

BUILDING CONSENSUS ON SEAWEED FOOD SAFETY

**PROCEEDINGS OF A VIRTUAL COLLABORATIVE
LEARNING WORKSHOP**

HELD MARCH 8 – 16, 2021



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Chapter 1

“Building Consensus on Seaweed Food Safety”: Project Overview & Workshop Summary

I. Introduction

Seaweed farming is the fastest growing aquaculture sector in the United States. Seaweed is a type of marine macroalgae that is broadly classified as either a green, red, or brown algae.¹ Seaweed is currently cultivated in about 50 countries, but East Asian countries like China, Japan, and Indonesia lead the way in seaweed culture.² According to the United Nations Food and Agriculture Organization, the global seaweed industry is currently worth about \$6 billion annually, with about 85% coming from food products intended for human consumption.³ In a recent report by the World Wildlife Federation and Knorr, seaweed was listed as one of the top foods for the future.⁴

While the foreign seaweed industry is well-established, the industry in the United States is still emerging. Both wild harvest and culture of seaweed occur in the United States. Wild harvest of seaweed predominantly occurs in Alaska, Maine, and Washington. A growing number of states have permitted commercial seaweed farms, although scale varies dramatically across the country. Brief snapshots of the seaweed industry in the United States are provided below.⁵

- Maine has nearly 150 seaweed farm sites. In 2019, 325,000 pounds of farmed seaweed was harvested in Maine, which was six times the amount harvested during the 2018 season. Most of the farm sites are small starter farms with limited licenses, but the state is starting to see a move to larger-scale farm leases, typically between 4-10 acres in size. The primary species cultivated in the state are: Sugar Kelp (*Saccharina latissima*), Skinny Kelp (*Saccharina angustissima*), and Winged Kelp (*Alaria esculenta*).
- Seaweed landings in Alaska are increasing. Around 250,000 pounds of seaweed was produced in 2019, while 2018 landings were 89,279 pounds. The primary species cultivated in the state are: Sugar Kelp (*Saccharina latissima*), Ribbon Kelp (*Alaria marginata*), and Bull Kelp (*Nereocystis leutkeana*).

¹ Kandale, Ajit et al., *Marine Algae: An Introduction, Food Value and Medicinal Uses*, 4 J. OF PHARMACY RESEARCH 219 (2011).

² FOOD & AGRIC. ORG. OF THE UNITED NATIONS, THE GLOBAL STATUS OF SEAWEED PRODUCTION, TRADE AND UTILIZATION (2018).

³ *Id.*

⁴ WORLD WILDLIFE FED’N & KNORR, [FUTURE 50 FOODS](#) (2019).

⁵ State information taken from [Sea Grant Seaweed Hub State of the States](#).

- Seaweed culture in California is very small as there are less than five farms or businesses. The primary species cultivated in California are: Red Ogo (*Gracilaria pacifica*), Sea Lettuce (*Ulva spp.*), and Dulse (*Palmaria mollis*).
- In Washington, 14,000 pounds of seaweed were harvested in 2017. In 2019, Hood Canal Mariculture became Washington's first open water commercial seaweed facility in 30 years. The primary species cultivated in the state are Sugar Kelp (*Saccharina latissima*) and Bull Kelp (*Nereocystis leutkeana*).
- Connecticut was one of the first states to engage in seaweed aquaculture with its first farm established in 2011. Species cultivated include Sugar Kelp (*Saccharina latissima*), as well as Gracilaria (a red algae) in tank cultures. There is no commercial wild harvest industry in the state.
- The primary species cultivated in Massachusetts is Sugar Kelp (*Saccharina latissima*). Reporting on landings is difficult in the state, but it is estimated that the commercial harvest was less than 1,000 pounds in 2019.
- In Rhode Island in 2019, commercial farms landed 135,000 pounds of seaweed, and the primary species cultivated in the state is Sugar Kelp (*Saccharina latissima*).

Dried nori and seaweed salads are familiar to Americans who frequent sushi restaurants, but seaweed farmers and processors are starting to introduce new seaweed food products. These products vary from raw seaweed for use in salads to value-added products like salsa or seasonings. For instance, Alaskan companies produce value-added food products like seaweed salsa, hot sauce, and dried kelp seasonings, and seaweed itself is sold either dried, blanched, or frozen. In comparison, seaweed in California is a niche market. Cultivated seaweed is almost exclusively sold to restaurants and directly to consumers in a fresh/raw state. Seaweed sold in Connecticut and Rhode Island is also often raw, though farmers in Connecticut also sell blanched and cut forms, such as kelp noodles.

Most seaweed harvested in Maine is used for value added products sold in food service, retail, and specialty retail. Processors in Maine have the capacity to produce products that are raw, dried, blanched, frozen, fermented, and products include salads, kimchi, tea, jerky, and snack bars, as well as dried whole leaf, flakes, and powders.

II. Regulatory Environment

The emerging industry in the United States presents novel legal considerations, including how to regulate the sale of seaweed in its whole form for human food. The U.S. Food and Drug Administration's (FDA) current regulations are helpful to seaweed aquaculture operations seeking to sell their product for use as a food additive, but they do not apply to the sale of seaweed in its whole form.

States have the authority to fill this regulatory gap. However, states often rely on federal frameworks when developing their own laws and regulations related to food safety. Without

federal guidance, states are independently developing regulatory programs to address the needs of the emerging industry in their states. Rooted in this uncertainty is the decision agencies must make regarding whether to regulate seaweed as a seafood (like fish or shellfish) or as a plant. This decision has regulatory implications, as it may affect which governmental entity regulates the seaweed product.

While several states have implemented regulations governing aspects of seaweed aquaculture, no state has enacted a law or regulation specifically addressing food safety inspection for cultured seaweed.⁶ Because states are independently developing regulatory programs, there is a risk that each state answers the above questions and others slightly differently. Inconsistencies, overlaps, and gaps among neighboring states can reduce the effectiveness of regulatory programs and lead to confusion among the regulated community. Thus, there is a need for states to develop policy consensus regarding the sale of seaweed in its whole form to serve as a foundation for the development of more consistent state laws. Harmonization of state laws regarding the sale of seaweed products as human food would reduce confusion among industry members and facilitate interstate sales in the future.

III. Workshop Background

In 2019, the National Sea Grant Law Center (NSGLC), in partnership with Connecticut Sea Grant, applied for and received funding from the National Sea Grant College Program to begin to address this need for increased consistency among state regulatory frameworks. The project, entitled “Building Consensus on Seaweed Food Safety,” sought to enhance coordination and cooperation among states to build policy consensus as to the preferred approaches for regulating the sale of seaweed in its whole form for food for human consumption. “Building Consensus” refers to a collaborative approach developed by the NSGLC and its partners during a previous effort to draft a model legal framework for state watercraft inspection and decontamination programs.⁷ Building Consensus is a collaborative learning process where key players in policy development are brought together in one room to engage in facilitated discussions with the goal to reach agreement, or consensus, on aspects of an existing policy dispute or question.

The NSGLC Building Consensus on Seafood Food Safety project has three main aspects: (1) legal research, (2) a collaborative learning workshop, and (3) the development of a guidance document for state regulation of the sale of seaweed in its whole form as food. As an initial step in workshop planning, the NSGLC hired a professional facilitator to work with the Project Team. The Project Team consisted of:

- NSGLC attorneys Stephanie Otts, Catherine Janasie, and Zachary Klein;
- Anoushka Concepcion, Aquaculture Extension Specialist, Connecticut Sea Grant; and

⁶ AMANDA NICHOLS, NAT’L SEA GRANT LAW CTR., [INVENTORY OF STATE LAW AFFECTING COMMERCIAL SEAWEED AQUACULTURE](#) (2019). The states included in this inventory were Maine, New Hampshire, New York, Massachusetts, Rhode Island, New Jersey, Alaska, Washington, Oregon, and California.

⁷ See NAT’L SEA GRANT LAW CTR., [Building Consensus in the West: Developing a Model Legal Framework for Watercraft Inspection and Decontamination Programs](#).

- Kristin DeRosia-Banick, Supervising Environmental Analyst, Connecticut Department of Agriculture.

A. Planning Committee

In January 2020, the NSGLC formed a Planning Committee to provide a sounding board for the Project Team and the professional facilitator. Committee feedback and input was sought on a number of issues, including workshop objectives, agenda, speakers, participant list, and desired outcomes. The Planning Committee consisted of:

- Jeremy Ayers, Division of Environmental Health, Alaska Department of Environmental Conservation, Anchorage, AK;
- Steven Bloodgood, Center for Food Safety and Applied Nutrition (CSFAN), U.S. Food and Drug Administration, College Park, MD;
- Jason Bolton, University of Maine Cooperative Extension, Orono, ME;
- Kristin DeRosia-Banick, Connecticut Department of Agriculture, Hartford, CT;
- Michael Graham, Moss Landing Marine Laboratories, Moss Landing, CA;
- Emanuel Hignutt, Jr., Office of Food Safety, FDA Center for Food Safety and Applied Nutrition, College Park, MD;
- Randy Lovell, California Department of Fish and Wildlife, Sacramento, CA;
- Jennifer Perry, University of Maine, Orono, ME;
- Caird Rexroad, Agricultural Research Service, USDA, Beltsville, MD;
- Jaclyn Robidoux, Maine Sea Grant and University of Maine Cooperative Extension, Portland, ME; and
- Mark Tedesco, Long Island Sound Office, U.S. Environmental Protection Agency, Stamford, CT.

B. Response to COVID-19 Pandemic

The Workshop Planning Committee held its first call in February 2020. Discussions focused on the organization of an in-person workshop to be held in Fall 2020 in the New England region. As the COVID-19 pandemic unfolded, the target date for the workshop was pushed back until Spring 2021. To avoid indefinite delays as COVID-19 restrictions continued, the Planning Committee eventually decided to move forward in a virtual format. To prevent the complete loss of project momentum during the six-month COVID-induced delay, as discussed below, the NSGLC and its facilitator designed a number of pre-workshop engagements to develop a state agency network and a foundational base of knowledge for workshop discussions.

The *Building Consensus on Seaweed Food Safety* workshop was originally envisioned as a 2.5 day gathering with approximately 15 hours of workshop sessions. Moving from an in-person to a virtual workshop proved challenging. As this workshop would be the first national effort to bring together state regulators responsible for seaweed food safety to initiate discussions about

model state guidance, the NSGLC felt it was crucial to preserve as much of the original content and discussions as possible. Working closely with the professional facilitator, the NSGLC developed an agenda for the workshop that involved eight, three-hour sessions (24 hours) spread out over the course of two weeks. The increase in the total number of contact hours was due to recommendations from the facilitator to build in more time for small group discussion and reflection.

IV. Workshop Goal and Participants

The goal of the collaborative learning workshop on seaweed food safety was to bring together state agency staff responsible for seaweed licensing, harvesting, and food safety. The workshop was envisioned to provide state regulators with the opportunity to:

- Learn more about federal and state legal frameworks governing seaweed food safety;
- Network with other colleagues working on these issues;
- Gain a better understanding of the seaweed food safety workflow in their state; and
- Collaboratively determine what type of guidance documents would be helpful to move interstate conversations forward.

The responsibility for implementing regulations and programs related to seaweed aquaculture and food safety is often split among multiple agencies, including state departments of marine resources, agriculture, and public health. The NSGLC therefore sought to develop an invitation list that identified three points of contact for each state: seaweed harvesting, seaweed aquaculture, and seaweed food safety.

An initial invitation list was developed by the NSGLC with the assistance of partners in the National Seaweed Hub. The National Seaweed Hub, established by the Sea Grant network, serves as a science-based, non-advocate resource for the domestic seaweed and seaweed aquaculture industry. The Seaweed Hub brings seaweed stakeholders from across the country to work together to find a path forward in addressing challenges, finding solutions to needs, and pursuing opportunities for growth. Sea Grant extension agents involved in the Seaweed Hub helped the NSGLC develop a list of state agency contacts to invite to the workshop. The NSGLC supplemented this list with the names of individuals listed in the “Directory of State and Local Officials” maintained by the Association of Food and Drug Officials.⁸

Personal invitations were sent via email to individuals identified on the invitation list. Individuals were encouraged to share the invitation with other colleagues they thought should participate in the workshop. Invitations were also extended to Sea Grant extension agents working on seaweed aquaculture, as well as members of the Planning Committee and select federal representatives from NOAA as the project funder. Information about the workshop was also shared on Sea Grant aquaculture listservs to encourage wide dissemination to interested individuals beyond our invitation list.

⁸ ASS’N OF FOOD AND DRUG OFF., [*Directory of State and Local Officials*](#).

Registration was open to all state agency personnel, regardless of the extent of seaweed aquaculture in their state. Each state, however, was limited to no more than four participants to ensure geographical equity within our target limit of 50 participants. The NSGLC ultimately received 32 registrations representing 11 states. The NSGLC had another 16 registrations representing Sea Grant extension agents, Planning Committee members, and federal partners.

V. Pre-Workshop Activities

A. Research

The NSGLC conducted an extensive amount of research prior to the workshop. The NSGLC began by compiling an inventory of state seaweed laws and regulations relating to the wild harvest of seaweed, seaweed aquaculture, and seaweed food safety. This compilation was identified as a key deliverable in the grant proposal and is included as Appendix A.

The NSGLC also conducted research on the current federal framework for food safety, specifically the Food, Drug, and Cosmetics Act (FDCA) and the Food Safety Modernization Act (FSMA). The objective of this research was to gain an understanding of federal food safety regulations and their applicability to the sale of seaweed in its whole form as human food. Although seaweed does not fit neatly into any of the existing food categories, several existing regulatory approaches could serve as models including Seafood HACCP and the Produce Safety Rule. The results of this research are summarized in Chapters 3 – 6 of these workshop proceedings.

During Workshop Planning Committee calls, questions were often raised about what is already known about the food safety risks of raw seaweed. Members of the Planning Committee also wanted to know what other countries were doing to address food safety risks, especially countries like Japan and South Korea with a long history of seaweed production and consumption. With the assistance of a toxicology researcher at the University of Mississippi, the NSGLC conducted a literature review to gain a basic understanding of the state of the science regarding seaweed food safety. We also compiled information on health standards adopted in select foreign jurisdictions. A summary of these findings is contained in Chapter 2.

B. Stakeholder Webinars

The rescheduling of the workshop to March 2021 provided the NSGLC with the opportunity to design additional engagement opportunities for prospective workshop participants. With input from the Planning Committee, the NSGLC organized and hosted a series of webinars from August through November. These additional engagements helped to raise the visibility of the project, advertise the March 2021 workshop, and maintain project momentum despite the COVID-19 pandemic-related delays.

The webinar series was designed to build foundational knowledge and initiate networking opportunities among state regulators, federal partners, and industry members. The series consisted of three webinars highlighting three different perspectives: federal, state, and industry. The first webinar, held on August 27, 2020, focused on the federal framework, and featured presentations on food safety hazards associated with seaweed and the role of the U.S. Food and Drug Administration and U.S. Department of Agriculture. The speakers included:

- Nancy Balcom, *Guidance for the U.S. Seaweed Industry: Why is it Needed?*;
- Emanuel Hignutt, Jr., *FSMA Preventive Controls for Human Foods with Emphasis on Seaweed*; and
- Catherine Janasie, *USDA Regulation of Seaweed*.

The second webinar, held on September 23, 2020, focused on recent state efforts to develop or reform laws, policies, and programs to facilitate the emerging seaweed industry. Speakers from Alaska, California, Connecticut, and Hawaii provided brief overviews of their state's approach to seaweed food safety and shared some current regulatory challenges. Unlike the federal and industry webinars which were advertised widely, recorded, and posted on the NSGLC project page, the state webinar was by invitation only and not recorded so state regulators could discuss the issues openly and "off the record."

The third and final webinar, held on November 17, 2020, featured a panel of seaweed industry members from across the country discussing food safety approaches and challenges. Because registration for the March 2020 workshop was not open to industry members, this webinar provided an opportunity for seaweed growers to highlight issues that they thought state regulators should consider. In conjunction with the webinar, the NSGLC sought to obtain additional input from the seaweed industry through the distribution of a short survey. The survey sought information on existing food safety risk management approaches used by seaweed growers, external testing for food safety, and knowledge about state regulatory framework. The survey was distributed through Sea Grant extension networks, but failed to solicit enough responses to provide informative data. The NSGLC received nine responses from individuals located in five states, but three respondents were not industry members. Survey responses were shared among the core project team but were not summarized for wider distribution.

During the industry webinar, panelists were encouraged to share some information about their current Best Management Practices or sanitation practices, as well as what they would like regulators to know about the food safety challenges they are facing. Panelists included:

- Sebastian Belle, Maine Aquaculture Association;
- Markos Scheer, Sea Grove Kelp (Alaska);
- Michael Graham, Monterey Bay Seaweeds (California); and
- Suzie Flores, Stonington Kelp Company (Connecticut).

The webinars were well attended. Participation was 100, 75, and 50 respectively for the federal, industry, and state webinars. The lower participation levels for the state webinar was

expected as registration was limited to state regulators only.

C. Coffee Chats

As registration for the March 2021 workshop closed in January 2021, the NSGLC encountered an unanticipated challenge. Some registrants had participated in all or some of the webinars, while others had not. This meant that participants would be coming into the workshop discussions with different levels of knowledge about the project objectives and substantive content.

To provide an opportunity for registrants to “catch up” on project discussions, the NSGLC hosted a series of informal video “coffee chats” in the four weeks leading up to the March 2021 workshop. During the sessions, participants could drop by and discuss different topics the NSGLC was researching. The NSGLC circulated drafts of the proceedings chapters it was working on in advance. The four sessions covered the following topics:

- Federal regulatory framework
- State of the science regarding hazards
- International models
- Catch-up/grab bag

The NSGLC was already asking a lot of participants to attend eight 3-hour sessions over the course of two weeks. It was unclear whether participants would take another four hours out of their busy schedules to join the coffee chats. However, participation greatly exceeded the NSGLC’s expectations. An average of 20 individuals participated in each of the four coffee chats, which represented about half of workshop registrants.

VI. Virtual Workshop

The NSGLC used a combination of technology to run the virtual workshop. Zoom was used to host the virtual meeting and participants could join by phone or video conference. The Department of Commerce (DOC) issued a moratorium on the use of Zoom by DOC employees on April 17, 2020 which limited some participants to joining Zoom meetings via audio only. While these individuals would be able to hear the discussions and could be placed into breakout rooms, they would be unable to view shared screens, utilize chat features, or complete polls.

To address this challenge, the NSGLC used MURAL (<https://www.mural.co/>) to create a collaborative workshop space outside of Zoom. MURAL is an online collaborative whiteboard platform that enables remote individuals to brainstorm and collaborate as if they were in the same room. With MURAL, workshop participants could view slides, post sticky notes on virtual flipcharts, vote on priorities, and add ideas to the virtual parking lot. The use of MURAL in parallel with Zoom enabled all workshop participants to directly engage in interactive workshop exercises by being able to both hear the audio discussion through calling in to Zoom and see the visual components through MURAL.

A brief overview of the agenda and workshop sessions is provided below.

- **Day 1: Regulations, Technology & Seaweed, Oh My!:** The first day of the workshop focused on providing an overview of the project, the tools that would be used during the workshop (Zoom, MURAL), and the workshop goals and deliverables. Through small group discussions, participants identified and documented their desired goals for participation in the workshop. The session concluded with a brief introductory presentation about the commercial seaweed industry in the United States and food safety concerns.
- **Day 2: Understanding the Gaps:** The second day of the workshop was designed to collaboratively build participants' understanding of the legal gaps in the federal food safety regime regarding the sale of seaweed in its whole form. Following a presentation of a draft flowchart to illustrate the application of federal food safety regulations to seaweed, participants engaged in small group discussions to provide constructive feedback on the graphic and conduct a SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis of the existing federal regime.
- **Day 3: Filling the Gap:** The third day of the workshop primarily focused on brainstorming what concerns the regulators have regarding the sale of raw seaweed in their state. The session included presentations by the NSGLC sharing the results of the literature review and a presentation by Connecticut Sea Grant about the Connecticut Seaweed Guide.
- **Day 4: Policy, Regulations, & Stakeholders:** The fourth day of the workshop was designed to identify and document the needs of policy-makers, regulators, and other stakeholders regarding the regulation of the sale of seaweed in its whole form. Participants engaged in stakeholder mapping exercises, which included brainstorming the concerns and drivers of various stakeholder groups and the development of empathy maps.
- **Day 5: What Guidance?:** The fifth day of the workshop focused on preparing participants to develop graphic workflows to illustrate how the sale of seaweed in its whole form is currently regulated in their respective states. Participants were first randomly paired with a partner to interview each other to learn more about the type of work that they do and begin to document differences among states. A state workflow template was then shared with participants with instructions on completing the template.
- **Day 6: State Regulators Workday:** The sixth day of the workshop was an unstructured workday to provide state regulator participants with the time necessary to complete their

state templates. Participants could join the Zoom meeting during the regular workshop meeting time to take advantage of the breakout rooms or ask questions, but they were also free to work on the templates on their own time.

- **Day 7: Narrowing In:** The seventh day of the workshop started with a review of the discussions up to that point and the progress participants had made toward identifying priority food safety hazards and available control options. Participants then engaged in a brainstorming exercise to identify what types of tools and guidance would be useful to state regulators to begin to address these hazards.
- **Day 8: Moving Forward & Reflecting Back:** The eighth and final day of the workshop was a wrapup of participant discussions regarding seaweed food safety hazards and involved polling of participants regarding priorities moving into the second phase of the project (i.e., development of a guidance document).

VII. Outcomes

Despite the significant time commitment for participants, thirty-two state regulators representing eleven states participated in at least one workshop session. Participants assisted the NSGLC with the development of an FDA workflow (see Chapter 3) and participants from six states developed their own draft state workflows. Participants also brainstormed food safety hazards of concern and possible control methods (see Figure 1) which will provide a crucial foundation for the development of a guidance document in the second phase of the project.



Figure 1. Artistic interpretation of the high-level takeaways of the workshop brainstorming session on linking seaweed food safety hazards to possible control options.

In 2022, the NSGLC will work to translate the workshop participants’ preferred policy approaches into a model law, regulation, or guidance document for use by state managers in developing their seaweed aquaculture regulatory programs. With the assistance of a multidisciplinary Advisory Committee, which will include workshop participants, the NSGLC will identify the appropriate regulatory focus for the model document, identify key provisions that should be included, and draft the guidance document. A draft of the model document will be circulated for peer review and comment to workshop participants and appropriate committees of the Association of Food and Drug Officials (AFDO). The final document will be made available electronically on the project webpage and distributed via email, social media, and partner websites.

Chapter 2

Seaweed Food Safety Hazards

Seaweed is cultured in an open ocean environment. Unlike terrestrial plants that draw nutrients from the soil through their roots and stems, seaweed obtains the nutrients it needs directly from the surrounding water. As with shellfish, there is a risk that cultured seaweed could be contaminated by the waters that it is grown in. Bacterial contamination can also occur due to unsafe harvesting or processing practices, which is of particular concern for the sale of seaweed intended to be consumed raw.

Questions were frequently raised during initial workshop planning discussions about the known food safety risks of seaweed. To inform workshop discussions, the NSGLC undertook a review of the available scientific literature¹ to gain an awareness of the state of the science surrounding three seaweed food safety concerns: heavy metals, pathogens, and microplastics. This chapter provides a summary overview of the literature, as well as regulatory limits for some contaminants adopted by U.S. and foreign regulators.

I. Heavy metals

Seaweeds are known to accumulate heavy metals. Research has shown the concentration of heavy metals in seaweeds depends on a variety of factors, including the bioavailability of the metals in the water, environmental conditions, and the uptake capacity of the particular seaweed species. The scientific literature identifies four heavy metals of particular concern: arsenic, cadmium, lead, and mercury.

Arsenic: Arsenic is highly toxic in its inorganic form. Long-term exposure to inorganic arsenic can lead to chronic arsenic poisoning. The most characteristic effects of prolonged arsenic exposure are skin lesions and skin cancer. Algae are able to accumulate arsenic at relatively high levels compared to other food sources; food products or supplements based on algae, especially hijiki seaweed, have some of the highest levels.² Concentrations of total

¹ The NSGLC would like to thank Ann Fairly Pandelides for her assistance with the literature review. At the time, Ann Fairly was Associate Research and Development Chemist at the University of Mississippi School of Pharmacy. Additionally, we were able to gain insight into the regulatory frameworks that exist in Japan and South Korea thanks to research and translation undertaken by Dr. Yoichi Sato, a former officer of Japan's Ministry of Agriculture, Forestry, and Fisheries, and Professor Gwang Hoon Kim of Kongju National University. Our immense thanks to Vincent Doumeizel, Director of the Food Program at Lloyd's Register and author of the UN Global Compact's Seaweed Manifesto, for making himself available as a resource to workshop participants during a pre-workshop webinar and referring the NSGLC to Dr. Sato and Prof. Kim.

² See European Food Safety Authority, [Dietary exposure to inorganic arsenic in the European population](#), 12(3) EFSA J. 68 (2014).

arsenic in seaweeds are typically in the range of 0.03-300 mg/kg, but can reach extreme concentrations at contaminated sites.³

Cadmium: Cadmium mainly affects humans' renal system when consumed, specifically by causing irreversible damage to the renal tubules involved in nutrient reabsorption. Many studies have reported cadmium concentrations in seaweed, including data on the relationship between cadmium and the specific seaweed's taxonomic group and seasonal variations.⁴

Lead: Lead can accumulate in the body and cause serious damage to the central nervous system, especially in fetuses and children.⁵ It may also cause kidney disease, alterations of the gastrointestinal tract, and Alzheimer's disease.⁶ Recent research shows an association with heart disease.⁷ Several studies attest to the bioaccumulation of lead in seaweeds.⁸

Mercury: Mercury exists in various forms, including methylmercury, a highly toxic organic compound. The main source of human exposure to mercury — methylmercury in particular—is ingesting seafood.⁹ Mercury exposure in the womb may adversely affect fetuses' brains and nervous systems, and chronic exposure to high levels of mercury can lead to brain damage and paralysis. Seaweed is susceptible to accumulating mercury at levels unsafe for human consumption.¹⁰ The concentration of mercury in seaweed appears to vary widely based on the type of seaweed; studies generally report a higher content in brown seaweeds than in red seaweeds.¹¹ Moreover, mercury content can vary depending on the geographic location of seaweed cultivation.¹²

In tandem with the literature review, the NSGC conducted research to determine what, if any, regulatory thresholds exist for seaweed and seaweed products. The review here includes thresholds from U.S. regulatory agencies, the European Union, and some foreign countries. The foreign thresholds can be especially helpful, as those limits are sometimes specific to seaweed, or at least seafood. It is important to note that this review is not comprehensive as it is limited to

³ Vanessa A.T. Reis & Armando C. Duarte, [Analytical methodologies for arsenic speciation in macro-algae: a critical review](#), 102 TRAC TRENDS ANAL. CHEM. 170 (2018).

⁴ J.L. Banach et al., [Food safety hazards in the European seaweed chain](#), 19 COMPREHENSIVE REVIEWS IN FOOD SCIENCE AND FOOD SAFETY 332, 336 (2020).

⁵ NAT'L INST. OF ENVTL. HEALTH SCI., [LEAD AND YOUR HEALTH](#) (2021).

⁶ *Id.*

⁷ Tom Neltner, T., [Heart disease and adult lead exposure - the evidence grows more compelling](#), ENVTL. DEF. FUND BLOG (June 30, 2021).

⁸ Banach et al., *supra* note 4 at 337.

⁹ See [How People are Exposed to Mercury](#), ENVTL. PROT. AGENCY (Mar. 1, 2021).

¹⁰ Banach et al., *supra* note 4 at 338.

¹¹ *Id.*

¹² *Id.*

English language sources that were readily available online or in legal databases. Regulatory thresholds in the U.S. for some food categories are included by way of comparison.

A. France

France was the first European country to establish a specific regulation concerning the use of seaweeds for human consumption as non-traditional food substances. Twenty-one species of macroalgae and three species of microalgae are authorized as vegetables and condiments by French authorities. These authorities have implemented permissible thresholds for heavy metals in authorized species. (Table 1).

Table 1: France’s Legal Limits for Heavy Metals in Seaweed	
Heavy metal	Maximum level (mg/kg dry weight)
<i>Inorganic Arsenic (As)</i>	3.0
<i>Cadmium (Cd)</i>	0.5 ¹³
<i>Mercury (Hg)</i>	0.1
<i>Lead (Pb)</i>	5.0
<i>Tin (Sn)</i>	5.0

B. European Union

The European Union (EU) is an economic and political union between 27 nations that share policy and legal frameworks spanning a variety of areas, including the environment, trade, and food safety.¹⁴ EU Recommendations are a type of EU legal instrument, through which EU institutions make their views known and suggest a line of action without imposing any legal obligations on member countries.¹⁵

Commission Recommendation (EU) 2018/464 encourages EU Member States to monitor the presence of arsenic, cadmium, lead, and mercury in seaweed, halophytes, and products containing seaweed. Recommendation 2018/464 does not indicate specific regulatory thresholds for seaweed that Member States should adopt. The Recommendation observes that maximum allowable limits for lead, cadmium, and mercury have already been established for various

¹³ The French Agency for Food, Environmental and Occupational Health & Safety recently recommended lowering the maximum level to 0.35 mg/kg of dry matter in edible seaweed. [ANSES makes recommendations to limit cadmium exposure from consumption of edible seaweed](#), FRENCH AGENCY FOR FOOD, ENVTL. & OCCUPATIONAL HEALTH & SAFETY (July 28, 2020).

¹⁴ [The EU in Brief](#), EUROPEAN UNION (Mar. 16, 2021).

¹⁵ [Types of EU Law](#), EUROPEAN COMMISSION (last accessed Dec. 7, 2021).

foodstuffs, including some seafood, by Commission Regulation (EC) No 1881/2006 in 2006. (Table 2).

Table 2: EU Recommended Limits for Heavy Metals (mg/kg)			
<i>Food Type</i>	Cadmium	Lead	Mercury
<i>Muscle meat of anchovies, sea bream, eel, sardines, tuna, et al.</i>	0.1		
<i>Muscle meat of anglerfish, eel, halibut, sturgeon, swordfish, tuna, et al.</i>			1.0
<i>Muscle meat of swordfish</i>	0.3		
<i>Muscle meat of all other fish species</i>	0.05	0.3	0.05 (includes all other fishery products)
<i>Crustaceans</i>	0.5	0.5	
<i>Bivalve mollusks</i>	1.0	1.5	
<i>Cephalopods</i>	1.0	1.0	
<i>Leaf vegetables, fresh herbs, cultivated fungi, and celeriac</i>	0.2	0.3 (brassica and leaf vegetables, cultivated fungi)	
<i>Stem vegetables, root vegetables, and potatoes</i>	0.1		
<i>Muscle meat of anchovies, sea bream, eel, sardines, tuna, et al.</i>	0.1		

C. Ireland

Irish law generally forbids the importation, sale, and distribution of any food containing arsenic in a proportion exceeding 1 part per million (ppm) (1.0 mg/kg).¹⁶ However, any fish, edible seaweed, or product containing fish or edible seaweed may contain arsenic in a proportion exceeding 1 ppm where such arsenic is naturally present in that fish or edible seaweed, or in that product because it contains fish or edible seaweed.

¹⁶ [Health \(Arsenic and Lead in Food\) Regulations](#) (SI 44/1972) (Ir.).

Irish law likewise prohibits the importation, sale, and distribution of any food containing lead in a proportion exceeding 2 ppm.¹⁷ While the relevant provisions create an exception for fish similar to the exception identified above for arsenic, “alginic, acid, alginate, agar, carrageen and similar products derived from seaweed” are given an allowance of 10 ppm.¹⁸ These provisions contain no further references to seaweed. A review of the Irish Statute Book, Ireland’s compiled national legislative code, did not uncover any references to limits for cadmium or mercury in the context of food safety.

D. South Korea

In South Korea, quantitative standards for food safety can be found in the Ministry of Food and Drug Safety Notifications No. 2019-57 and 2019.7.3 (the Food Code).¹⁹ While these standards are nominally for all algae products, the limit for lead applies only to sea mustard (0.5 mg/kg) and the limit for cadmium applies only to sea mustard and laver (0.3 mg/kg).²⁰ South Korea has adopted heavy metal limits for some seafood categories.²¹ (Table 3). Rice is the only commodity that is assigned a limit for arsenic (0.2 mg/kg of inorganic arsenic).

Table 3: South Korea’s Limits for Heavy Metals (mg/kg)			
<i>Food Type</i>	Cadmium	Lead	Mercury
<i>Fish</i>	0.1	0.5	0.5
<i>Mollusks</i>	2.0	2.0	0.5
<i>Crustaceans</i>	1.0	0.5	
<i>Leafy vegetables (including flowerhead brassicas)</i>	0.2	0.3	
<i>Leaf and stem vegetables</i>	0.05	0.1	
<i>Fruiting vegetables</i>	0.05	0.1	
<i>Mushrooms</i>	0.3	0.3	

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ [Food Code](#), Ministry of Food and Drug Safety Notification, No.2019-57, 2019.7.3 (S. Kor.).

²⁰ *Id.* at 44.

²¹ *See id.* at 42-44.

E. Australia and New Zealand

Food Standards Australia New Zealand (FSANZ) is responsible for developing food standards for both Australia and New Zealand. The only heavy metal for which FSANZ has implemented a maximum level for seaweed is inorganic arsenic (1 mg/kg at 85% hydration).²² FSANZ maximum levels (MLs) of cadmium, lead, and mercury for vegetables, fish, and shellfish are identified below.²³ (Tables 5 – 7).

Table 5: Australian Legal Limits for Cadmium (mg/kg)	
<i>Leafy vegetables</i>	0.1
<i>Root and tuber vegetables</i>	0.1
<i>Mollusks (excluding dredge/bluff oysters and queen scallops)</i>	2.0

Table 6: Australian Legal Limits for Lead (mg/kg)	
<i>Brassicas</i>	0.3
<i>Fish</i>	0.5
<i>Mollusks</i>	0.5
<i>All vegetables except brassicas</i>	0.1

Table 7: Australian Legal Limits Mercury (mg/kg)	
<i>Gemfish, billfish, southern bluefin tuna, barramundi, ling, orange roughy, rays, and all species of shark</i>	0.3
<i>All other fish, fish products, crustaceans, and mollusks</i>	0.5

F. Japan

Japan’s Ministry of Health, Labour, and Welfare oversees the standards for heavy metals in food and food additives.²⁴ The only food the NSGLC found in its review with a heavy metal standard is rice: the legal limit for cadmium in rice is 0.4 ppm.

G. United States

At the federal level, all food for human consumption is subject to the Federal Food, Drug, and Cosmetic Act (FDCA), including the prohibition on introducing adulterated food into interstate commerce. The U.S. Food & Drug Administration (FDA) administers the FDCA and sets levels for the maximum amount of contaminants in food and bottled water. The FDA has

²² [Australia New Zealand Food Standards Code, Schedule 19: Maximum levels of contaminants and natural toxicants §§ S19-4, S19-7](#) (2016).

²³ *Id.*

²⁴ See [Standards for Food, Additives](#), MINISTRY OF HEALTH, LABOUR, AND WELFARE (translated by Dr. Yoichi Sato in email correspondence dated Jan. 29, 2021).

established regulatory thresholds for arsenic, cadmium, lead, and mercury for a variety of food products and bottled water.²⁵ (Table 8).

Table 8: U.S. Regulatory Thresholds Established by FDA				
Food/Drink Item	Arsenic	Cadmium	Lead	Mercury
Bottled water		5 ppb	5 ppb	
Food (general)	3 ppb (children); 12.5 ppb (adults)			
Juice			50 ppb	
Candy			0.1 ppm	
Rice Cereals	100 ppb			
Seafood				1 ppm (methyl)

II. Iodine

The human body needs iodine to make thyroid hormones, which control the body’s metabolism and contribute to proper bone and brain development during pregnancy and infancy. However, exposure to too much iodine can be harmful. High levels of iodine can cause goiter, thyroid gland inflammation, and thyroid cancer. A very large dose of iodine—several grams, for example—can have immediate and severe consequences, such as fever, stomach pain, vomiting, diarrhea, and coma.

Intake of iodine due to a single serving of seaweed may exceed the tolerable daily dose for iodine intake in adults (0.6 gram). For example, one study found that 3.3 grams of *Laminaria digitata* would provide 4017% of the tolerable daily intake for iodine, and suggested that habitual intake of seaweed with an iodine content exceeding 45 mg/kg (dry weight) could impair thyroid function.²⁶ For this reason, some researchers recommend avoiding the culture of high-iodine species until their long-term exposure effects on consumers is better understood.²⁷

France has established a maximum level of iodine in seaweed of 2,000 mg/kg dry weight. The EU’s Scientific Committee for Food has established an upper limit for iodine intake of 600

²⁵ [Lead in Food, Foodwares, and Dietary Supplements](#), U.S. FOOD & DRUG ADMIN. (last edited Feb. 27, 2020). U.S. DEPT. OF HEALTH AND HUMAN SERVICES, [TOXICOLOGICAL PROFILE FOR CADMIUM](#) 8 (2012). U.S. FOOD & DRUG ADMIN, [SUPPORTING DOCUMENT FOR ACTION LEVEL FOR INORGANIC ARSENIC IN RICE CEREALS FOR INFANTS](#) (2020).

²⁶ Donatella Desideri et al., [Essential and toxic elements in seaweeds for human consumption](#), Vol. 79(3) J. OF TOXICOLOGY AND ENVTL. HEALTH, PART A: CURRENT ISSUES 1120 (2016).

²⁷ National Food Institute et al., [Analysis and Risk Assessment of Seaweed](#), 17(S2) EFSA J. e170915, 1 (2019).

µg/day for adults and 200 µg/day for children of 1-3 years. Most notably for purposes of seaweed regulation, the Committee’s report expressly states that the ingestion of iodine-rich algal products—particularly dried products—can lead to dangerously excessive iodine intake if such products contain more than 20 mg/kg of dry iodine matter and the exposed population lives in an area of endemic iodine deficiency.

The FDA currently regulates iodine levels in kelp only when that kelp is used in food additives.²⁸ (Table 9). The rule only applies to dehydrated, ground product prepared from *Macrocystis pyrifera*, *Laminaria digitata*, *Laminaria saccharina*, and *Laminaria cloustoni*, and the agency has prescribed its legal thresholds in this context by reference to the age and physiological state of consumers targeted by the product’s labeling.

Table 9: FDA Limits for Iodine in Kelp When Used as a Supplement	
Infants	45 µg
Children aged 4 years or younger	105 µg
Adults and children aged 4+ years	225 µg
Pregnant and lactating women	300 µg
Daily limit for foods labeled without reference to age or physiological state	225 µg

A review of Ireland, Australia/NZ, South Korea and Japan did not reveal any iodine thresholds.

III. Pathogens

The FDA identifies foodborne pathogens as a serious concern, estimating that contaminated foods cause nearly 48 million cases of illness, roughly 128,000 hospitalizations, and 3,000 deaths in the U.S. every year.²⁹ Seafood grown and harvested from coastal waters are at potential risk of bacteria from both land-based and ocean sources. While the risk of bacteria contamination has not been thoroughly assessed for seaweed culture in the United States, researchers stress the importance of monitoring five pathogens: *Vibrio*, *Salmonella*, *Norovirus*, *E. coli*, and *Listeria*. These pathogens are highlighted due to the danger they pose to humans, especially when consumed via raw food, and the likelihood that these pathogens may be present in the growing environment of seaweed eventually sold for human consumption.

²⁸ See 21 C.F.R. § 172.365.

²⁹ [Foodborne Pathogens](#), U.S. FOOD & DRUG ADMIN. (Mar. 5, 2020). Olivia N. Barberi et al., [Assessment of bacterial pathogens on edible macroalgae in coastal waters](#), 32 J. OF APPLIED PHYCOLOGY 683 (2020).

Vibrio: *Vibrio* are a family of bacteria that are known to thrive in marine environments and can be extremely harmful to humans when consumed. *Vibrio parahaemolyticus* (*V. parahaemolyticus*) is a bacterium found in brackish and marine waters that can cause gastroenteritis, wound infections, and septicemia. Contaminated seafood is known to cause *V. parahaemolyticus* infections around the world. While shellfish are the most commonly identified sources of *V. parahaemolyticus*, outbreaks are increasingly being traced back to seaweeds used as food.³⁰

Salmonella: *Salmonella* is a bacterium that can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. It is the leading cause of U.S. hospitalizations and deaths from gastroenteritis.³¹ In rare circumstances, infection with *Salmonella* can result in the organism getting into the bloodstream and producing more severe illnesses, such as arterial infections and endocarditis.

Norovirus: Norovirus is a highly contagious virus that causes gastroenteritis through foodborne infection, with symptoms typically involving vomiting and diarrhea.

E. coli: *Escherichia coli* (*E. coli*) are a large and diverse group of bacteria. Some kinds of *E. coli* cause diarrhea, while others lead to urinary tract infections, respiratory illness, pneumonia, and other illnesses.

Listeria: *Listeria monocytogenes* (*L. monocytogenes*) is a bacterium that causes listeriosis, a disease often resulting in fever, muscle aches, and diarrhea. In pregnant women, listeriosis may lead to miscarriage, premature delivery, or life-threatening infection of the newborn. In addition to pregnant women, people with weakened immune systems and adults aged 65 years or older are also at heightened risk.

A. Seaweed Specific Risks

V. parahaemolyticus is the most common type of *Vibrio* to arise in the context of edible algae. Coastal seaweeds can act as a reservoir for diverse *V. parahaemolyticus* populations, and the concentration of *V. parahaemolyticus* in seaweeds correlates closely with water temperature. Coastal seaweeds are more likely to be unsafe due to *V. parahaemolyticus* during the summer months, as the bacterium is generally not detected during winter months.³² In turn, rapid ocean warming caused by climate change has stimulated the growth of *V. parahaemolyticus* in the North Atlantic, where cases of infection have consequently increased.³³

³⁰ Zahid Hayat Mahmud et al., [Seaweeds as a reservoir for diverse *Vibrio parahaemolyticus* populations in Japan](#), 118 INTL. J. OF FOOD MICROBIOLOGY 92, 92 (2007).

³¹ Barberi et al., *supra* note 25 at 684.

³² *Id.* at 684.

³³ *Id.*

Vibrio vulnificus (*V. vulnificus*) and *Vibrio cholerae* (*V. cholerae*) have also been observed in seaweed.³⁴ *V. vulnificus* is known to cause gastroenteritis and septicemia, and it is the most common cause of death due to seafood in the U.S.³⁵ Like *V. parahaemolyticus*, *V. vulnificus* tends to do better in warm waters; most cases in the U.S. are reported in the Gulf Coast states and are most common during warm weather months. *V. cholerae* is the causative agent of cholera, an illness that can cause diarrhea, vomiting, low blood pressure, kidney failure, and coma. The main reservoirs of *V. cholerae* are aquatic sources, such as rivers, estuaries, and brackish waters, often in association with zooplankton, shellfish, and aquatic plants.³⁶

Salmonella is considered a major hazard in seaweed.³⁷ It can be present in the seaweed's cultivation and harvest environment, or seaweed can be contaminated through exposure during post-harvest handling and processing. Seaweed eaten raw is more likely to transmit *Salmonella* because it is less likely to have undergone thermal or physical decontamination techniques, such as drying, prior to consumption. In 2016, fourteen cases of *Salmonella* in Hawaii were traced to the consumption of seaweed sold by Marine Agrifuture LLC of Kahuku, HI.³⁸ After receiving a cease and desist order from the Hawaii Department of Health, the company recalled product sold to distributors and other direct customers in Hawaii, California, Washington, Nevada, and Japan. Some of the product in question was sold directly to consumers at farmers markets in Hawaii. Hawaii's Department of Health later determined *Salmonella* was present in packing and processing tanks at the Kahuku farm.

Norovirus is resistant to harsh environmental conditions and has traditionally been eliminated from seaweed via a process of heating or dry storage. However, norovirus can remain actively infectious on nori seaweed for over two months at ambient temperature under dry conditions.³⁹ There are multiple examples of norovirus outbreaks linked to contaminated dried seaweeds in Japan and South Korea. In January and February of 2017 alone, seven foodborne norovirus outbreaks were reported across Japan, reportedly causing illness in 2,094 persons. All seven outbreaks were ultimately traced back to dried shredded seaweed—specifically, nori that was most likely contaminated during manufacturing.⁴⁰ However, it is often difficult to pinpoint

³⁴ See Zahid Hayat Mahmud et al., [Occurrence, seasonality and genetic diversity of *Vibrio vulnificus* in coastal seaweeds and water along the Kii Channel, Japan](#), 64 FEMS MICROBIOLOGY ECOLOGY 2 209 (2008); D.J. Vugia et al., [Cholera from Raw Seaweed Transported from the Philippines to California](#), 35 J. OF CLINICAL MICROBIOLOGY 1 284 (1997).

³⁵ Nicholas A. Daniels, [Vibrio vulnificus Oysters: Pearls and Perils](#), 52:6 CLINICAL INFECTIOUS DISEASES 788 (2011).

³⁶ Carla Lutz et al., [Environmental reservoirs and mechanisms of persistence of *Vibrio cholerae*](#), 4 FRONTIERS IN MICROBIOLOGY 1, 6-7 (2013).

³⁷ Banach et al., *supra* note 4 at 354.

³⁸ *Id.*

³⁹ Naomi Sakon et al., [Foodborne Outbreaks Caused by Human Norovirus GII.P17-GII.17—Contaminated Nori, Japan, 2017](#), 24(5) EMERGING INFECTIOUS DISEASES 920, 922 (2018).

⁴⁰ *Id.*; [Outbreaks in Japan likely from contaminated seaweed facility](#), FOOD SAFETY NEWS (Apr. 18, 2018).

precisely when or how edible seaweeds become contaminated by norovirus in the period between harvest and consumption.⁴¹

Seaweed generally becomes contaminated with *E. coli* due to the bacteria's presence in the seaweed's growth environment. An outbreak of more than 3,000 cases of *E. coli* in Japan in 2020 was attributed to contaminated seaweed salad, and *E. coli* has recently been recovered from freshly harvested kelp samples in Maine.⁴² While more research may be necessary to fully understand the relationship between *E. coli* and seaweed, it has already been established that levels of *E. coli* increase in near-shore areas after heavy precipitation.⁴³

With respect to seaweed, the threat of *Listeria monocytogenes* primarily arises in the context of post-harvest cross-contamination, but the bacterium can also be introduced during the growth, cultivation, harvest or handling of seaweed.⁴⁴ Because seaweed may be consumed raw, there is greater opportunity for pathogens like *L. monocytogenes* to survive. *L. monocytogenes* is particularly resilient for a pathogen, especially at low temperatures. For example, whereas freezing raw fish kills most of the parasites it contains, doing so only slows *L. monocytogenes*' growth rate.⁴⁵

B. Regulatory Example

Under South Korean law, seaweed operations are required to use a food safety management system, such as HACCP, to identify and address any potential food safety concerns before products are sold to the public. Additionally, the Food Code identifies acceptable thresholds for specific pathogens. While the list of pathogens addressed by the Food Code is extensive, the limits for pathogens that are most likely to be of interest are highlighted in Table 10.

⁴¹ Eiji Kusumi et al., [Multiple Norovirus Outbreaks Due to Shredded, Dried, Laver Seaweed in Japan](#), 38 INFECTION CONTROL & HOSPITAL EPIDEMIOLOGY 885–886 (2017).

⁴² Barberi et al., *supra* note 25 at 687-88 (2020).

⁴³ C.E. Tilburg, et al., [The effects of precipitation, river discharge, land use and coastal circulation on water quality in coastal Maine](#), 2: 140429 ROYAL SOC'Y OPEN SCIENCE 1, 14-17 (2015)..

⁴⁴ Banach et al., *supra* note 4 at 349.

⁴⁵ [What is a "Kill Step" in Food Safety?](#), FDA READER (July 25, 2017).

Table 10: Limits for Biological Pathogens in Food Under South Korean Law - Summary	
Total bacteria	n = 5, c = 2
<i>E. coli</i>	n = 5, c = 2, m = 0, M = 10
<i>Salmonella spp.</i> , <i>Vibrio parahaemolyticus</i> , <i>Listeria monocytogenes</i> , Enterohemorrhagic <i>Escherichia coli</i> , <i>Campylobacter jejuni/coli</i> , <i>Yersinia enterocolitica</i>	n = 5, c = 0, m = 0/25g
<i>Bacillus cereus</i>	<10,000 cell/g
<i>Staphylococcus aureus</i>	n = 5, c = 1, m = 10, M = 100

- “n” means the number of test samples
- “c” refers to the maximum number of samples allowed; the number of samples exceeding the allowable limit (m) but not more than the maximum allowable limit (M); if the number of samples that exceed “m” but not more than “M” is not more than “c”, the results is determined to be conforming.
- “m” is the allowable limit of microorganisms; if all samples are not more than “m,” the result is determined to be conforming.
- “M” indicates the maximum limit of microorganisms allowed; if one or more samples exceed M, the result is determined to be non-conforming.

IV. Microplastics

Metals and pathogens are not the only environmental contaminants that seaweeds are capable of accumulating. Microplastics are increasingly present in most aquatic environments and are an emerging area of study in marine ecosystems. Plastics are often made with additives that are potentially toxic, and microplastics can accumulate toxic and carcinogenic substances, such as polychlorinated biphenyls (PCBs). Macroalgae collected at the New Bedford Harbor Superfund Site contained PCB levels equal to or exceeding FDA tolerance levels.⁴⁶

Micro- and nanoplastics can attach to algal surfaces by binding to cellulose in the algal tissue, which has ramifications throughout the ecosystem and food chain.⁴⁷ For instance, snails that naturally feed on algae cannot distinguish between clean algae and algae containing

⁴⁶ Donald P. Cheney et al, [Bioaccumulation of PCBs by a seaweed bloom \(*Ulva rigida*\) and transfer to higher trophic levels in an estuarine food web](#), 611 MARINE ECOLOGICAL PROGRESS SERIES 75, 86 (2019).

⁴⁷ Priyanka Bhattacharya et al., [Physical Adsorption of Charged Plastic Nanoparticles Affects Algal Photosynthesis](#), 114 J. OF PHYSICAL CHEMISTRY C 16556 (2010).

microplastics.⁴⁸ Critically, these seaweeds not only accumulated high levels of PCBs, but also passed them on through the food web to mummichogs, a keystone fish species in the area.⁴⁹ Microplastics can continue passing through the food chain to humans, and gestating mothers are even able to pass on microplastics to their fetuses through the placenta.⁵⁰

V. Summary

Scientific inquiry into the hazards associated with the human consumption of seaweed, especially in its raw form, is in its early stages. Nevertheless, the available scientific literature identifies a variety of food safety risks that must be taken into account as the industry develops in the United States. The literature identifies heavy metals, biological pathogens, and microplastics as the top potential threats to human health that may contaminate raw seaweed. While studies abound on these contaminants more generally, their presence and risk in seaweed is not yet fully understood, leading to gaps in the current knowledge about the thresholds that are appropriate for these contaminants in seaweed specifically, especially raw seaweed. Additionally, the scientific literature review revealed that many of these contaminants are known to be associated with or exacerbated by warm waters. Rising ocean temperatures caused by climate change may consequently amplify the severity and/or geographic distribution of these hazards.

⁴⁸ Lars Gutow et al., [Experimental Evaluation of Seaweeds as a Vector for Microplastics into Marine Food Webs](#), 50 ENVTL. SCIENCE & TECHNOLOGY 915 (2016).

⁴⁹ *Id.*

⁵⁰ Antonio Ragusa et al., [Plasticenta: First evidence of microplastics in human placenta](#), 146 ENVIRONMENT INTL. 106274 1, 1-7 (2021).

Chapter 3

Federal Food Safety Framework: Where does Seaweed Fit in?

I. Introduction

What is seaweed? Scientifically speaking, it is macroalgae that are classified into three major groups: brown algae (*Phaeophyceae*), green algae (*Chlorophyta*), and red algae (*Rhodophyta*). Legally, it is unclear. Legal definitions do not always track scientific ones. For instance, the U.S. Supreme Court once ruled that a tomato could be treated as a vegetable for regulatory purposes, even though scientifically it is a fruit. Seaweed is not a plant in biological terms, but at least one state defines seaweed as a “marine aquatic plant.”¹ Further, while the Food and Drug Administration (FDA) does not consider seaweed to be a “plant” or “produce,”² the U.S. Department of Agriculture (USDA) has referred to seaweed as an aquatic plant.³

With respect to food safety, there is no federal definition directly related to seaweed. Seaweed does not clearly fit into the FDA’s definition of “fish or fishery product,” which would subject it to Seafood HACCP requirements, or the definition of produce, which would subject it to the Produce Safety Rule. Seaweed clearly is not a shellfish, but the National Shellfish Sanitation Program could be a potential model in considering the health risks of seaweed related to water quality and cultivating, harvesting, processing, shipping, or handling of seaweed products.

Even if seaweed does not fit neatly into the definition of fish, produce, or shellfish, it can be classified generally as food. On the federal level, all food for human consumption is subject to the Federal Food, Drug, and Cosmetic Act (FDCA), including the prohibition on introducing adulterated food into interstate commerce. The adulterated food prohibition applies to harvested seaweed intended for consumption as food, including that it not be “prepared, packed, or held under insanitary conditions.”⁴

In February 2021, the FDA, in a response to a request from the Association of Food & Drug Officials, stated that harvested seaweed is a raw agricultural commodity.⁵ Like other raw agricultural commodities, the FDA therefore considers the growing and harvesting of seaweed to be “farm” activities. This distinction is important because activities that fit within FDA’s definition of a “farm” are not considered food processing that would be subject to further requirements besides the adulteration prohibition mentioned above. Some activities that may be

¹ See WASH. REV. CODE § 79.135.400.

² See Emanuel Hignutt, Jr., Office of Food Safety, FDA Center for Food Safety and Applied Nutrition, [FSMA Preventive Controls for Human Foods \(PCHF\) with Emphasis on Seaweed](#), NSGLC Seaweed Food Safety Webinar Series: Federal Considerations, Aug. 27, 2020.

³ See U.S.D.A. NAT’L ORGANIC PROGRAM, [USDA NOP 5027, GUIDANCE: THE USE OF KELP IN ORGANIC LIVESTOCK FEED](#) (2013) (stating that “[s]eaweeds are simple, saltwater-dwelling algae that can be referred to as aquatic plants).

⁴ 21 U.S.C. § 342(a)(4).

⁵ Email on file with author.

thought of as processing can still fall within the farm definition, such as drying.⁶ If an operation goes beyond harvesting and drying, such as by blanching, freezing, or cutting the seaweed, it would be considered a “food facility.”

Under the Food Safety Modernization Act (FSMA), food facilities that need to register with the FDA are also subject to 21 CFR Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Rule. However, there are certain exemptions to these requirements that may result in few seaweed operations in the United States being subject to the full requirements of Part 117. For instance, businesses with less than \$1 million in sales a year are exempt from the Preventive Controls requirements.

Further, while the FDA has wide authority to regulate food that circulates in interstate commerce, states have the authority to regulate food sold in restaurants and retail stores found within the state. Thus, states have options in deciding how to approach the regulation of seaweed when grown and sold for human food in intrastate sales. However, when developing food safety rules, states often rely on the FDA Food Code, which is a guidance document updated every four years. The most recent version was released in 2017, but it does not address seaweed.

Without federal guidance, states are independently developing regulatory programs to address the emerging industry needs in their states. Rooted in this uncertainty is the decision agencies must make regarding whether to regulate seaweed as a raw agricultural commodity, seafood (like fish or shellfish), or as a plant. This decision has regulatory implications, as it may affect which governmental entity regulates the seaweed product. Regulatory authority for food safety may be shared or split among several agencies within a state, and, therefore, oversight responsibility for different food categories may fall to different agencies. For example, the Connecticut Department of Agriculture (DOAG), Bureau of Aquaculture regulates kelp intended to be sold as a *raw agricultural commodity* under a *seaweed producer license*. The DOAG also implements the Produce Safety in the state under FMSA. However, the Connecticut Department of Consumer Protection Food and Standards Division (DCP) regulates kelp that is *packaged or processed* under a *food manufacturing license*.

As Connecticut shows, states have already taken steps in regulating seaweed as a food source. While Connecticut has chosen to apply Seafood HACCP, Alaska has chosen to regulate seaweed under its general food provisions.⁷ These choices do have an effect on the relevant state agencies and the regulated community. For instance, Maine takes a mixed approach, with the Maine Department of Marine Resources regulating seaweed as seafood up until the point of harvest and the Maine Department of Agriculture, Conservation and Forestry regulating it as a produce for post-harvest activities, including handling, processing, distribution, and sale. While these choices are not set in stone, experiences with these regulatory models can be useful for states as they collaborate in discussing the next steps forward for seaweed food safety regulation.

The following sections explore the legal framework governing the sale of food products in the United States and how that framework applies to seaweed. Topics covered include the FDA

⁶ 21 C.F.R. § 1.227.

⁷ See the Alaska Food Code, ALASKA ADMIN. CODE tit. 18, Chapter 31.

framework for regulating food and FDA's current regulatory standards for seaweed in its use as an additive.

II. The FDA Framework for Regulating Food

States and the federal government have split authority when it comes to regulating food safety. Under the U.S. Constitution, the federal government has the authority to regulate interstate commerce. Known as the Commerce Clause power, this is the legal basis for FDA to regulate food under the FDCA and the FSMA.

A. FDCA

The FDCA prohibits activities involving the movement of adulterated food in interstate commerce. The statute lists the different circumstances where a food could become adulterated.⁸ Relevant to seaweed is the category of poisonous or unsanitary ingredients in food, which includes, among other items, the following:

- Poisonous or deleterious substances that make the food injurious to health, though a food is not adulterated if the potentially harmful substance is not added to the food and the amount is not usually injurious to health.
- Added poisonous or deleterious substance, pesticide chemical residue, unsafe food additives, or new animal drugs that are unsafe under the Act.
- Food that consists in whole or in part of filthy, putrid, or decomposed substances, or is otherwise unfit to be eaten.
- Food that is prepared, packed, or held in conditions where it can become "contaminated with filth" or rendered injurious to health."
- Food that is held in a container that could be injurious to health.⁹

Finally, food is adulterated if it is transported in a way that does not comply with the regulations for sanitary transportation practices, which can be found at 21 CFR Sections 1.900-1.934.¹⁰ This standard could be important when considering the transportation of seaweed from the farm to a farmers market, restaurant, or similar location.

⁸ 21 U.S.C. § 342. Other categories of adulterated food that are not discussed in this paper include color additives that do not meet the standards of the FDCA, confections containing alcohol or nonnutritive substances, oleomargarine that is unfit as food, limits on dietary supplements or ingredients, and certain imported food that does not meet the standards of the FDCA. *Id.* Additional adulterated food categories include food "(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is." *Id.*

⁹ *Id.*

¹⁰ *Id.*

FDCA Important Definitions	
Food	(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article
Processed Food	Any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.
Raw Agricultural Commodity	Any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

B. FSMA

FSMA was enacted in 2011 as a way to strengthen food safety regulation in the United States. The law is structured to prevent food safety issues before they occur, instead of reacting to problems after the fact. New authorities given to the FDA under FSMA include a legislative mandate to prevent food safety issues, mandatory inspection and testing protocols, and enhanced response authority. Under FSMA, the responsible agent of a food processing facility is required to analyze potential hazards and create a written plan that includes preventative control measures for each potential hazard. Since FSMA was enacted, the FDA has finalized seven major rules to implement the Act, including rules related to (1) Good Manufacturing Practice, Hazard Analysis, and Preventive Controls and (2) Produce Safety, which are discussed in more detail below.

It should be noted that FSMA is applicable only to food facilities that “engaged in manufacturing, processing, packing, or holding food for consumption...”.¹¹ The FDA has published detailed definitions for each of these terms in the agency’s regulations implementing FSMA.

Manufacturing/Processing: Making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients.

- Examples include: baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, *drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins)*, evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing.

¹¹ 21 U.S.C. § 350d.

- For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.¹²

Packing: Placing food into a container other than packaging the food. The definition also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)). It does not include activities that transform a raw agricultural commodity into a processed food.

Holding: Storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)).

- Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but it does not include activities that transform a raw agricultural commodity into a processed food.
- Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with the FDA.¹³ Certain entities are exempt from the facility registration process, including farms, retail food establishments, and restaurants.

C. Current Regulatory FDA Standards for Seaweed

With respect to the sale of seaweed in its whole form as a food product, there are no federal regulations or guidance. There are, however, federal regulations and actions related to other uses of seaweed. The FDA's current regulations can help seaweed farmers and processors who wish to sell their product for use as a food additive, but the regulations are limited to certain marine algae species and do not encompass the sale of seaweed in its whole form.

The FDA currently has several regulations controlling the legal consumption of seaweed and kelp products in the United States, but *only* when used in other foods as an additive. A "food additive" legally refers to any substance the intended use of which results or may reasonably be

¹² 21 C.F.R. § 1.227.

¹³ 21 U.S.C. § 350d.

expected to result—directly or indirectly—in its becoming a component or otherwise affecting the characteristics of any food.¹⁴ Food additives are subject to FDA’s premarket review and approval, unless the substance is given a “generally recognized as safe” (GRAS) designation.¹⁵

The FDA has made a GRAS determination for certain seaweeds when they are used as additives. The FDA has set forth maximum daily amounts of kelp additive (including Giant Kelp (*Macrosystis pyrifera*), Oarweed (*Laminaria digitata*), and Sugar Kelp (*Saccharina latissima*)) that certain subsets of people should be able to ingest without consuming too much iodine. For most people, the daily amount is 225 micrograms.¹⁶ For infants, the maximum amount is 45 micrograms, while the limit for pregnant or lactating women is 300 micrograms. Additionally, the agency notes that its GRAS determination and regulations apply generally to certain species of dehydrated, ground kelp, including giant kelp, oarweed, sugar kelp, and cuvie (*Laminaria cloustoni*).¹⁷

Besides these general regulations, the FDA adopted specific regulations for brown and red algae.¹⁸ These regulations list the names of applicable GRAS species, and note both brown and red algae’s functional uses include “flavor enhancer” and “flavor adjuvant.” Listed brown and red algae species may be considered GRAS, whether or not they are meant to impart any of their own taste to the food to which they are added. GRAS determinations do not apply to singular products such as kelp or seaweed in its whole raw, cooked, or dried forms. Until the FDA promulgates relevant regulations to that effect, commercial aquaculturists and harvesters could experience complications when trying to get such products to market.

D. Raw Agricultural Commodity Determination

In February 2021, the FDA released a statement in response to a question from the Association of Food and Drug Officials (AFDO).¹⁹ In the statement, FDA clarified that raw seaweed is not a seafood or plant, but rather, a raw agricultural commodity. On the federal level, food that is not a fish or fishery product, shellfish, or produce is regulated under 21 CFR Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Rule (Part 117), which is discussed in the next chapter.

¹⁴ *Id.* § 321(s).

¹⁵ [Generally Recognized as Safe \(GRAS\)](#), U.S. FOOD & DRUG ADMIN. (Sept.6, 2019).

¹⁶ 21 C.F.R. § 172.365.

¹⁷ *Id.*

¹⁸ *Id.* §§ 184.1120, 1121.

¹⁹ Email on file with the author.

Chapter 4

Treating Seaweed as a General Food Product under 21 CFR Part 117 - Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Rule

I. Introduction

On the federal level, food that is not a fish or fishery product, shellfish, or produce is regulated under 21 CFR Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Rule (Part 117). The rule can be considered in two parts: requirements for Current Good Manufacturing Practices (CGMPs) and requirements for Hazard Analysis/Preventive Controls (HA/PC). CGMPs aim to ensure food safety by addressing matters like “personal hygienic practices, design and construction of a food plant and maintenance of plant grounds, plant equipment, sanitary operations, facility sanitation, and production and process controls during the production of food.”¹ HA/PC requires food facilities to have a food safety plan in place that includes an analysis of hazards and risk-based preventive controls to minimize or prevent the identified hazards. However, as discussed more below, there are some major exemptions to the rule.

Many seaweed growers in operation in the United States today would not be subject to Part 117 due to the small size of their operations and type of products sold. In particular, Part 117 does not apply to: 1) seaweed that is a raw agricultural commodity; 2) seaweed subject to certain exempt on-farm manufacturing, process, packing, or holding activities; or 3) seaweed operations below certain size thresholds (modified requirements). Figure 1 shows the overall framework for determining which parts of Part 117 apply to a facility. The details of the framework are discussed more fully later in this section.

¹ *Current Good Manufacturing Practices (CGMPs) for Food and Dietary Supplements*, U.S. Food & Drug Admin. (Jan. 31, 2020).

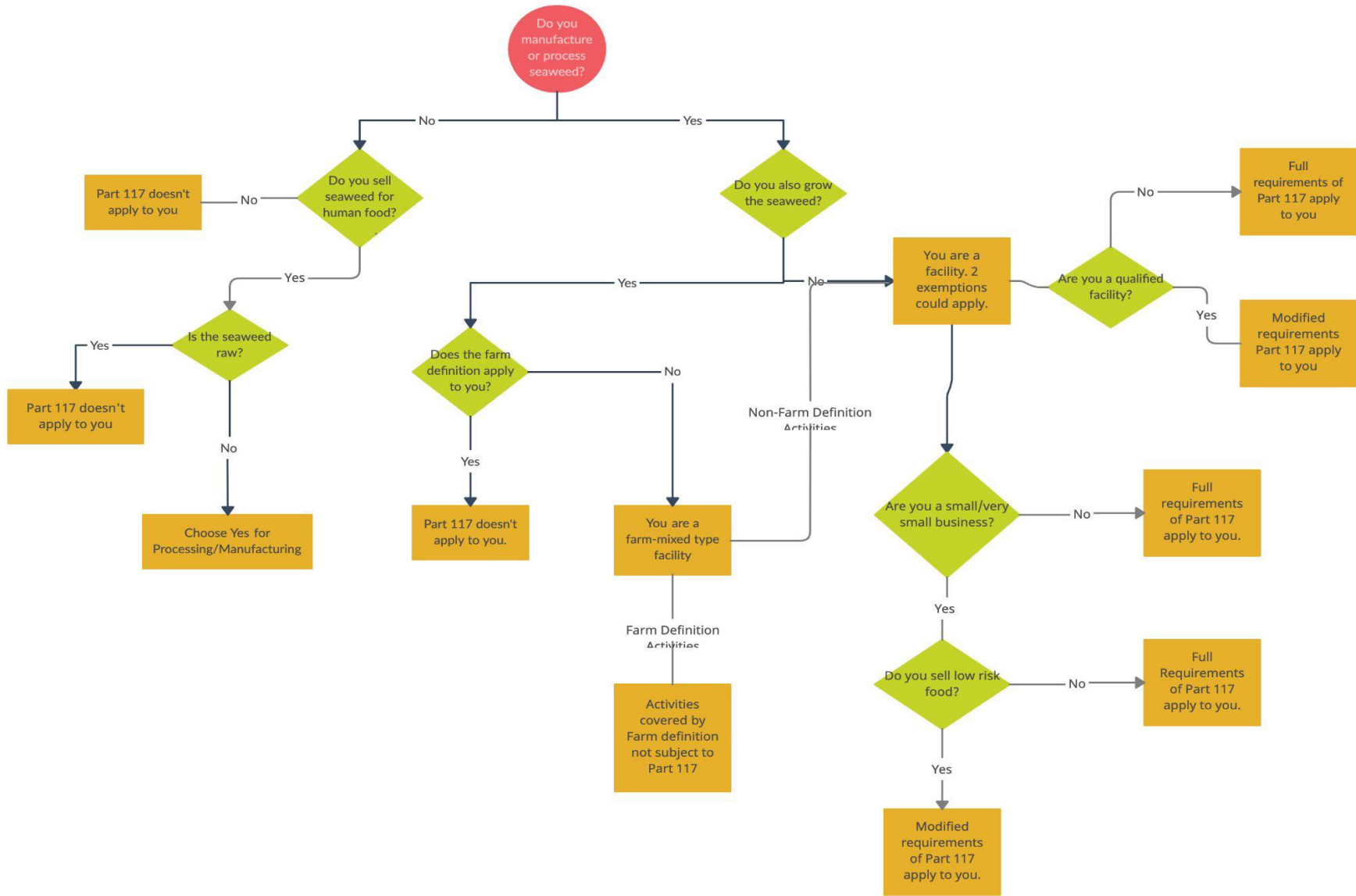


Figure 1. Overview of Part 117.

II. Applicability

The application of the CGMPs and HA/PC depends on whether the operation needs to register as a facility under FSMA. Facilities, mixed-type facilities, and qualified facilities all need to register. However, depending on the characteristics of the operation, the operation may only be subject to modified CGMP and HA/PC requirements. Farms and retail food establishments are not required to register, and thus, are not subject to the CGMPs and HA/PC. The meaning of these terms is therefore very important. The difference among these categories is discussed below, as well as how seaweed operations might fit into each category.

A. Full Applicability

Facilities are subject to all the requirements of CGMPs and HA/PC. Part 117 defines a facility as simply “a domestic facility or foreign facility that is required to register” under FDCA Section 415.² The FDA’s regulations for facility registration more fully define what constitutes a facility:

any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility....³

B. Full Exemption

Farms are not subject to Part 117. The definition of farm is complicated and divided into two subcategories: “primary production” farms and “secondary activities” farms. The definition of farms in Part 117 includes some manufacturing and processing activities. Farms that engage in manufacturing or processing activities beyond those listed in the farm definition are classified as a mixed-type facility, discussed more below.

A primary production farm includes operations “under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities.”⁴ A secondary activities farm is “an operation, not located on a primary production farm, devoted to

² 21 C.F.R. § 117.3.

³ *Id.* § 1.227.

⁴ *Id.*

harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm.”⁵ Table 1 provides a summary of the activities included in the farm definition.

Table 1: Manufacturing and Processing Activities Included Within the Farm Definition in 21 C.F.R. § 1.227	
Activity	Requirements to Meet Farm Definition
Pack/Hold Raw Agricultural Commodities	None
Pack/Hold Processed Food	<ul style="list-style-type: none"> ● All processed food is either consumed on the farm or another farm under the same management; OR ● processed food is a dried or dehydrated raw agricultural commodity that created a distinct product (ie. drying grapes to make raisins) and the packaging and labeling of the new product occurred without any additional manufacturing or processing.
Manufacture/Process Food	<ul style="list-style-type: none"> ● all food is consumed on the farm or another farm under the same management; OR ● it is one of the following: <ul style="list-style-type: none"> ○ a dried or dehydrated raw agricultural commodity that created a distinct product (ie. drying grapes to make raisins) and the packaging and labeling of the new product without any additional manufacturing or processing; ○ treating a raw agricultural commodity to manipulate its ripening and packaging or labeling it without any additional; or manufacturing or processing; or ○ packaging or labeling a raw agricultural commodity without any additional manufacturing or processing.

⁵ *Id.*

Farms are also allowed to perform “harvesting,” “packing,” and “holding” activities that are incidental to the farming operations and take place on the farm without jeopardizing their status as a farm. In addition, the registration requirement specifically states: “For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.”⁶ Overlapping terms include:

- cooling, cutting, drying/dehydrating raw agricultural commodities to create a distinct commodity, labeling, packaging (including modified atmosphere packaging), treating to manipulate ripening, trimming, washing (raw agricultural commodities grown on a farm).

Retail food establishments are businesses whose primary function is to sell food directly to consumers. Included in the definition of retail food establishment are establishments that sell “food products directly to consumers as its primary function.”⁷ Consumers do not mean businesses, and a “retail food establishment” can be a grocery store, convenience store, or vending machine location. Retail food operations also include facilities:

that manufacture, process, pack, or hold food if the establishment’s primary function is to sell from that establishment food, including food that it manufactures, processes, packs, or holds, directly to consumers. A retail food establishment’s primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers.⁸

In terms of seaweed operations, those that sell directly to consumers or produce value-added products could fit within the retail food establishment definition. The farm-operated business simply has to make a majority of its sales directly to the consumers.

C. Partial Applicability

Qualified facilities face modified requirements under Part 117. There are two ways to be deemed a qualified facility. The first is to be a “very small business,” which is a business that grossed less than \$1 million a year for the previous three years in its sales of human food, including food it held for a fee.⁹ The second route is based on direct sales to consumers and other “qualified end users,” which includes restaurants and retail food establishments in the same state or within 275 miles that sell food directly to consumers. To meet this requirement, the value of

⁶ *Id.* § 117.3.

⁷ *Id.* § 1.227.

⁸ *Id.* § 1.227.

⁹ *Id.* § 117.3.

the food sold to consumers and other qualified end users in the previous three years must be greater than the value of the food sold to other purchasers and less than \$500,000 per year.¹⁰

Mixed-type facilities are establishments that engage in a mix of activities, some of which are exempt from registration and others that require registration. For instance, a “farm mixed-type facility” “is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.”¹¹

There is a partial exemption for farm mixed-type facilities if the facility is a small or very small business and the only manufacturing/processing it engages in are considered low-risk for certain foods. The FDA’s list for these activities and foods is extensive.¹² If a mixed-type facility does not fall within this exemption, it is subject to the full requirements of Part 117. Table 2 summarizes these exemptions.

Table 2: Applicability of FSMA Requirements			
Type	Registration	Current Good Manufacturing Practices	Hazard Analysis/Preventive Controls
Facility	Yes	Yes	Yes
Qualified Facility	Yes	Yes	Modified Requirements
Farm	No	No	No
Retail Food Establishment	No	No	No
Farm Mixed-Type Facility	Yes	Depends on characteristics of the operation	Depends on characteristics of the operation

III. Part 117 Requirements

Because of the small scale of most seaweed farms and operations in the United States, Part 117 is likely not widely applicable to the seaweed industry. However, the structure and requirements of Part 117 may be helpful when considering potential food safety models.

¹⁰ *Id.*

¹¹ *Id.*

¹² A full list of the low-risk foods and activities that qualify for the exemption can be found on page 20 of the FDA’s [Small Entity Compliance Guide](#) for Part 117..

A. Good Manufacturing Practices

The FDA first established CGMPs for food in the Federal Register in 1969.¹³ The CGMPs were modernized in 2015 following the passage of FSMA. Brief summaries of the CGMP categories are provided below.

Personnel: These CGMPs require employees who are visibly ill to be excluded from operations, unless the illness, like open wounds or lesions, can be adequately covered. An additional requirement for cleanliness mandates that “[a]ll persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food.”¹⁴

Plants and Grounds: These CGMPs require that grounds under the operator’s control be kept in a condition that prevents the contamination of food. Further, “[t]he plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes.”¹⁵

Sanitary Operation: These CGMPS include requirements for the general maintenance of the facility, cleaning materials (including the storage of toxic chemicals), sanitizing food and non-food contact surfaces, and storing and handling utensils and portable equipment.¹⁶

Sanitary Facilities and Controls: These CGMPS include requirements for water supply, plumbing, sewage disposal, toilet and hand-washing facilities, and rubbish disposal.¹⁷

Equipment and Utensils: These CGMPS include requirements for equipment and utensils that are cleanable, avoid adulteration, and able to be kept in a sanitary condition. Food-contact surfaces must be made of corrosion resistant and non-toxic materials, maintained to protect against allergen cross contamination or any other type of contamination, and kept to avoid the build-up of dirt and organic matter.¹⁸

Processes and Controls: These CGMPS include general requirements for the manufacturing, processing, packing, and holding of food that will ensure adequate sanitation

¹³ FDA, [Current Good Manufacturing Practices \(CGMPs\) for Food and Dietary Supplements](#).

¹⁴ 21 C.F.R. § 117.10.

¹⁵ *Id.* § 117.20.

¹⁶ *Id.* § 117.35.

¹⁷ *Id.* § 117.37.

¹⁸ *Id.* § 117.40.

and ensure the food is suitable for human consumption. There are additional requirements for raw materials.¹⁹

Warehousing and Distribution: These CGMPS include requirements for storing and transporting food “under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.”²⁰

Defect Action Levels: These CGMPS include requirements for “quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible” and prohibits the mixing of defected, adulterated food with another lot of food.²¹

B. Hazard Analysis and Preventive Controls

Under the Hazard Analysis and Preventive Controls requirements, the agent in charge of the facility must prepare a food safety plan. A food safety plan is a written plan that documents all of the procedures by which the facility complies with the HA/PC requirements. The required contents of the food safety plan are summarized in Table 3. The document must be available to the FDA by oral or written request. A “preventive controls qualified individual” must write or oversee the preparation of the food safety plan. Who this person or persons can be depends upon the following definitions:

- *Preventive controls qualified individual:* a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.
- *Qualified Individual:* a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual’s assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.²²

¹⁹ *Id.* § 117.80.

²⁰ *Id.* § 117.93.

²¹ *Id.* § 117.110.

²² *Id.* § 117.3.

Table 3: Contents of Food Safety Plan	
Component	Description
Hazard Analysis	Must be written and must include natural, unintentional hazards as well as hazards that may be intentionally introduced.
Preventive Controls	Must have the effect of minimizing or preventing the named hazards and assuring that the food processed in the facility will not be adulterated.
Procedures for Monitoring the Implementation of Preventive Controls	The required monitoring should assure the preventive controls are achieved.
Supply Chain Program	Required for processing facilities that receive from a supplier raw materials/ingredients for which the facility has identified a hazard.
Recall Plan	A recall plan is required for identified foods with hazards that require preventive controls.
Corrective Action Procedures	The agent in charge of the facility shall have corrective action procedures in the case that the preventative controls are not implemented or are ineffective, ensuring that the controls are put back in place, the affected food is evaluated for safety, and the affected food is not put into commerce if the agent cannot ensure safety.
Verification Procedures	The agent in charge of the facility must personally verify that the control measures are adequate, effective, documented, and in accordance with these provisions.

It should be noted that facilities are required to reanalyze hazards whenever significant changes are made in the facility’s activities or once every three years, whichever is earlier. Further, FSMA provides for the Secretary of the U.S. Department of Health and Human Services to work in coordination with the USDA to review new health science at least every two years and release new guidance documents and regulations to help prevent the adulteration of food.²³ In conjunction with 21 U.S.C. § 350g(i), this section implies that the issuance of a guidance document might be a cause for a food facility to reanalyze potential hazards.

²³ 21 U.S.C. § 2201.

1. Hazard Analysis

Through Hazard Analysis, a facility must identify and evaluate “known or reasonably foreseeable hazards” that require preventive controls.²⁴ All facilities must complete a written hazard analysis, even if the facility ultimately determines that there are no hazards that require implementing preventive controls.

The analysis must be “based on experience, illness data, scientific reports, and other information” for all the food the facility manufactures, processes, packs, or holds.²⁵ The facility must consider both biological hazards, like parasites and pathogens; chemical hazards, like pesticide residue, unapproved food additives, and food allergens; and physical hazards, like fragments of stone, metal, or glass. Finally, the facility must consider any hazards that naturally occur or are introduced unintentionally or intentionally for economic gain.²⁶

Once the facility identifies the relevant hazards, it needs to evaluate them “to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.”²⁷ The evaluation must consider effects of the following factors on the finished product’s safety for the consumer:

- (i) The formulation of the food;
- (ii) The condition, function, and design of the facility and equipment;
- (iii) Raw materials and other ingredients;
- (iv) Transportation practices;
- (v) Manufacturing/processing procedures;
- (vi) Packaging activities and labeling activities;
- (vii) Storage and distribution;
- (viii) Intended or reasonably foreseeable use;
- (ix) Sanitation, including employee hygiene; and
- (x) Any other relevant factors, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins).²⁸

2. Preventive Controls

If required by the facility’s hazard analysis, the facility must create and implement written preventive controls.²⁹ The preventive controls must ensure that the hazards “will be significantly minimized or prevented” and the food will not be adulterated.³⁰ Preventive controls can include

²⁴ 21 C.F.R. § 117.130(a).

²⁵ *Id.*

²⁶ *Id.* § 117.130(b).

²⁷ *Id.* § 117.130(c).

²⁸ *Id.*

²⁹ Part 117 does provide circumstances for when a facility is not required to implement preventive controls.

³⁰ 21 C.F.R. § 117.135(a).

controls at any critical control points (CCPs) and other controls that are necessary for food safety.³¹ There is flexibility in developing preventive controls, which can include:

- Process controls;
- Food allergen controls;
- Sanitation controls;
- Supply-chain controls;
- A recall plan; and
- Other controls needed to minimize or prevent hazards, such as hygiene training or other current good manufacturing practices.³²

³¹ *Id.* § 117.135(b).

³² *Id.* § 117.135(c).

Chapter 5

Treating Seaweed as Seafood: Seafood HACCP and National Shellfish Sanitation Program

I. Introduction

While seaweed is a macroalgae that does not fit into the FDA’s definition of “fish or fishery product,” Seafood Hazard Analysis Critical Control Point (Seafood HACCP) may still be instructive when considering possible regulatory models for states to adopt when regulating seaweed as a human food product. For instance, in Connecticut, state regulators are currently treating raw seaweed sold in its whole form like seafood and requiring seaweed growers to comply with the Seafood HACCP. While seaweed is clearly not shellfish, the National Shellfish Sanitation Program could be a potential model in considering the health risks of seaweed related to water quality and cultivating, harvesting, processing, shipping, or handling of seaweed products.

II. Seafood Hazard Analysis Critical Control Point (Seafood HACCP)

The FDA issued regulations in 1995 that require processors of fish and fishery products to develop and implement HACCP systems for their operations.¹ Under the Seafood HACCP regulations, a seafood processor must identify “food safety hazards that are reasonably likely to occur for each kind of fish and fishery product produced by” the processor and “identify the preventative measures that the processor can apply to control those hazards.”² Food safety hazards are defined as “any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.”³ Additional information about the Seafood HACCP risk management process and requirements can be found in the FDA’s Fish and Fishery Products Hazards and Control Guidance.⁴

The Seafood HACCP regulation applies to processors, where processing means the “[h]andling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding” of a fish or fishery product.⁵ Specifically, processing does not mean: “(i) Harvesting or transporting fish or fishery products, without otherwise engaging in processing; (ii) Practices such as heading,

¹ [Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products](#), 60 FR 65096 (December 18, 1995).

² 21 C.F.R. § 123.6.

³ *Id.*

⁴ U.S. FOOD & DRUG ADMIN., CTR. FOR FOOD SAFETY AND APPLIED NUTRITION, OFF. OF FOOD SAFETY, [FISH AND FISHERY PRODUCTS HAZARDS AND CONTROLS GUIDANCE](#) (2021).

⁵ *Id.*

eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel; (iii) The operation of a retail establishment.”⁶

A seafood processor’s failure to have and implement a compliant Seafood HACCP plan renders that processor’s products adulterated under the FDCA. HACCP plans are also required for juice processors and encouraged for dairy plants and retail and food service.⁷

Seaweed is not included in the FDA’s definition of “fish” or “fishery product.” Fish is defined as “fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.”⁸ A fishery product is defined as “any human food product in which fish is a characterizing ingredient.”⁹

A. State Approaches

Although the FDA does not consider seaweed a “fish or fishery product,” states may choose to extend the Seafood HACCP requirements to seaweed as Connecticut has done. In addition to adopting the Seafood HACCP model, Connecticut has developed a guide examining the potential food safety hazards present in the production and processing of seaweed in the state.¹⁰

Other states are also treating seaweed as a seafood, but have not gone as far as Connecticut in requiring Seafood HACCP. For example, there are no seaweed processors in Massachusetts, so seaweed is a seasonal commodity sold raw and fresh. Under the Department of Public Health’s food protection and the Division of Marine Fisheries regulations, kelp is required to be sold directly to a wholesale seafood dealer. From there, the wholesalers distribute the seaweed to restaurants.¹¹

B. Foreign HACCP Models

HACCP has been used in other parts of the world as a method to ensure seaweed food safety. Included below are brief overviews of the use of HACCP in the European Union, Ireland, and Japan.

⁶ *Id.*

⁷ [Hazard Analysis Critical Control Point \(HACCP\)](#), U.S. FOOD & DRUG ADMIN. (Jan. 29, 2018).

⁸ 21 C.F.R. § 123.3.

⁹ *Id.*

¹⁰ ANOUSHKA CONCEPCION ET AL., CONNECTICUT SEA GRANT & CONNECTICUT DEPARTMENT OF AGRICULTURE, BUREAU OF AQUACULTURE, [SEAWEED PRODUCTION AND PROCESSING IN CONNECTICUT: A GUIDE TO UNDERSTANDING AND CONTROLLING POTENTIAL FOOD SAFETY HAZARDS](#) (2020).

¹¹ SEA GRANT NATIONAL SEAWEED HUB, [STATE OF THE STATES](#) (2020).

1. European Union

Under the EU legal system, treaties are the primary source of law. Among other things, treaties detail the objectives of the European Union, the rules for EU institutions (*e.g.*, the European Commission, the European Parliament, and the European Council), and the rules for decision-making. Regulations, in turn, are legal acts by EU institutions that are binding in their entirety on all EU countries, applying automatically and uniformly as soon as they enter into force without needing to be transposed into national law.

Article 5 of European Commission Regulation (EC) No. 852/2004 requires all food business operators (FBOs) to implement and maintain permanent procedures based on HACCP principles.¹² FBOs include any entity carrying out production, processing, or distribution of food at any stage of the food chain after primary production and associated activities. The Regulation highlights the need to provide flexibility to small FBOs in complying with the requirement, specifically indicating:

It is necessary to recogni[z]e that, in certain food businesses, it is not possible to identify critical control points and that, in some cases, good hygienic practices can replace the monitoring of critical control points. Similarly, the requirement of establishing “critical limits” does not imply that it is necessary to fix a numerical limit in every case. In addition, the requirement of retaining documents needs to be flexible in order to avoid undue burdens for very small businesses.¹³

The Commission has published a guidance document on implementing procedures based on the HACCP principles, particularly in certain food businesses.¹⁴ Likewise, sector-specific guides developed by the EU and a register of available national guides to good hygienic practices (GHP) are also available.¹⁵ Although seaweed is not mentioned in the European Commission guidance document and seaweed does not appear to have its own GHP guide at present, the guidance document and national guides represent a model that could be adapted for U.S. markets should policymakers have concerns about the burden that a HACCP requirement might impose on small businesses that handle raw seafood sold for human consumption.

2. Ireland

A HACCP-based food safety management system has been a legal requirement for all food businesses in Ireland since 1998. The term “food business” is defined rather broadly under current legislation as, “. . .any undertaking, whether for profit or not and whether public or private, carrying out any or all of the following: preparation, processing, manufacturing,

¹² EUR. PARL. DOC. No. 852/2004 1 (covering the hygiene of foodstuffs).

¹³ *Id.* at 15.

¹⁴ See [Food Hygiene](#), EUROPEAN COMM’N (last visited Dec. 8, 2021).

¹⁵ [Guidance Platform](#), EUROPEAN COMM’N (last visited Dec. 8, 2021).

packaging, storing, transportation, distribution, handling or offering for sale or supply of foodstuffs.” This definition pertains to seaweed harvesters and cultivators.

The Ireland-based Irish Seaweeds company states on its website that the company has a HACCP system in place, with the company explicitly indicating that this is a legal requirement for any registered food facility or manufacturer in Ireland.¹⁶ Emerald Isle Seaweed, a different Irish seaweed operation focusing on organic products, also has a HACCP system in place, but their materials are silent with respect to a legal mandate.¹⁷

3. Japan

Under Japan’s Food Sanitation Act (FSA), a seaweed operation’s legal obligations will ultimately depend on whether that operation qualifies as a food business operator (FBO). The FSA defines an FBO as anyone who (1) engages in collecting, producing, importing, processing, cooking, storing, transporting, or selling food or additives or (2) provides food to the public on an ongoing basis at schools, hospitals or other facilities.¹⁸ The term “food business operator” is likely interpreted quite broadly under the FSA, as the Japanese government announced the mandatory adoption of HACCP “by all FBOs in the food chain” in anticipation of the 2020/2021 Tokyo Olympics.¹⁹ However, small-scale FBOs are afforded flexibility in complying with this requirement, with a greater emphasis on utilizing guidance issued by the appropriate industry association as long as that guidance is HACCP-based.²⁰

III. National Shellfish Sanitation Program

Here in the United States, states ensure that molluscan shellfish (oysters, clams, mussels, and whole or roe-in scallops) are safe for human consumption through participation in the National Shellfish Sanitation Program (NSSP). The NSSP is a cooperative program recognized by the FDA and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of bivalve molluscan shellfish produced and sold for human consumption.²¹ The NSSP offers guidance to states through a Model Ordinance that “establishes the minimum requirements necessary to regulate the interstate commerce of molluscan shellfish and to establish a program to protect the public health of consumers by assuring the sale or distribution of shellfish from safe sources and assuring shellfish have not been adulterated during cultivating, harvesting, processing, shipping,

¹⁶ [About Us](#), IRISH SEaweeds (last visited Dec. 8, 2021).

¹⁷ See [EMERALD ISLE ORGANIC IRISH SEaweED](#) (last visited Dec. 8, 2021).

¹⁸ [Food Sanitation Act](#), Act No. 233 of 1947, as amended by Act No. 46 of 2018, at Article 3(1).

¹⁹ [Summary of the Final Report on the Implementation of Mandatory HACCP Program in Food Industry adopted by the ad hoc Panel on International Standardization of Food Hygiene Control](#), MINISTRY OF HEALTH, LABOUR, AND WELFARE (2016)[hereinafter *Summary of the Final Report*]; see Tingmin Koe, [International requirements: How Japanese food manufacturers can benefit from global food safety guidelines](#), FOODNAVIGATOR-ASIA (Jan. 9, 2019).

²⁰ *Summary of the Final Report*, *supra* note 19.

²¹ [National Shellfish Sanitation Program \(NSSP\)](#), U.S. FOOD & DRUG ADMIN. (Oct. 29, 2020).

or handling.”²² States participating in the NSSP agree to adopt and enforce the Model Ordinance.²³

The NSSP Model Ordinance requires states to conduct sanitary surveys of shellfish growing areas to assess water quality and determine their suitability for harvest. Growing areas may be classified as Approved, Conditionally Approved, Restricted, Conditionally Restricted, or Prohibited. Each of these classifications has different implications regarding whether shellfish can be harvested from the area and how the shellfish can be used after harvest. In growing areas where harvest is approved, other NSSP Model Ordinance requirements for biotoxin control and management must still be met before harvest.²⁴ The NSSP Model Ordinance also establishes specific regulations regarding the shipping and handling of molluscan shellfish, including specific time and temperature requirements for safe transport.

Unlike shellfish, seaweed is not a particulate filter feeder, and different water quality characteristics and considerations to ensure seaweed food safety likely exist. However, a similar approach could be applied to seaweed, especially seaweed that is grown on shellfish farms. For instance, states could identify growing waters for seaweed and establish regulations regarding the harvest, shipment, and sale of the state’s seaweed.

As an example, in Maine, seaweed is treated as seafood up until the point of harvest. The Maine Department of Marine Resources approves the cultivation of kelp for human consumption in waters that are classified as Approved or Conditionally Approved for shellfish, controlling water quality at the source by identifying suitable growing areas and monitoring for bacterial contaminants. However, seaweed farmed in Maine is not regulated as seafood for post-harvest activities, including handling, processing, distribution, and sale, and is regulated as produce by the Maine Department of Agriculture, Conservation and Forestry. The next chapter provides an overview of the FDA’s Produce Safety Rule.

²² U.S. FOOD & DRUG ADMIN, [NATIONAL SHELLFISH SANITATION PROGRAM \(NSSP\), GUIDE FOR THE CONTROL OF MOLLUSCAN SHELLFISH](#) 3 (2019).

²³ See Lisa Schiavinato, et al, [Molluscan Shellfish Aquaculture in Federal Waters of the Exclusive Economic Zone \(EEZ\): Agencies, Industry, and Academia Working Together on Compliance and Permitting Requirements](#), in *OVERCOMING IMPEDIMENTS TO SHELLFISH AQUACULTURE THROUGH LEGAL RESEARCH AND OUTREACH: CASE STUDIES* (2019).

²⁴ See U.S. FOOD & DRUG ADMIN., *supra* note 22.

Chapter 6

Treating Seaweed as a Plant: the Produce Safety Rule

I. Introduction

In 2019, the Maine Supreme Court likened rockweed, a kind of seaweed, to a plant.¹ In the decision, the Maine Supreme Court refused to consider harvesting seaweed in the intertidal zone as a form of fishing, citing the fundamental biological differences between fish and rockweed, as well as the differing methods used to harvest seaweed. The court stated that rockweed is “biologically dissimilar from fish, lobster, clams, oysters, and bloodworms—it draws nutrients from the air and seawater using a photosynthetic process and, once attached to the intertidal substrate, does not move.”² Although this case involved legal issues outside the food safety context, the court’s analysis provides an opportunity to explore what food safety regulation would look like if seaweed was classified as a plant, or more specifically in the food safety context: produce.

While seaweed is a macroalgae that does not fit into the FDA’s definition of “plant” or “produce,” the Produce Safety Rule may still be instructive when looking at regulatory models for regulating seaweed as a food product. In 2015, the FDA adopted Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, known as the Produce Safety Rule (PSR). The PSR, which went into effect in 2016, establishes mandatory science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.³ The FDA issued the PSR as part of the agency’s efforts to implement the Food Safety Modernization Act of 2011.

Generally, the PSR is intended to apply to produce that will be eaten raw. The FDA provided a list of produce that is covered by the rule.⁴ Produce included on this list is not subdivided into

¹ *Ross v. Acadian Seaplants*, 206 A.3d 283 (Maine 2019).

² *Id.* at 291.

³ [Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption](#), 80 Fed. Reg. 74353 (Nov. 27, 2015) [hereinafter Produce Safety Rule].

⁴ 21 C.F.R. §112.1. Covered produce includes: Fruits and vegetables such as almonds, apples, apricots, apriums, Artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and unqi fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel–Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell and hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams.

different categories (i.e., fruits, vegetables, tree nuts, etc.). Only two categories of produce exist: (1) produce covered by the PSR; and (2) foods that are not. In practical terms, this just means that the same rules apply to greens as would apply to tree nuts.

Neither seaweed or algae is currently on the list of produce covered by the PSR, although the list could be amended in the future. In fact, the FDA explicitly addressed the inclusion of seaweed within the scope of the PSR when responding to public comments as part of the PSR rulemaking process. While it was drafting the PSR, the FDA received comments inquiring whether the term “produce” included a list of other commodities, including algae. In response, the FDA defined produce to include, “fruits (the harvestable or harvested part of a plant developed from a flower) and vegetables (harvested part of any plant or fungus), which by definition does not include algae.”⁵ The agency went on to discuss how algae differ from and are not considered produce. The agency does provide an example which references seaweed stating, “the blue-green algae, also known as cyanobacteria, are generally considered to be bacteria, but because blue-greens are aquatic and possess photosynthetic pigments like seaweeds, they are still called algae.”⁶ However, the agency mentioned that algae that are used for food will continue to be covered under the FDCA and its applicable implementing regulations. As mentioned in previous chapters, the FDA has asserted that seaweed sold in its whole form will be regulated as a raw agricultural commodity under the FDCA. The agency left open the opportunity to address algae in the future, stating, “[a]s appropriate, we may consider issuing guidance on the topic of algae production for human food use in the future.”⁷

II. PSR Requirements

The PSR standards are designed to work effectively for food safety across the wide diversity of produce farms.⁸ Generally, the PSR requires produce growers to “take appropriate measures to minimize risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated.”⁹ In other words, farms covered by the rule are held to certain standards designed to reduce the presence of potentially dangerous bacteria in the food supply, with the ultimate goal of reducing the number of illnesses caused by contaminated produce. Key elements of the PSR include:

- Qualifications and training requirements for personnel who handle/contact covered produce or food contact surfaces. (Subpart “C”).

⁵ Produce Safety Rule, *supra* note 3, at 74385.

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ 21 C.F.R. §112.11.

- Specific measures farms must take to reduce potential contamination of covered produce by personnel and other visitors, as well as hygienic practices that must be followed by personnel. (Subpart “D”).
- Requirements for agricultural water quality and testing designed to detect contamination. (Subpart “E”).
- Requirements related to domestic and wild animals in instances where a covered activity takes place outdoors or in a partially enclosed building. (Subpart “I”). *Note that these requirements do not apply when a covered activity takes place in a fully-enclosed building or to fish used in aquaculture operations.*
- Requirements governing growing, harvesting, packing and holding activities. (Subpart “K”).
- Equipment, tools, buildings, and standards and requirements regarding operation, maintenance, and sanitation. (Subpart “L”).

In terms of handling produce under PSR Subpart K, immediately prior to and during harvesting activities, growers must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including animal excreta. Further, during covered activities, growers must handle harvested covered produce in a manner that protects against contamination with known or reasonably foreseeable hazards. During packaging, covered produce must be packaged in a manner that prevents the formation of *Clostridium Botulinum* toxins if such toxin is a known or reasonably foreseeable hazard.

If seaweed were to be regulated under the PSR, the agricultural water provisions could play a significant role. First, per this rule, “agricultural water” is defined as:

Water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).¹⁰

The general requirement under this subpart is that “all agricultural water must be safe and of adequate sanitary quality for its intended use.”¹¹ To ensure this requirement is met, all agricultural water systems must be inspected at the beginning of a growing season. In addition, all agricultural water distribution systems and agricultural water sources must be maintained to prevent the contamination of “covered produce, food contact surfaces, areas used for a covered

¹⁰ *Id.* §112.3.

¹¹ *Id.* §112.41.

activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system for continued compliance with the safety and sanitary standards.”¹²

In regard to water treatment, any method used to treat agricultural water must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria. There must be no detectable generic *E. coli* in 100 milliliters of agricultural water, and untreated surface water cannot be used for any following purposes:

- Sprout irrigation water;
- Water applied in any manner that directly contacts covered produce during or after harvest activities;
- Water used to contact food surfaces; and
- Water used for washing hands during and after harvest activities.¹³

In addition, when agricultural water is used during growing activities, using a direct water application method, the following criteria must be met:

- A geometric mean of grower’s agriculture water samples of 126 or less colony forming units of general *E. coli* per 100 milliliters of water; and
- A statistical threshold value of grower’s agricultural water samples of 410 or less colony forming units of generic *E. coli* per 100 milliliters of water.¹⁴

Each source of water must be tested. This testing comes in the form of an initial survey to develop the microbial water quality profile of the source. This profile must be updated annually. Other requirements include establishing a water changing schedule and monitoring water temperature.

II. Produce Safety Rule Application to Aquaponics or Hydroponics

Although seaweed and algae are not currently covered by the PSR, the FDA has commented on the applicability of some of the PSR requirements to listed produce grown in aquaponic or hydroponic systems. Similar requirements could serve as a model for seaweed grown in tanks. For instance, the FDA has stated that aquaponic farms should *not* be excluded from the PSR requirements for agricultural water. The agency reasoned that,

[T]he routes of contamination we considered for covered produce under this rule are applicable to aquaponic farming and covered produce grown in aquaponic systems is subject to the same potential for contamination from agricultural water,

¹² *Id.* §112.42.

¹³ *Id.* §112.44(a).

¹⁴ *Id.* §112.44(b).

biological soil amendments of animal origin, and animals as covered produce grown using non-aquaponic systems.¹⁵

The agency did however make a distinction regarding the use of agricultural water. The agency stated, “when covered produce is grown in an aquaponic system in which the water is not intended or likely to contact the harvestable portion of the produce, that water is *not* agricultural water for purposes of this rule.”¹⁶ In contrast, “when covered produce is grown in an aquaponic system in which water is intended or likely to contact the harvestable portion of the produce, that water *is* agricultural water for purposes of this rule and must meet the applicable standards.”¹⁷

However, aquaponic and hydroponic systems used to grow covered produce other than sprouts are not subject to the requirements under Subpart M. The FDA has not established additional standards applicable to aquaponic or hydroponic production of crops other than sprouts.¹⁸

¹⁵ Produce Safety Rule, *supra* note 3, at 74366.

¹⁶ *Id.* (emphasis added).

¹⁷ *Id.* (emphasis added).

¹⁸ *Id.*