, or held, over the last three years, and sold to a qualified end user is greater than the value of food sold to any other buyer AND the average value of all food sold over the last three years is less than \$500,000, adjusted for inflation.



Qualified Facility Exemptions

Qualified facilities are exempt from CFR part 117 subparts C and G of the FSMA PC regulation and must submit a self-attestation to FDA.

- **8.** Qualified facilities are subject to the modified requirement in <u>part 117.201</u> of the FSMA PC regulation, which state that in addition to the form FDA 3942A facilities must include either:
 - **8.1.** An attestation that you have identified the potential hazards associated with the seaweed produced, are implementing preventive controls to address the hazards, and are monitoring the controls to ensure they are effective, OR
 - **8.2.** An attestation that the facility is in compliance with NY State food safety requirements including an overview of those requirements.
 - » Since NY state has adopted the FSMA PC for Human Foods rule, those who meet the definition of a qualified facility must control potential food safety hazards but have the flexibility to choose the type of food safety plan or mechanisms they use. Keep in mind that if your facility grows over time and no longer meets the definition of a qualified facility, you will need to develop a FSMA PC compliant food safety plan.

Non-Qualified Facility Requirements

- **9.** Facilities that don't meet the definition of a qualified facility must be in compliance with the Food Safety and Modernization Act Preventive Controls for Human Foods (FSMA PC) regulation and meet the following requirements.
 - **9.1.** Growers/processors are subject to FDA regulation and inspection which may require the business to register as an FDA Food Facility. Additional guidance on facility registration and exemptions is available on the FDA's website.

- **9.2.** Processors must have a Preventive Controls Qualified Individual (PCQI), which is an individual with the relevant training or experience in food safety preventive controls, develop and implement their food safety plan.
- **9.3.** Processors must develop and implement a FSMA PC compliant food safety plan. See NYSG Seaweed Guide #1 for more information.

Checklist for Processed Seaweed

O Aquaculture Permit Temperature Controls Source Controls O 20-C Processing License AGM Inspection O GMP Compliance Sanitation Control Program Scheduled Process O Compliance with Labeling Requirements • Qualified Facility? - NO FDA Facility Registration O FSMA PC Qualified Individual O FSMA PC Food Safety Plan O Qualified Facility? - YES FDA Self-attestation Potential Food Safety Hazard Controls in Place



Selling Processed Seaweed Through E-Commerce

This guide covers the requirements for selling processed farmed seaweed through e-commerce platforms in NY.

Aquaculture

- 1. Aquaculture operations (growers) in NY State that have or have applied for an off-bottom lease/ license from the appropriate township or County must obtain Aquaculture Permits /Licenses from the Department of Environmental Conservation (DEC), Army Corps of Engineers, and NY State Department of State. Aquaculture Licenses/Permits issued by DEC permit growers to grow and sell their products, no additional dealers permits are required unless growing molluscan shellfish species (See molluscan shellfish regulatory guide).
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Preventive Controls Qualified Facility

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E-Commerce Sales

E-commerce is the selling of seaweed products direct to consumers through online platforms.

- **10.** When selling pre-packaged seaweed, it must meet the packaging and labeling requirements in <u>1</u> NYCRR 221. See NYSG Seafood Guide #1 on labeling.
- **11.** Growers who wish to sell directly to consumers should ensure they are familiar with the Federal Trade Commission's (FTC) requirements for businesses marketing online.
- **12.** Growers who wish to sell directly to consumers online must comply with federal <u>laws prohibiting</u> <u>unfair or deceptive advertising</u>.
- **13.** The FTC provides guidance on how small businesses can <u>maintain cybersecurity</u> and handle <u>data security</u> to protect the personal information of consumers using online services.
- 14. If you are considering e-commerce sales, check out several existing platforms that could assist you in getting online. This list of e-commerce platforms is not exhaustive and NYSG does not endorse any of the platforms linked: Barn2Door | Cropolis | Farmigo | Food4All | Local Food Marketplace | Local Line | WIX | Square | WOO Commerce | Squarespace | Open Food Network | GrazeCart | Harvie | OurHarvest | WhatsGood | CSAware | Farmers Web | GrownBy | Harvest Hand | Local Orbit | Shopify
 - **14.1.** When selling seaweed through e-commerce be sure to determine shipping and delivery methods that will ensure buyers receive safe high quality products. For more information refer to NYSG Seafood Guide #8 on best practices for seafood/seaweed delivery and shipping.



E-Commerce Checklist

- O Aquaculture Permit
 - O Temperature Controls
 - Source Controls
- O 20-C Processing License
- O AGM Inspection
- O GMP Compliance
- Sanitation Control Program
- O Scheduled Process
- O Compliance with Labeling Requirements
- Qualified Facility? NO
 - FDA Facility Registration
 - O FSMA PC Qualified Individual
 - O FSMA PC Food Safety Plan
- O Qualified Facility? YES
 - O FDA Self-attestation
 - Potential Food Safety Hazard
 Controls in Place
- Online Sales Platform
- O Shipping and Delivery Logistics



Selling Raw Unprocessed Seaweed Through E-Commerce

This guide covers the requirements for selling whole unprocessed farmed seaweed through e-commerce platforms in NY.

Aquaculture

- 1. Aquaculture operations (growers) in NY State that have or have applied for an off-bottom lease/ license from the appropriate township or County must obtain Aquaculture Permits /Licenses from the Department of Environmental Conservation (DEC), Army Corps of Engineers, and NY State Department of State. Aquaculture Licenses/Permits issued by DEC permit growers to grow and sell their products, no additional dealers permits are required unless growing molluscan shellfish species (See molluscan shellfish regulatory guide).
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E-Commerce Checklist

- O Aquaculture Permit
 - O Temperature Controls
 - O Source Controls
- O Labeling Requirements
- Online Sales Platform
- O Shipping and Delivery Logistics





Selling Processed Seaweed at Farm Stands

This guide covers the requirements for selling processed farmed seaweed at farm stands in New York.

Aquaculture

- 1. Aquaculture operations (growers) in NY State that have or have applied for an off-bottom lease/ license from the appropriate township or County must obtain Aquaculture Permits /Licenses from the Department of Environmental Conservation (DEC), Army Corps of Engineers, and NY State Department of State. Aquaculture Licenses/Permits issued by DEC permit growers to grow and sell their products, no additional dealers permits are required unless growing molluscan shellfish species (See molluscan shellfish regulatory guide).
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 - **6.1.** Note that fouling crustaceans often grow on seaweeds and should be labeled as an allergen on all seaweed products.

Preventive Controls Qualified Facility

- 7. To accurately determine what additional regulatory requirements are necessary, processors must determine whether or not they meet the definition of a qualified facility according to the Food Safety and Modernization Act Preventive Controls for Human Foods (FSMA PC) regulation outlined in part 117.5. Refer to FDA's "Guidance for Industry: Determination of Status as a Qualified Facility" for detailed guidance on determining if your business is a qualified facility, definitions of terminology, and guidance on sales and value calculations.
 - **7.1.** A qualified facility is either:
 - » A very small business which averages, over the last three year period, <\$1,000,000 in annual sales of human foods. This calculation should include sales of affiliates or subsidiaries, OR
 - » A facility in which the average value of food manufactured, processed, packed, or held, over the last three years, and sold to a qualified end user is greater than the value of food sold to any other buyer AND the average value of all food sold over the last three years is less than \$500,000, adjusted for inflation.

Non-Qualified Facility Requirements

- **8.** Facilities that don't meet the definition of a qualified facility must be in compliance with the Food Safety and Modernization Act Preventive Controls for Human Foods (FSMA PC) regulation and meet the following requirements.
 - **8.1.** Growers/processors are subject to FDA regulation and inspection which may require the business to register as an FDA Food Facility. Additional guidance on facility registration and exemptions is available on the FDA's website.
 - **8.2.** Facilities must have a Preventive Controls Qualified Individual (PCQI), which is an individual with the relevant training or experience in food safety preventive controls, develop and implement their food safety plan.
 - **8.3.** Processors must develop and implement a FSMA PC compliant food safety plan. See NYSG Seaweed Guide #1 for more information.

Qualified Facility Exemptions

Qualified facilities are exempt from CFR part 117 subparts C and G of the FSMA PC regulation and must submit a self-attestation to FDA.

- **9.** Qualified facilities are subject to the modified requirement in <u>part 117.201</u> of the FSMA PC regulation, which state that in addition to the form <u>FDA 3942A</u> facilities must include either:
 - **9.1.** An attestation that you have identified the potential hazards associated with the seaweed produced, are implementing preventive controls to address the hazards, and are monitoring the controls to ensure they are effective, OR
 - **9.2.** An attestation that the facility is in compliance with NY State food safety requirements including an overview of those requirements.
 - » Since NY State has adopted the FSMA PC for Human Foods rule, those who meet the definition of a qualified facility must control potential food safety hazards but have the flexibility to choose the type of food safety plan or mechanisms they use. Keep in mind that if your facility grows over time and no longer meets the definition of a qualified facility, you will need to develop a FSMA PC compliant food safety plan.



Farm Stand

Selling direct to consumers at farmers markets or roadside stands.

Farm Stand Requirements

- 10. Farm stands or markets will be subject to inspection by the <u>Department of Agriculture and Markets</u> (AGM) and must be in compliance with the State food sanitation requirements in <u>Article 17</u> of the Agriculture and Markets Law. For more detailed information refer to the AGM <u>guidance on sanitary regulations for New York State farmers market vendors</u>. In addition, all packaged food sold must be properly labeled according to NY State <u>food labeling requirements</u>.
 - **10.1.** Individual municipalities may have their own licensing/permitting requirements. You should reach out to the local municipality to inquire about any additional regulations. The New York State
 Department of Health provides links to the websites of each county's health department.
- **11.** When selling seaweed products by weight, signage indicating price should be displayed and these products must be weighed on a <u>National Type Evaluation Program (NTEP)</u> certified scale, which has been inspected and sealed by a County Weights and Measures Inspector.
 - **11.1.** The Department of Weights and Measures should be notified when a new or new-to-you scale will be used or if the official seal has been removed or damaged for repairs.
 - **11.2.** Check with your county Weights and Measures Office to schedule an inspection: Suffolk County | Nassau County | New York City.
- **12.** Businesses that seek to set up a direct marketing operation must be aware that a change in land use might require additional permitting and authorization by your local zoning authority, city council, etc.
- **13.** If selling prepared foods intended for on-site or immediate consumption, you will also need to meet the requirements of a temporary food service establishment.



Farm Stands Checklist - Processed

- O Aquaculture Permit
 - Temperature Controls
 - Source Controls
- O 20-C Processing License
- O AGM Inspection
- O GMP Compliance
- O Sanitation Control Program
- O Scheduled Process
- O Compliance with Labeling Requirements
- Qualified Facility? NO
 - FDA Facility Registration
 - O FSMA PC Qualified Individual
 - O FSMA PC Food Safety Plan
- O Qualified Facility? YES
 - O FDA Self-attestation
 - Potential Food Safety Hazard
 Controls in Place
- O Appropriate Price Signage
- O Certified and Inspected Scale
- O Check for Local Zoning Requirements or Restrictions



Selling Raw Unprocessed Seaweed at Farm Stands

This guide covers the requirements for selling raw unprocessed seaweed at farm stands in New York.

Aquaculture

- 1. Aquaculture operations (growers) in NY State that have or have applied for an off-bottom lease/ license from the appropriate township or County must obtain Aquaculture Permits /Licenses from the Department of Environmental Conservation (DEC), Army Corps of Engineers, and NY State Department of State. Aquaculture Licenses/Permits issued by DEC permit growers to grow and sell their products, no additional dealers permits are required unless growing molluscan shellfish species (See molluscan shellfish regulatory guide).
 - **1.1.** Marine aquaculture of seaweeds are permitted through the Bureau of Marine Resources (631-444-0481). Note that not all leasing programs allow seaweed cultivation.

Seaweed Harvest

- 2. Seaweed Harvested for food must meet minimum food safety requirements including temperature and source controls. Your buyers will likely have specific requirements outlined in their food safety plans that must be met, as they are responsible for ensuring they are sourcing safe foods.
 - **2.1.** Temperature Controls: Mechanical refrigeration (40°F or below) or ice should be used to control temperature and maintain seaweed safely. Seaweed should be chilled as soon as possible after harvest to avoid quality deterioration and pathogen growth.
 - **2.2.** Source Controls: Seaweed intended for human consumption should be grown in certified waters (visit the <u>Department of Environmental Conservation's Shellfish Closures Website</u> to identify certified waters in NY).

- If a farm is operating in uncertified waters, adequate testing prior to harvest should indicate chemical contaminants, heavy metals, and pathogens are not present at levels that pose a potential health risk to consumers. For more information on hazards associated with seaweed refer to CT Sea Grant's Seaweed Hazards Guide.
- **2.3.** Raw seaweed has a short shelf-life and deteriorates quickly after harvest, it will be important to educate your buyers on the stability of your product. Consider using expiration dates to prevent deterioration and growth of pathogens before consumption. The shelf-life and stability of processed products will vary depending on the facility and processes used, producers should evaluate the stability of their products and educate buyers on appropriate handling and storage practices. Consider labeling raw products "Raw Cook Before Consuming" when selling direct to consumers.



Photo Credit: The Moore Foundation Lazy Point Farms



Farm Stand Requirements

- 3. Farm stands or markets will be subject to inspection by the <u>Department of Agriculture and Markets</u> and must be in compliance with the State food sanitation requirements in <u>Article 17</u> of the Agriculture and Markets Law. For more detailed information refer to the AGM <u>guidance on sanitary regulations for New York State farmers market vendors</u>. In addition, all packaged food sold must be properly labeled according to NY State <u>food labeling requirements</u>.
 - **3.1.** Individual municipalities may have their own licensing/permitting requirements. You should reach out to the local municipality to inquire about any additional regulations. The New York State Department of Health provides links to the websites of each county's health department.
- **4.** When selling seaweed products by weight, signage indicating price should be displayed and these products must be weighed on a <u>National Type Evaluation Program (NTEP)</u> certified scale, which has been inspected and sealed by a County Weights and Measures Inspector.
 - **4.1.** The Department of Weights and Measures should be notified when a new or new-to-you scale will be used or if the official seal has been removed or damaged for repairs.
 - **4.2.** Check with your county Weights and Measures Office to schedule an inspection: Suffolk County | Nassau County | New York City.
- **5.** Businesses that seek to set up a direct marketing operation must be aware that a change in land use might require additional permitting and authorization by your local zoning authority, city council, etc.
- **6.** If selling prepared foods intended for on-site or immediate consumption, you will also need to meet the requirements of a temporary food service establishment.

Farm Stands Checklist - Unprocessed

- O Aquaculture Permits
 - O Temperature Controls
 - Source Controls
- O Food Sanitation Requirements
- Check for local zoning requirements or restrictions
- O Appropriate price signage
- O Compliance with labeling requirements (price signage)
- O Certified & inspected scale



Photo Credit: The Moore Foundation Lazy Point Farms



Selling Seaweed at Mobile Food Service Locations

This guide covers the requirements for selling seaweed at mobile food service establishments such as food trucks and carts.

Aquaculture

- 1. Aquaculture operations (growers) in NY State that have or have applied for an off-bottom lease/license from the appropriate township or County must obtain Aquaculture Permits /Licenses from the Department of Environmental Conservation (DEC), Army Corps of Engineers, and NY State Department of State.

 Aquaculture Licenses/Permits issued by DEC permit growers to grow and sell their products, no additional dealers permits are required unless growing molluscan shellfish species (See molluscan shellfish regulatory guide).
 - **1.1.** Marine aquaculture of seaweeds are permitted through the Bureau of Marine Resources (631-444-0481). Note that not all leasing programs allow seaweed cultivation.

Seaweed Harvest

- 2. Seaweed Harvested for food must meet minimum food safety requirements including temperature and source controls. Your buyers will likely have specific requirements outlined in their food safety plans that must be met, as they are responsible for ensuring they are sourcing safe foods.
 - **2.1.** Temperature Controls: Mechanical refrigeration (40°F or below) or ice should be used to control temperature and maintain seaweed safely. Seaweed should be chilled as soon as possible after harvest to avoid quality deterioration and pathogen growth.
 - **2.2.** Source Controls: Seaweed intended for human consumption should be grown in certified waters (visit the <u>Department of Environmental Conservation's Shellfish Closures Website</u> to identify certified waters in NY).

- If a farm is operating in uncertified waters, adequate testing prior to harvest should indicate chemical contaminants, heavy metals, and pathogens are not present at levels that pose a potential health risk to consumers. For more information on hazards associated with seaweed refer to <u>CT Sea Grant's</u> Seaweed Hazards Guide.
- 2.3. Raw seaweed has a short shelf-life and deteriorates quickly after harvest, it will be important to educate your buyers on the stability of your product. Consider using expiration dates to prevent deterioration and growth of pathogens before consumption. The shelf-life and stability of processed products will vary depending on the facility and processes used, producers should evaluate the stability of their products and educate buyers on appropriate handling and storage practices. Consider labeling raw products "Raw- Cook Before Consuming" when selling direct to consumers.

Seaweed Processing

If seaweed is prepared for sale and consumption from its raw unprocessed form at mobile food service locations, it is not subject to the AGM "seaweed processing" requirements listed below. These apply when seaweeds are processed (i.e. dried) in advance and then those products are used for on-site food preparation.

Growers/processors interested in selling seaweed that is processed in any way (dried, blanched, etc.) must possess a <u>20-C Food Processing License</u> from the Department of Agriculture and Markets (AGM) and meet the requirements outlined below.

- **3.** Processors must be compliant with the current Good Manufacturing Practices (GMP) in <u>Title 21</u> <u>CFR117 Subpart B</u>. For more detailed information on GMP's, review <u>NYSG Seafood Guide #4 on Good Manufacturing Practices</u>.
 - **3.1.** The <u>Institute for Food Safety at Cornell</u> manages an online GMP training program.



- **4.** Processors must develop and implement Sanitation Control Procedures or Standard Sanitation Operating Procedures (SSOP's) for their facility to ensure that the facility, products, and packaging are maintained safely. See NYSG Seafood Guide #5 for more information on sanitation.
- **5.** Processors must have a scheduled process (detailed outline of process/procedures) developed by a recognized processing authority. NY State recognized processing authorities can be found on the Department of Agriculture and Markets website. A scheduled process should outline the temperature and source control parameters necessary at harvest, which the processor is responsible for ensuring are met when received. The scheduled process should also indicate any additional controls necessary for hazards specific to the processing procedures used.
- **6.** State and federal labeling requirements are applicable to all avenues of commercial sale, see NYSGSeafood Guide #1 for more information on labeling.
 - **6.1.** Note that fouling crustaceans often grow on seaweeds and should be labeled as an allergen on all seaweed products.

Preventive Controls Qualified Facility

- 7. To accurately determine what additional regulatory requirements are necessary, processors must determine whether or not they meet the definition of a qualified facility according to the Food Safety and Modernization Act Preventive Controls for Human Foods (FSMA PC) regulation outlined in part 117.5. Refer to FDA's "Guidance for Industry: Determination of Status as a Qualified Facility" for detailed guidance on determining if your business is a qualified facility, definitions of terminology, and guidance on sales and value calculations.
 - **7.1.** A qualified facility is either:
 - » A very small business which averages, over the last three year period, <\$1,000,000 in annual sales of human foods. This calculation should include sales of affiliates or subsidiaries, OR

» A facility in which the average value of food manufactured, processed, packed, or held, over the last three years, and sold to a qualified end user is greater than the value of food sold to any other buyer AND the average value of all food sold over the last three years is less than \$500,000, adjusted for inflation.

Non-Qualified Facility Requirements

- **8.** Facilities that don't meet the definition of a qualified facility must be in compliance with the <u>Food Safety and Modernization Act Preventive Controls for Human Foods (FSMA PC)</u> regulation and meet the following requirements.
 - **8.1.** Growers/processors are subject to FDA regulation and inspection which may require the business to register as an <u>FDA Food Facility</u>. Additional guidance on facility registration and exemptions is available on the <u>FDA's website</u>.
 - **8.2.** Facilities must have a Preventive Controls Qualified Individual (PCQI), which is an individual with the relevant training or experience in food safety preventive controls, develop and implement their food safety plan.
 - **8.3.** Processors must develop and implement a FSMA PC compliant food safety plan. See NYSG Seaweed Guide #1 for more information.

Qualified Facility Exemptions

Qualified facilities are exempt from CFR part 117 subparts C and G of the FSMA PC regulation and must submit a self-attestation to FDA.

- **9.** Qualified facilities are subject to the modified requirement in <u>part 117.201</u> of the FSMA PC regulation, which state that in addition to the form FDA 3942A facilities must include either:
 - **9.1.** An attestation that you have identified the potential hazards associated with the seaweed produced, are implementing preventive controls to address the hazards, and are monitoring the controls to ensure they are effective, OR



- **9.2.** An attestation that the facility is in compliance with NY State food safety requirements including an overview of those requirements.
- » Since NY State has adopted the FSMA PC for Human Foods rule, those who meet the definition of a qualified facility must control potential food safety hazards but have the flexibility to choose the type of food safety plan or mechanisms they use. Keep in mind that if your facility grows over time and no longer meets the definition of a qualified facility, you will need to develop a FSMA PC compliant food safety plan.

Mobile Food Service Requirements

10. Growers interested in selling seaweed (retail food service) must comply with the sanitation rules and regulations of the local Department of Health (DOH). Statewide sanitation rules and regulations can be found in 10NYCRR 14-4. You should also check with your local DOH to determine more stringent sanitary requirements specific to your county.

Checklist for Mobile Food Service - Raw

This checklist applies to mobile food service locations prepping seaweed for consumption from its raw unprocessed state.

- O Aquaculture Permit
 - O Temperature Controls
 - O Source Controls
- DOH Sanitation Rules Compliance
- O Check Local Restrictions

Mobile Food Service

Selling prepared foods direct through mobile food service establishments (push carts, food trucks etc.).

10.1. The New York State Department of Health provides links to the websites of each county's DOH.

- » Guidance on mobile food service for Suffolk County is available <u>here</u>.
- » Additional informatinol information for Nassau County is available here.

Checklist for Mobile Food Service - Processed

This checklist applies to mobile food service locations involved in processing seaweed prior to prepping for consumption (i.e. drying or blanching to store until served).

- O Aquaculture Permit
 - Temperature Controls
 - Source Controls
- O 20-C Processing License
- O AGM Inspection
- O GMP Compliance
- Sanitation Control Program
- O Scheduled Process
- O Compliance with Labeling Requirements
- O Qualified Facility? NO
 - O FDA Facility Registration
 - O FSMA PC Qualified Individual
 - O FSMA PC Food Safety Plan
- O Qualified Facility? YES
 - O FDA Self-attestation
 - Potential Food Safety Hazard
 Controls in Place
- O DOH Sanitation Rules Compliance
- O Check Local Restrictions



Selling Seaweed at Temporary Food Service Locations

This guide covers the requirements for selling farmed seaweed at temporary food service locations such as fairs, festivals, and other events.

Aquaculture

- 1. Aquaculture operations (growers) in NY State that have or have applied for an off-bottom lease/license from the appropriate township or County must obtain Aquaculture Permits /Licenses from the Department of Environmental Conservation (DEC), Army Corps of Engineers, and NY State Department of State .

 Aquaculture Licenses/Permits issued by DEC permit growers to grow and sell their products, no additional dealers permits are required unless growing molluscan shellfish species (See molluscan shellfish regulatory guide).
 - **1.1.** Marine aquaculture of seaweeds are permitted through the Bureau of Marine Resources (631-444-0481). Note that not all leasing programs allow seaweed cultivation.

Seaweed Harvest

- 2. Seaweed Harvested for food must meet minimum food safety requirements including temperature and source controls. Your buyers will likely have specific requirements outlined in their food safety plans that must be met, as they are responsible for ensuring they are sourcing safe foods.
 - **2.1.** Temperature Controls: Mechanical refrigeration (40°F or below) or ice should be used to control temperature and maintain seaweed safely. Seaweed should be chilled as soon as possible after harvest to avoid quality deterioration and pathogen growth.
 - **2.2.** Source Controls: Seaweed intended for human consumption should be grown in certified waters (visit the <u>Department of Environmental Conservation's Shellfish Closures Website</u> to identify certified waters in NY).

- If a farm is operating in uncertified waters, adequate testing prior to harvest should indicate chemical contaminants, heavy metals, and pathogens are not present at levels that pose a potential health risk to consumers. For more information on hazards associated with seaweed refer to CT Sea Grant's Seaweed Hazards Guide.
- **2.3.** Raw seaweed has a short shelf-life and deteriorates quickly after harvest, it will be important to educate your buyers on the stability of your product. Consider using expiration dates to prevent deterioration and growth of pathogens before consumption. The shelf-life and stability of processed products will vary depending on the facility and processes used, producers should evaluate the stability of their products and educate buyers on appropriate handling and storage practices. Consider labeling raw products "Raw Cook Before Consuming" when selling direct to consumers.

Seaweed Processing

If seaweed is prepared for sale and consumption from its raw unprocessed form at temporary food service locations, it is not subject to the AGM "seaweed processing" requirements listed below, jump to Temporary Food Service Requirements section. These apply when seaweeds are processed (i.e. dried) in advance and then those products are used for on-site food preparation.

Growers/processors interested in selling seaweed that is processed in any way (dried, blanched, etc.) must possess a 20-C Food Processing License from the Department of Agriculture and Markets (AGM) and meet the requirements outlined below.

3. Processors must be compliant with the current Good Manufacturing Practices (GMP) in <u>Title 21</u> <u>CFR117 Subpart B</u>. For more detailed information on GMP's, review <u>NYSG Seafood Guide #4 on Good Manufacturing Practices</u>.



- **3.1.** The <u>Institute for Food Safety at Cornell</u> manages an online GMP training program.
- **4.** Processors must develop and implement Sanitation Control Procedures or Standard Sanitation Operating Procedures (SSOP's) for their facility to ensure that the facility, products, and packaging are maintained safely. See NYSG Seafood Guide #5 for more information on sanitation.
- **5.** Processors must have a scheduled process (detailed outline of process/procedures) developed by a recognized processing authority. NY State recognized processing authorities can be found on the Department of Agriculture and Markets website. A scheduled process should outline the temperature and source control parameters necessary at harvest, which the processor is responsible for ensuring are met when received. The scheduled process should also indicate any additional controls necessary for hazards specific to the processing procedures used.
- **6.** State and federal labeling requirements are applicable to all avenues of commercial sale, see NYSG Seafood Guide #1 for more information on labeling.
 - **6.1.** Note that fouling crustaceans often grow on seaweeds and should be labeled as an allergen on all seaweed products.

Preventive Controls Qualified Facility

7. To accurately determine what additional regulatory requirements are necessary, processors must determine whether or not they meet the definition of a qualified facility according to the Food Safety and Modernization Act Preventive Controls for Human Foods (FSMA PC) regulation outlined in part 117.5. Refer to FDA's "Guidance for Industry: Determination of Status as a Qualified Facility" for detailed guidance on determining if your business is a qualified facility, definitions of terminology, and guidance on sales and value calculations.

Non-Qualified Facility Requirements

- **7.1.** A qualified facility is either:
- » A very small business which averages, over the last three year period, <\$1,000,000 in annual sales of human foods. This calculation should include sales of affiliates or subsidiaries, OR
- » A facility in which the average value of food manufactured, processed, packed, or held, over the last three years, and sold to a qualified end user is greater than the value of food sold to any other buyer AND the average value of all food sold over the last three years is less than \$500,000, adjusted for inflation.
- **8.** Facilities that don't meet the definition of a qualified facility must be in compliance with the <u>Food Safety and Modernization Act Preventive Controls for Human Foods (FSMA PC)</u> regulation and meet the following requirements.
 - **8.1.** Growers/processors are subject to FDA regulation and inspection which may require the business to register as an <u>FDA Food Facility</u>. Additional guidance on facility registration and exemptions is available on the <u>FDA's website</u>.
 - **8.2.** Facilities must have a Preventive Controls Qualified Individual (PCQI), which is an individual with the relevant training or experience in food safety preventive controls, develop and implement their food safety plan.
 - **8.3.** Processors must develop and implement a FSMA PC compliant food safety plan. See NYSG Seaweed Guide #1 for more information.

Qualified Facility Exemptions

Qualified facilities are exempt from CFR part 117 subparts C and G of the FSMA PC regulation and must submit a <u>self-attestation to FDA</u>.

- **9.** Qualified facilities are subject to the modified requirement in <u>part 117.201</u> of the FSMA PC regulation, which state that in addition to the form FDA 3942A facilities must include either:
 - **9.1.** An attestation that you have identified the potential hazards associated with the seaweed produced, are implementing preventive controls to address the hazards, and are monitoring the controls to ensure they are effective, OR



- **9.2.** An attestation that the facility is in compliance with NY State food safety requirements including an overview of those requirements.
- » Since NY state has adopted the FSMA PC for Human Foods rule, those who meet the definition of a qualified facility must control potential food safety hazards but have the flexibility to choose the type of food safety plan or mechanisms they use. Keep in mind that if your facility grows over time and no longer meets the definition of a qualified facility, you will need to develop a FSMA PC compliant food safety plan.

Temporary Food Service Requirements

10. Growers interested in selling processed seaweed at temporary food service locations/establishments must comply with the Department of Health (DOH) sanitation rules and regulations. Statewide rules and regulations for temporary food service can be found in <u>10NYCRR 14-2</u>. You should also check with your <u>local DOH</u> to determine if there are more stringent requirements specific to your county.

Temporary Food Service - Raw

This checklist applies to temporary food service locations prepping seaweed for consumption from its raw unprocessed state.

- O Aquaculture Permit
 - O Temperature Controls
 - O Source Controls
- O DOH Sanitation RulesCompliance
- O Check Local Restrictions

Temporary Food Service

Selling products direct for consumption periodically at temporary events such as fairs and festivals.

- **10.1.** Additional information on requirements for temporary food service events in Suffolk County can be found here.
- **10.2.** Additional information information for Nassau County is available <u>here</u>.

Temporary Food Service - Processed

This checklist applies to temporary food service locations involved in processing seaweed prior to prepping for consumption (i.e. drying or blanching to store until served).

- Aquaculture Permit
 - Temperature Controls
 - Source Controls
- O 20-C Processing License
- O AGM Inspection
- O GMP Compliance
- O Sanitation Control Program
- O Scheduled Process
- O Compliance with Labeling Requirements
- O Qualified Facility? NO
 - O FDA Facility Registration
 - O FSMA PC Qualified Individual
 - O FSMA PC Food Safety Plan
- O Qualified Facility? YES
 - O FDA Self-attestation
 - O Potential Food Safety Hazard Controls in Place
- O DOH Sanitation Rules Compliance
- O Check Local Restrictions





Selling Processed Seaweed off the Boat or Farm

This guide covers the requirements for selling processed farmed seaweed off the boat or farm.

Aquaculture

- 1. Aquaculture operations (growers) in NY State that have or have applied for an off-bottom lease/license from the appropriate township or County must obtain Aquaculture Permits /Licenses from the Department of Environmental Conservation (DEC), Army Corps of Engineers, and NY State Department of State.

 Aquaculture Licenses/Permits issued by DEC permit growers to grow and sell their products, no additional dealers permits are required unless growing molluscan shellfish species (See molluscan shellfish regulatory guide).
 - **1.1.** Marine aquaculture of seaweeds are permitted through the Bureau of Marine Resources (631-444-0481). Note that not all leasing programs allow seaweed cultivation.

Seaweed Harvest

- 2. Seaweed Harvested for food must meet minimum food safety requirements including temperature and source controls. Your buyers will likely have specific requirements outlined in their food safety plans that must be met, as they are responsible for ensuring they are sourcing safe foods.
 - **2.1.** Temperature Controls: Mechanical refrigeration (40°F or below) or ice should be used to control temperature and maintain seaweed safely. Seaweed should be chilled as soon as possible after harvest to avoid quality deterioration and pathogen growth.
 - **2.2.** Source Controls: Seaweed intended for human consumption should be grown in certified waters (visit the <u>Department of Environmental Conservation's Shellfish Closures Website</u> to identify certified waters in NY).

- If a farm is operating in uncertified waters, adequate testing prior to harvest should indicate chemical contaminants, heavy metals, and pathogens are not present at levels that pose a potential health risk to consumers. For more information on hazards associated with seaweed refer to CT Sea Grant's Seaweed Hazards Guide.
- **2.3.** Raw seaweed has a short shelf-life and deteriorates quickly after harvest, it will be important to educate your buyers on the stability of your product. Consider using expiration dates to prevent deterioration and growth of pathogens before consumption. The shelf-life and stability of processed products will vary depending on the facility and processes used, producers should evaluate the stability of their products and educate buyers on appropriate handling and storage practices. Consider labeling raw products "Raw Cook Before Consuming" when selling direct to consumers.

Seaweed Processing

Growers/processors interested in selling seaweed that is processed in any way (dried, blanched, etc.) must possess a <u>20-C Food Processing License</u> from the Department of Agriculture and Markets (AGM) and meet the requirements outlined below.

- **3.** Processors must be compliant with the current Good Manufacturing Practices (GMP) in <u>Title 21</u> <u>CFR117 Subpart B</u>. For more detailed information on GMP's, review <u>NYSG Seafood Guide #4 on Good Manufacturing Practices</u>.
 - **3.1.** The <u>Institute for Food Safety at Cornell</u> manages an online GMP training program.
- **4.** Processors must develop and implement Sanitation Control Procedures or Standard Sanitation Operating Procedures (SSOP's) for their facility to ensure that the facility, products, and packaging are maintained safely. See NYSG Seafood Guide #5 for more information on sanitation.



- **5.** Processors must have a scheduled process (detailed outline of process/procedures) developed by a recognized processing authority. NY State recognized processing authorities can be found on the Department of Agriculture and Markets website. A scheduled process should outline the temperature and source control parameters necessary at harvest, which the processor is responsible for ensuring are met when received. The scheduled process should also indicate any additional controls necessary for hazards specific to the processing procedures used.
- **6.** State and federal labeling requirements are applicable to all avenues of commercial sale, see NYSG Seafood Guide #1 for more information on labeling.
 - **6.1.** Note that fouling crustaceans often grow on seaweeds and should be labeled as an allergen on all seaweed products.

Preventive Controls Qualified Facility

- 7. To accurately determine what additional regulatory requirements are necessary, processors must determine whether or not they meet the definition of a qualified facility according to the Food Safety and Modernization Act Preventive Controls for Human Foods (FSMA PC) regulation outlined in part 117.5. Refer to FDA's "Guidance for Industry: Determination of Status as a Qualified Facility" for detailed guidance on determining if your business is a qualified facility, definitions of terminology, and guidance on sales and value calculations.
 - **7.1.** A qualified facility is either:
 - » A very small business which averages, over the last three year period, <\$1,000,000 in annual sales of human foods. This calculation should include sales of affiliates or subsidiaries, OR
 - » A facility in which the average value of food manufactured, processed, packed, or held, over the last three years, and sold to a qualified end user is greater than the value of food sold to any other buyer AND the average value of all food sold over the last three years is less than \$500,000, adjusted for inflation.

Non-Qualified Facility Requirements

- **8.** Facilities that don't meet the definition of a qualified facility must be in compliance with the <u>Food Safety and Modernization Act Preventive Controls for Human Foods (FSMA PC)</u> regulation and meet the following requirements.
 - **8.1.** Growers/processors are subject to FDA regulation and inspection which may require the business to register as an <u>FDA Food Facility</u>. Additional guidance on facility registration and exemptions is available on the <u>FDA's website</u>.
 - **8.2.** Facilities must have a Preventive Controls Qualified Individual (PCQI), which is an individual with the relevant training or experience in food safety preventive controls, develop and implement their food safety plan.
 - **8.3.** Processors must develop and implement a FSMA PC compliant food safety plan. See NYSG Seaweed Guide #1 for more information.

Qualified Facility Exemptions

Qualified facilities are exempt from CFR part 117 subparts C and G of the FSMA PC regulation and must submit a self-attestation to FDA.

- **9.** Qualified facilities are subject to the modified requirement in <u>part 117.201</u> of the FSMA PC regulation, which state that in addition to the form <u>FDA 3942A</u> facilities must include either:
 - **9.1.** An attestation that you have identified the potential hazards associated with the seaweed produced, are implementing preventive controls to address the hazards, and are monitoring the controls to ensure they are effective, OR
 - **9.2.** An attestation that the facility is in compliance with NY State food safety requirements including an overview of those requirements.
 - » Since NY State has adopted the FSMA PC for Human Foods rule, those who meet the definition of a qualified facility must control potential food safety hazards but have the flexibility to choose the type of food safety plan or mechanisms they use. Keep in mind that if your facility grows over time and no longer meets the definition of a qualified facility, you will need to develop a FSMA PC compliant food safety plan.



Off the Boat/Farm Requirements

- **10.** Check with your local municipality and harbor to ensure that they do not have restrictions or require rezoning should direct sales at that location take place.
- **11.** When selling seaweed products by weight, signage indicating price should be displayed and these products must be weighed on a <u>National Type Evaluation Program (NTEP)</u> certified scale, which has been inspected and sealed by a county Weights and Measures Inspector.
 - **11.1.** The Department of Weights and Measures should be notified when a new or new-to-you scale will be used or if the official seal has been removed or damaged for repairs.
- **12.** Check with your county Weights and Measures Office to schedule an inspection: Suffolk County | Nassau County | New York City.

Off the Boat/Farm Checklist - Processed

- O Aquaculture Permit
 - O Temperature Controls
 - O Source Controls
- O 20-C Processing License
- O AGM Inspection
- O GMP Compliance
- Sanitation Control Program
- O Scheduled Process
- O Compliance with Labeling Requirements
- O Qualified Facility? NO
 - O FDA Facility Registration
 - O FSMA PC Qualified Individual
 - O FSMA PC Food Safety Plan
- O Qualified Facility? YES
 - O FDA Self-attestation
 - Potential Food Safety Hazard
 Controls in Place
- O Appropriate Price Signage
- O Certified and Inspected Scale
- O Check for Local Zoning Requirements or Restrictions



Photo Credit: The Moore Foundation- Lazy Point Farms



Selling Raw Unprocessed Seaweed off the Boat or Farm

This guide covers the requirements for selling raw unprocessed seaweed from a boat or farm.

Aquaculture

- 1. Aquaculture operations (growers) in NY State that have or have applied for an off-bottom lease/ license from the appropriate township or County must obtain Aquaculture Permits /Licenses from the Department of Environmental Conservation (DEC), Army Corps of Engineers, and NY State Department of State. Aquaculture Licenses/Permits issued by DEC permit growers to grow and sell their products, no additional dealers permits are required unless growing molluscan shellfish species (See molluscan shellfish regulatory guide).
 - **1.1.** Marine aquaculture of seaweeds are permitted through the Bureau of Marine Resources (631-444-0481). Note that not all leasing programs allow seaweed cultivation.



Photo Credit: The Moore Foundation-Lazy Point Farms

Off the Boat/Farm Requirements

- 2. Seaweed Harvested for food must meet minimum food safety requirements including temperature and source controls. Your buyers will likely have specific requirements outlined in their food safety plans that must be met, as they are responsible for ensuring they are sourcing safe foods.
 - **2.1.** Temperature Controls: Mechanical refrigeration (40°F or below) or ice should be used to control temperature and maintain seaweed safely. Seaweed should be chilled as soon as possible after harvest to avoid quality deterioration and pathogen growth.
 - 2.2. Source Controls: Seaweed intended for human consumption should be grown in certified waters (visit the <u>Department of Environmental Conservation's Shellfish Closures Website</u> to identify certified waters in NY). If a farm is operating in uncertified waters, adequate testing prior to harvest should indicate chemical contaminants, heavy metals, and pathogens are not present at levels that pose a potential health risk to consumers. For more information on hazards associated with seaweed refer to <u>CT Sea Grant's Seaweed Hazards Guide</u>.
 - 2.3. Raw seaweed has a short shelf-life and deteriorates quickly after harvest, it will be important to educate your buyers on the stability of your product. Consider using expiration dates to prevent deterioration and growth of pathogens before consumption. The shelf-life and stability of processed products will vary depending on the facility and processes used, producers should evaluate the stability of their products and educate buyers on appropriate handling and storage practices. Consider labeling raw products "Raw Cook Before Consuming" when selling direct to consumers



Off the Boat/Farm Requirements

- **3.** Check with your local municipality and harbor to ensure that they do not have restrictions or require re-zoning should direct sales at that location take place.
- **4.** When selling seaweed products by weight, signage indicating price should be displayed and these products must be weighed on a <u>National Type Evaluation Program (NTEP)</u> certified scale, which has been inspected and sealed by a county Weights and Measures Inspector.
 - **4.1.** The Department of Weights and Measures should be notified when a new or new-to-you scale will be used or if the official seal has been removed or damaged for repairs.
- **5.** Check with your county Weights and Measures Office to schedule an inspection: Suffolk County | Nassau County | New York City.

Off the Boat/Farm Checklist - Unprocessed

- O Aquaculture Permits
 - O Temperature Controls
 - O Source Controls
- O Check for local zoning requirements or restrictions
- O Appropriate price signage
- Compliance with labeling requirements (price signage)
- O Certified & inspected scale





Selling Processed Seaweed Through CSFs

This guide covers the requirements for selling processed seaweed through Community Supported Fisheries or CSFs.

Aquaculture

- 1. Aquaculture operations (growers) in NY State that have or have applied for an off-bottom lease/ license from the appropriate township or County must obtain Aquaculture Permits /Licenses from the Department of Environmental Conservation (DEC), Army Corps of Engineers, and NY State Department of State. Aquaculture Licenses/Permits issued by DEC permit growers to grow and sell their products, no additional dealers permits are required unless growing molluscan shellfish species (See molluscan shellfish regulatory guide).
 - **1.1.** Marine aquaculture of seaweeds are permitted through the Bureau of Marine Resources (631-444-0481). Note that not all leasing programs allow seaweed cultivation.

Seaweed Harvest

- 2. Seaweed Harvested for food must meet minimum food safety requirements including temperature and source controls. Your buyers will likely have specific requirements outlined in their food safety plans that must be met, as they are responsible for ensuring they are sourcing safe foods.
 - **2.1.** Temperature Controls: Mechanical refrigeration (40°F or below) or ice should be used to control temperature and maintain seaweed safely. Seaweed should be chilled as soon as possible after harvest to avoid quality deterioration and pathogen growth.
 - **2.2.** Source Controls: Seaweed intended for human consumption should be grown in certified waters (visit the <u>Department of Environmental Conservation's Shellfish Closures Website</u> to identify certified waters in NY).

- If a farm is operating in uncertified waters, adequate testing prior to harvest should indicate chemical contaminants, heavy metals, and pathogens are not present at levels that pose a potential health risk to consumers. For more information on hazards associated with seaweed refer to CT Sea Grant's Seaweed Hazards Guide.
- 2.3. Raw seaweed has a short shelf-life and deteriorates quickly after harvest, it will be important to educate your buyers on the stability of your product. Consider using expiration dates to prevent deterioration and growth of pathogens before consumption. The shelf-life and stability of processed products will vary depending on the facility and processes used, producers should evaluate the stability of their products and educate buyers on appropriate handling and storage practices. Consider labeling raw products "Raw Cook Before Consuming" when selling direct to consumers

Seaweed Processing

Growers/processors interested in selling seaweed that is processed in any way (dried, blanched, etc.) must possess a <u>20-C Food Processing License</u> from the Department of Agriculture and Markets (AGM) and meet the requirements outlined below.

- **3.** Processors must be compliant with the current Good Manufacturing Practices (GMP) in <u>Title 21</u> <u>CFR117 Subpart B</u>. For more detailed information on GMP's, review <u>NYSG Seafood Guide #4 on Good Manufacturing Practices</u>.
 - **3.1.** The <u>Institute for Food Safety at Cornell</u> manages an online GMP training program.
- **4.** Processors must develop and implement Sanitation Control Procedures or Standard Sanitation Operating Procedures (SSOP's) for their facility to ensure that the facility, products, and packaging are maintained safely. See NYSG Seafood Guide #5 for more information on sanitation.



- **5.** Processors must have a scheduled process (detailed outline of process/procedures) developed by a recognized processing authority. NY State recognized processing authorities can be found on the Department of Agriculture and Markets website. A scheduled process should outline the temperature and source control parameters necessary at harvest, which the processor is responsible for ensuring are met when received. The scheduled process should also indicate any additional controls necessary for hazards specific to the processing procedures used.
- **6.** State and federal labeling requirements are applicable to all avenues of commercial sale, see NYSG Seafood Guide #1 for more information on labeling.
 - **6.1.** Note that fouling crustaceans often grow on seaweeds and should be labeled as an allergen on all seaweed products.

Preventive Controls Qualified Facility

- 7. To accurately determine what additional regulatory requirements are necessary, processors must determine whether or not they meet the definition of a qualified facility according to the Food Safety and Modernization Act Preventive Controls for Human Foods (FSMA PC) regulation outlined in part 117.5. Refer to FDA's "Guidance for Industry: Determination of Status as a Qualified Facility" for detailed guidance on determining if your business is a qualified facility, definitions of terminology, and guidance on sales and value calculations.
 - **7.1.** A qualified facility is either:
 - » A very small business which averages, over the last three year period, <\$1,000,000 in annual sales of human foods. This calculation should include sales of affiliates or subsidiaries, OR
 - » A facility in which the average value of food manufactured, processed, packed, or held, over the last three years, and sold to a qualified end user is greater than the value of food sold to any other buyer AND the average value of all food sold over the last three years is less than \$500,000, adjusted for inflation.

Non-Qualified Facility Requirements

- **8.** Facilities that don't meet the definition of a qualified facility must be in compliance with the <u>Food Safety and Modernization Act Preventive Controls for Human Foods (FSMA PC)</u> regulation and meet the following requirements.
 - **8.1.** Growers/processors are subject to FDA regulation and inspection which may require the business to register as an <u>FDA Food Facility</u>. Additional guidance on facility registration and exemptions is available on the FDA's website.
 - **8.2.** Facilities must have a Preventive Controls Qualified Individual (PCQI), which is an individual with the relevant training or experience in food safety preventive controls, develop and implement their food safety plan.
 - **8.3.** Processors must develop and implement a FSMA PC compliant food safety plan. See NYSG Seaweed Guide #1 for more information.

Qualified Facility Exemptions

Qualified facilities are exempt from CFR part 117 subparts C and G of the FSMA PC regulation and must submit a self-attestation to FDA.

- **9.** Qualified facilities are subject to the modified requirement in <u>part 117.201</u> of the FSMA PC regulation, which state that in addition to the form <u>FDA 3942A</u> facilities must include either:
 - **9.1.** An attestation that you have identified the potential hazards associated with the seaweed produced, are implementing preventive controls to address the hazards, and are monitoring the controls to ensure they are effective, OR
 - **9.2.** An attestation that the facility is in compliance with NY State food safety requirements including an overview of those requirements.
 - » Since NY State has adopted the FSMA PC for Human Foods rule, those who meet the definition of a qualified facility must control potential food safety hazards but have the flexibility to choose the type of food safety plan or mechanisms they use. Keep in mind that if your facility grows over time and no longer meets the definition of a qualified facility, you will need to develop a FSMA PC compliant food safety plan.



Community Supported Fishery

Advanced sales of the seaweed harvested and processed to consumers in advance of harvest, selling shares of an annual harvest to a group of "members."

CSF Requirements

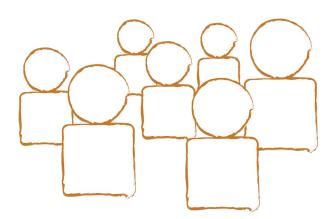
- **10.** Other than those already listed on the preceding pages, there are no CSF specific regulatory requirements, however, your product distribution channels may warrant additional regulation. For example, if distributing through e-commerce or at local fish/farm stands, see those guides for more information and additional considerations.
- **11.** When selling pre-packaged seaweed there are specific labeling requirements that must be followed, see NYSG Seafood Guide #1.



Photo Credit: The Moore Foundation- Lazy Point Farms

CSF Checklist for Processed Seaweed

- O Aquaculture Permit
 - O Temperature Controls
 - O Source Controls
- O 20-C Processing License
- O AGM Inspection
- O GMP Compliance
- Sanitation Control Program
- O Scheduled Process
- O Compliance with Labeling Requirements
- O Qualified Facility? NO
 - FDA Facility Registration
 - O FSMA PC Qualified Individual
 - FSMA PC Food Safety Plan
- O Qualified Facility? YES
 - O FDA Self-attestation
 - Potential Food Safety Hazard
 Controls in Place





Selling Raw Unprocessed Seaweed Through CSFs

This guide covers the requirements for selling whole unprocessed farmed seaweed through Community Supported Fisheries or CSFs.

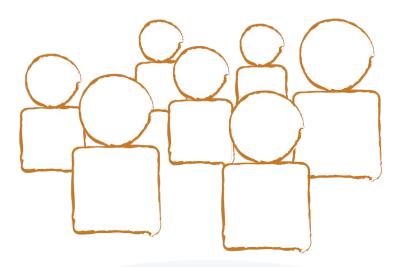
Community Supported Fishery

Advanced sales of the seaweed harvested and processed to consumers in advance of harvest, selling shares of an annual harvest to a group of "members."

Aquaculture

- 1. Aquaculture operations (growers) in NY State that have or have applied for an off-bottom lease/license from the appropriate township or County must obtain Aquaculture Permits /Licenses from the Department of Environmental Conservation (DEC), Army Corps of Engineers, and NY State Department of State.

 Aquaculture Licenses/Permits issued by DEC permit growers to grow and sell their products, no additional dealers permits are required unless growing molluscan shellfish species (See molluscan shellfish regulatory guide).
 - **1.1.** Marine aquaculture of seaweeds are permitted through the Bureau of Marine Resources (631-444-0481). Note that not all leasing programs allow seaweed cultivation.



Seaweed Harvest

- 2. Seaweed Harvested for food must meet minimum food safety requirements including temperature and source controls. Your buyers will likely have specific requirements outlined in their food safety plans that must be met, as they are responsible for ensuring they are sourcing safe foods.
 - **2.1.** Temperature Controls: Mechanical refrigeration (40°F or below) or ice should be used to control temperature and maintain seaweed safely. Seaweed should be chilled as soon as possible after harvest to avoid quality deterioration and pathogen growth.
 - 2.2. Source Controls: Seaweed intended for human consumption should be grown in certified waters (visit the Department of Environmental Conservation's Shellfish Closures Website to identify certified waters in NY). If a farm is operating in uncertified waters, adequate testing prior to harvest should indicate chemical contaminants, heavy metals, and pathogens are not present at levels that pose a potential health risk to consumers. For more information on hazards associated with seaweed refer to CT Sea Grant's Seaweed Hazards Guide.
 - 2.3. Raw seaweed has a short shelf-life and deteriorates quickly after harvest, it will be important to educate your buyers on the stability of your product. Consider using expiration dates to prevent deterioration and growth of pathogens before consumption. The shelf-life and stability of processed products will vary depending on the facility and processes used, producers should evaluate the stability of their products and educate buyers on appropriate handling and storage practices. Consider labeling raw products "Raw Cook Before Consuming" when selling direct to consumers



CSF Requirements

- **3.** Other than those already listed on the preceding pages, there are no CSF specific regulatory requirements, however, your product distribution channels may warrant additional regulation. For example, if distributing through e-commerce or at local fish/farm stands, see those guides for more information and additional considerations.
- **4.** When selling pre-packaged seaweed there are specific labeling requirements that must be followed, see NYSG Seafood Guide #1.

CSF Checklist for Raw Unprocessed

- O Aquaculture Permit
 - O Temperature Controls
 - O Source Controls
- Additional requirements for distribution method
- O Compliance with labeling requirements

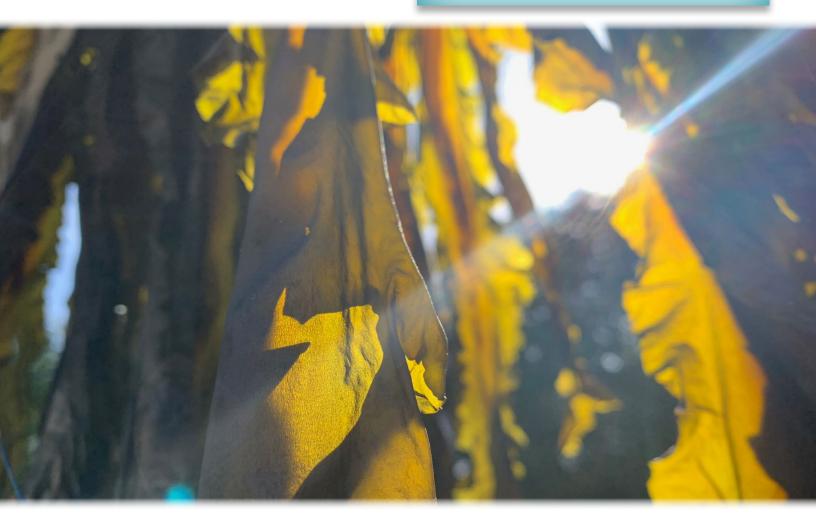


Photo Credit: The Moore Foundation - Lazy Point Farms



Additional Resources

Regulatory

Resource	Link
GMP Regulation	bit.ly/GMPRegulation
New York State (NYS) Laws	nysenate.gov/legislation/laws/CONSOLIDATED
NYS Codes, Rules, and Regulations	regs.health.ny.gov
NYS Department of Agriculture and Markets (AGM)	agriculture.ny.gov/food-safety
NYS AGM Laws and Regulations	agriculture.ny.gov/laws-regulations
NYS Department of Environmental Conservation (DEC)	https://www.dec.ny.gov/outdoor/110882.html
FSMA Preventive Controls FAQ's	https://bit.ly/FSMAPC_FAQ
FSMA Preventive Controls Rule	https://bit.lv/FSMAPC_Rule

Academic/Educational

Resource	Link
Cornell Cooperative Extension (CCE) Suffolk County	ccesuffolk.org/marine
Cornell Food Venture Center	<u>cfvc.foodscience.cals.cornell.edu</u>
Institute for Food Safety at Cornell	institute for foods a fety. cornell. edu
New York Sea Grant	seagrant.sunysb.edu/seafood
Seafood Network Information Center	seafood.oregonstate.edu
Stony Brook Small Business Development Center	stonybrook.edu/sbdc
National Seaweed Hub	seaweedhub.org

Marketing

Resource	Link
CCE Suffolk Local F.I.S.H. Program	localfish.org
Choose Long Island	<u>chooseli.org</u>
Fishermen's Direct Marketing Manual	bit.ly/MarketingManual
Local Catch	localcatch.org
Market Your Catch	marketyourcatch.msi.ucsb.edu
Seafood Network Information Center	bit.ly/SNICSeafoodMarketing

New York Sea Grant is a joint program of Cornell University, the State University of New York, and NOAA. Learn more at www.nyseagrant.org.