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I. Introduction

When one mentions seaweed as food, what do you think of? The dried nori used to wrap your sushi roll or perhaps the seaweed salad on the side? In fact, seaweed has many uses, including as both a food source in its own right and as a food additive. A quick Google search of "seaweed as a food source" generates a multitude of results touting seaweed's nutritional benefits and many claiming that it is a food of the future. While the seaweed market has been dominated by East Asian countries, seaweed is cultivated in about 50 countries, and the U.S. seaweed industry is steadily growing.[1] The global seaweed industry is currently worth about $6 billion annually.[2] Food products for human consumption account for about 85% of this value.[3]

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[1] FOOD AND AGRIC. ORG., REPORT OF THE EXPERT MEETING ON FOOD SAFETY FOR SEAWEED 6 &10 (2021), https://www.fao.org/3/cc0846en/cc0846en.pdf [hereafter *FAO Report*].

[2] Fatima Ferdouse et al., *The Global Status of Seaweed Production, Trade, and Utilization*, FAO GLOBEFISH RSCH. PROGRAMME 1 (2018), https://www.fao.org/3/ca1121en/CA1121EN.pdf.

[3] *Id.* at 1-2.

Seaweed can either be wild harvested or cultivated at an aquaculture farm.[4] In the United States, seaweed is produced on both the East and West coasts and in Hawaii and Alaska. Maine and Alaska currently lead production in the U.S. Seaweed farmers in Maine harvested 500,000 lbs of seaweed in 2020, and there are over 30 active seaweed farms in the state.[5] Maine is also a leader in wild harvest, where the industry harvested over 16 million lbs in 2020. In Alaska, seaweed farms sold 536,390 lbs of seaweed in 2021, which is over double the amount of 231,015 lbs sold in 2020.[6] Alaska is also a good example of the types of seaweed operations that exist in the United States. Of its active farms in 2021, there were 5 seaweed only farms and 14 multi-trophic farms growing both shellfish and seaweed.[7]

Seaweed operations in other states also help to show the diversity of businesses in the United States. Washington, Oregon, and California all have land-based, tank culture operations, though in 2021 Blue Dot Sea Farms became the first open-water, commercial seaweed farm in Washington in 30 years.[8] New Hampshire, Massachusetts, Rhode Island, and Connecticut all have multiple permitted seaweed farms, and New York has a couple of research sites. However, due to a lack of processing facilities in these states, the seaweed produced is often sold raw or dried to restaurants or consumers, or to processors in other states.[9]

Maine and Alaska provide examples of the wide variety of processed seaweed food products produced in the United States, such as seaweed salsas, hot sauces, kimchi, snack bars, teas and smoothie cubes, and spice mixes. Other examples of processed foods include seaweed farmers in New Hampshire selling some of their harvested seaweed to breweries to create

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[4] *See Id.*
[5] Jaclyn Robidoux & Meg Chadsey, *State of the States: Status of U.S. Seaweed Aquaculture*, SEA GRANT (Mar. 29, 2022), https-seaweedhub-org-wp-content-uploads-2022-03-state-of-the-states_forposting_mar2022-1-pdf/.
[6] *Id.*
[7] *Id.* (A total of 11 seaweed-only farms have been issued permits by the state, and 17 multi-trophic farms have been permitted).
[8] *Id.*
[9] *Id.*

kelp beer, while seaweed from a Washington state farm is used to make Seacharrones[10], a vegan kelp snack puff.[11]

While the U.S. seaweed industry continues to grow, so do concerns about seaweed food safety. In 2016, a Salmonella outbreak was linked to seaweed from a farm in Oahu, Hawaii.[12] Researchers in New England are studying how to reduce pathogens in seaweed by using different drying and storage methods.[13] A recent literature review identified some potential food safety hazards, such as arsenic, iodine, heavy metals like lead, cadmium, and mercury, and biological hazards like pathogenic bacteria and viruses.[14] The species of seaweed, water quality, and harvesting, storage, processing, and transportation methods can all affect the food safety concerns in a batch of harvested seaweed.

Food safety risks necessarily raised the need for regulation to prevent food-borne illnesses. But from a regulatory standpoint, 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*).[15] 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.[16] Seaweed is not a plant in biological terms, but at least one state defines seaweed as a "marine aquatic plant."[17] Further, while the Food and Drug Administration (FDA) does not consider seaweed to be a

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[10] For more information on this packaged snack, visit the Seacharrones website. SEACHARRONES, https://www.seacharrones.com/ (last visited Oct 24, 2022).
[11] Robidoux & Chadsey, *supra* note 5 .
[12] *Salmonella Outbreak in Hawaii Linked to Seaweed in Raw Fish,* FOOD SAFETY NEWS (Nov. 8, 2016), https://www.foodsafetynews.com/2016/11/salmonella-outbreak-in-hawaii-linked-to-seaweed-in-raw-fish/.
[13] *More Food Uses for Seaweed Sparks Food Safety Research*, FOOD SAFETRY NEWS (June 2, 2022), https://www.foodsafetynews.com/2022/06/more-food-uses-for-seaweed-sparks-food-safety-research/.
[14] J.L. Banach et al., *Seaweed Value Chain Stakeholder Perspectives for Food and Environmental Safety Hazards*, 11 FOODS 1514 (May 23, 2022), https://www.mdpi.com/2304-8158/11/10/1514/htm.
[15] FAO Report, *supra* note 1 at 1-4.
[16] Nix v. Hedden, 149 U.S. 304, 307 (1893).
[17] WASH. REV. CODE § 79.135.400 (1993).

"plant" or "produce,"[18] the U.S. Department of Agriculture (USDA) has referred to seaweed as an aquatic plant.[19]

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 Hazard Analysis and Critical Control Points (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.[20] 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."[21]

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.[22] Like other raw agricultural commodities, the FDA therefore considers the growing and harvesting of seaweed to be "farm" activities.[23] This distinction is important because activities that

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[18] Emanuel Hignutt, Jr., Off. of Food Safety, FDA Ctr. 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).

[19] USDA 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).

[20] 12 U.S.C. § 321(f).

[21] 21 U.S.C. § 342(a)(4).

[22] Email on file with author. The FDCA defines a raw agricultural commodity as "any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing." 21 U.S.C. § 321(r).

[23] 21 U.S.C. § 321.

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.[24] Some activities that may be thought of as processing can still fall within the farm definition, such as drying.[25] If an operation goes beyond harvesting and drying, such as by blanching, freezing, or cutting the seaweed, it would be considered a "food facility."[26]

Under the Food Safety Modernization Act (FSMA), certain food facilities need to register with the FDA and are subject to 21 CFR Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Rule.[27] However, due to certain exemptions to these requirements, few seaweed operations in the United States are subject to the full requirements of Part 117.[28] For instance, businesses that sell only raw seaweed are completely exempt, while those businesses with less than $1 million in sales a year are exempt from the Preventive Controls requirements.[29]

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.[30]

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 state agencies must make regarding whether to

[24] *Id.*
[25] 21 C.F.R. § 1.227.
[26] *Id.*
[27] 21 U.S.C. § 117.3.
[28] *Id.* § 117.5.
[29] *Id.* § 117.3.
[30] FOOD & DRUG ADMIN., FOOD CODE (2017).

regulate seaweed on the state-level 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*.[31] The DOAG also implements the Produce Safety Rule in the state under FSMA. However, the Connecticut Department of Consumer Protection Food and Standards Division (DCP) regulates kelp that is *packaged or processed* under a *food manufacturing license*.[32] Therefore, how and when a state classifies seaweed can drive the regulatory agency in charge of the food source.

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.[33] These choices 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.[34] 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

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[31] ANOUSHKA CONCEPCION ET AL., SEAWEED PRODUCTION AND PROCESSING IN CONNECTICUT: A GUIDE TO UNDERSTANDING AND CONTROLLING POTENTIAL FOOD SAFETY HAZARDS 12 (Connecticut Sea Grant et al. 2020).
[32] *Id.* at 1.
[33] *See generally* ALASKA ADMIN. CODE tit. 18, §31 (2022).
[34] Private Communication with Maine Sea Grant Staff on file with author.

include the FDA 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.[35] Known as the Commerce Clause power, this is the legal basis for FDA to regulate food under the FDCA and the FSMA.

A. Federal Food, Drug, and Cosmetic Act (FDCA)

The FDCA prohibits activities involving the movement of adulterated food[36] in interstate commerce. The statute lists the different circumstances where a food could become adulterated.[37] 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.

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[35] U.S. CONST. art. 1 § 8, cl. 3.

[36] 21 U.S.C. § 331 (defines food as "means (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.").

[37] *Id.* § 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. 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.").

- 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.[38]

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.[39] This standard could be important when considering the transportation of seaweed from the farm to a farmer's market, restaurant, or similar location.

B. Food Safety Modernization Act (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.[40] 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

[38] *Id.* § 342(a)(6).
[39] *Id.* § 342(i).
[40] FDA Food Safety Modernization Act, Pub. L. No. 353.

Controls and (2) Produce Safety, which are discussed in more detail below. [41]

Importantly, FSMA is applicable only to food facilities that "engaged in manufacturing, processing, packing, or holding food for consumption…".[42] 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.
- For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.[43]

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

[41] 21 U.S.C. § 321(gg) (the FDCA defines processed food as "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.").
[42] *See Id.* § 350d.
[43] 21 C.F.R. § 1.227.

does not include activities that transform a raw agricultural commodity into a processed food.[44]

Holding: Storage of food and 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)).[45]

- 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.[46]

Domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States have to register with the FDA.[47] Certain entities are exempt from the facility registration process, including farms, retail food establishments, and restaurants.[48]

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 apply to seaweed farmers and processors who sell their product for use as a food additive, but the regulations are limited to certain

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[44] *Id.*
[45] *Id.*
[46] *Id.*
[47] *Id.* § 350d.
[48] 21 U.S.C. § 350d.

marine algae species and do not encompass the sale of seaweed in its whole form.[49]

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 expected to result—directly or indirectly—in its becoming a component or otherwise affecting the characteristics of any food.[50] Food additives are subject to FDA's premarket review and approval, unless the substance is given a "generally recognized as safe" (GRAS) designation.[51]

The FDA has made a GRAS determination for certain seaweeds when they are used as additives.[52] 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.[53] 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*).[54]

Besides these general regulations, the FDA adopted specific regulations for brown and red algae.[55] 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."[56] Listed brown and red algae species may be considered GRAS, whether or not they are

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[49] FOOD & DRUG ADMIN., GENERALLY RECOGNIZED AS SAFE (GRAS) (Sept. 6, 2019), https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras.
[50] 21 U.S.C. § 321(s).
[51] FOOD & DRUG ADMIN., *supra* note 49.
[52] 21 C.F.R. § 172.365.
[53] *Id.*
[54] *Id.*
[55] *Id.* §§ 184.1120, 1121.
[56] *Id.*

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.[57] 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).[58] In the statement, FDA clarified that raw seaweed is not a seafood or plant, but rather, a raw agricultural commodity.[59] 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 section.[60]

III. 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

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).[61] There are two important parts of the rule as it applies to seaweed operations: requirements for Current Good Manufacturing Practices (CGMPs) and requirements for Hazard Analysis/Preventive Controls (HA/PC).[62] CGMPs aim

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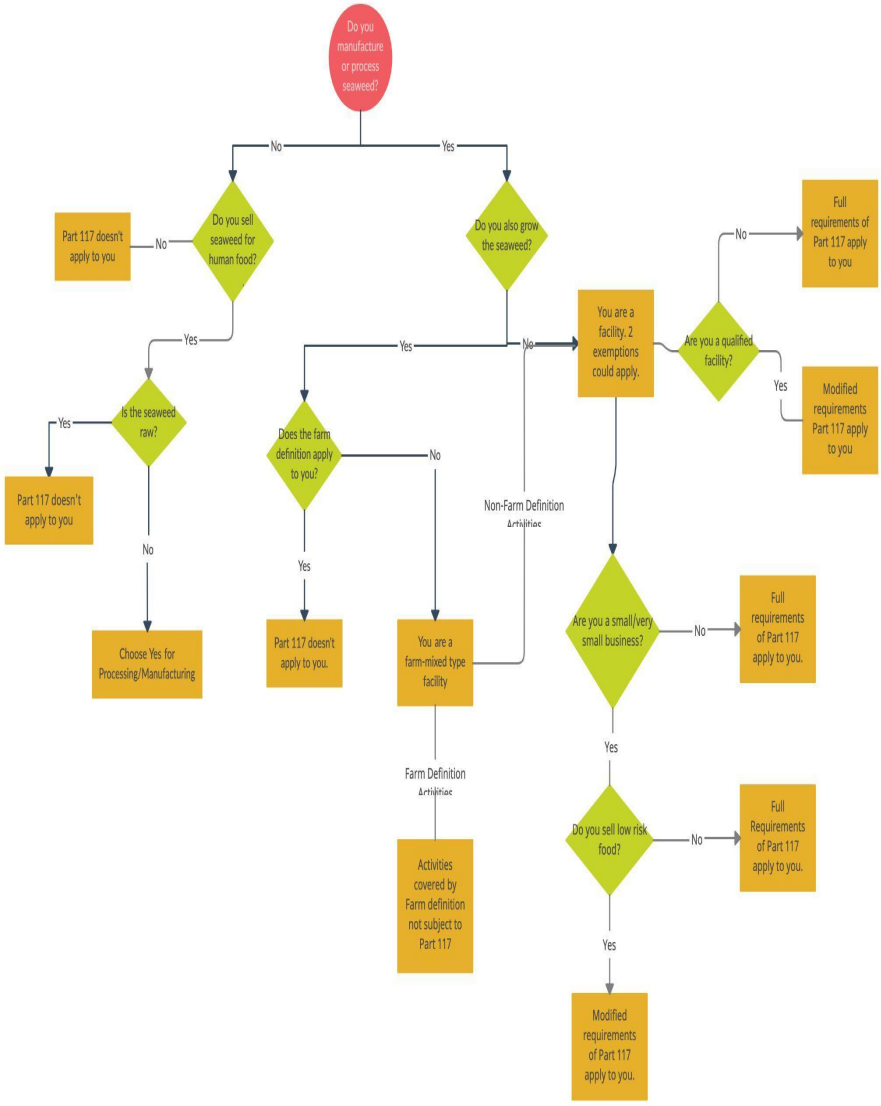
[57] 21 C.F.R. § 170.3(o)(11) (definition of flavor enhancer- Flavor enhancers: Substances added to supplement, enhance, or modify the original taste and/or aroma of a food, without imparting a characteristic taste or aroma of its own.").
[58] Email on file with the author.
[59] *Id.*
[60] 21 C.F.R. § 117.
[61] *Id*. §§ 117.4, 117.5.
[62] *Id.*

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."[63] 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.[64] However, as discussed more below, there are some major exemptions to the rule.

Many seaweed growers in operation in the United States today are not subject to Part 117 due to the small size of their operations and type of products sold.[65] 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).[66] 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.

[63] FOOD & DRUG ADMIN., CURRENT GOOD MANUFACTURING PRACTICES (CGMPS) FOR FOOD AND DIETARY SUPPLEMENTS (Jan. 31, 2020), https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/current-good-manufacturing-practices-cgmps-food-and-dietary-supplements.
[64] 21 C.F.R. § 117.126.
[65] *Id.* § 117.5.
[66] *Id.*

Figure 1. Overview of Part 117.



A. Applicability

The application of the CGMPs and HA/PC depends on whether the operation needs to register as a facility under FSMA.[67] Facilities, mixed-type facilities, and qualified facilities all need to register. However, depending on the characteristics of the operation, the registered facility 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.[68] 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.

i. Full Applicability

Facilities are subject to all the requirements of CGMPs and HA/PC.[69] Part 117 defines a facility as simply "a domestic facility or foreign facility that is required to register" under FDCA Section 415.[70] 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….[71]

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[67] *Id.* § 117.1.
[68] *Id.* § 117.5
[69] 21 C.F.R. § 117.1.
[70] *Id.* § 117.3.
[71] *Id.* § 1.227.

ii. Full Exemption

Farms are exempt from Part 117.[72] The definition of farm is complicated and divided into two subcategories: "primary production" farms and "secondary activities" farms.[73] 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."[74] A secondary activities farm is "an operation, not located on a primary production farm, devoted to 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."[75] Table 1 provides a summary of the activities included in the farm definition.

When reviewing these activities, it becomes clear that seaweed that is sold raw or is dried in accordance with farm definition is exempt from Part 117. Further, many of the seaweed producing states in the U.S. produce only raw or dried seaweed, meaning these operations are not subject to regulation under Part 117, leaving space for the respective states to step in and fill the regulatory gap.

[72] *Id.* § 117.5.
[73] *Id.* § 1.227.
[74] 21 C.F.R. § 1.227.
[75] *Id.*

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	● 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	● All food is consumed on the farm or another farm under the same management; OR ● it is one of the following: ○ 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.

Retail food establishments are also exempt from Part 117.[76] 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."[77] 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.[78]

In terms of seaweed operations, growers and harvesters who 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.

iii. Partial Applicability

Qualified facilities face modified requirements under Part 117.[79] 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.[80] 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

[76] *Id.* § 117.1
[77] *Id.* § 1.227.
[78] *Id.* § 1.227.
[79] 21 C.F.R. § 117.5.
[80] *Id.* § 117.3.

within 275 miles that sell food directly to consumers.[81] To meet this requirement, the value of the food sold to consumers and other qualified end users in the previous three years must be greater than the value of the food sold to other purchasers and less than $500,000 per year.[82]

Mixed-type facilities are establishments that engage in a mix of activities, some of which are exempt from registration and others that require registration.[83] 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."[84]

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.[85] The FDA's list for these activities and foods is extensive.[86] 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.

Seaweed operations which qualify as a Qualified Facility are put in an interesting situation- the business is currently exempt from Hazard Analysis and Preventive Controls, but could be subject to those requirements should the business grow in the future. Thus, it may make sense for the business to begin to follow Hazard Analysis and Preventive Controls while it is still currently exempt. However, further complicating matters is that some states such as New York are encouraging seaweed Qualified Facilities to develop a HACCP Plan- and not follow Hazard Analysis and Preventive Controls.[87]

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[81] *Id.*
[82] *Id.*
[83] *Id.* § 117.3.
[84] 21 C.F.R. § 117.3.
[85] *Id.*
[86] FOOD & DRUG ADMIN., WHAT YOU NEED TO KNOW ABOUT THE FDA REGULATION: CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (21CFR PART 117): GUIDANCE FOR INDUSTRY (2006).
[87] *Food Safety: Seaweed*, N.Y. DEP'T OF AGRIC. AND MKT., https://agriculture.ny.gov/food-safety/seaweed (last visited Oct. 24, 2022).

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

B. Part 117 Requirements

Because of the small scale of most seaweed farms and operations in the United States, Part 117 is not currently widely applicable to the seaweed industry. However, the structure and requirements of Part 117 may be helpful for state agencies considering potential food safety models to regulate the industry in their states.

i. Good Manufacturing Practices

The FDA first established CGMPs for food in the Federal Register in 1969.[88] The CGMPs were modernized in

[88] FOOD & DRUG ADMIN., *supra* note 63.

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."[89]

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."[90]

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.[91]

Sanitary Facilities and Controls: These CGMPS include requirements for water supply, plumbing, sewage disposal, toilet and hand-washing facilities, and rubbish disposal.[92]

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.[93]

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[89] 21 C.F.R. § 117.10.
[90] *Id.* § 117.20.
[91] *Id.* § 117.35.
[92] *Id.* § 117.37.
[93] *Id.* § 117.40.

Processes and Controls: These CGMPS include general requirements for the manufacturing, processing, packing, and holding of food that will ensure adequate sanitation and ensure the food is suitable for human consumption. There are additional requirements for raw materials.[94]

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."[95]

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.[96]

ii. 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.[97] A food safety plan is a written plan that documents all of the procedures by which the facility complies with the HA/PC requirements.[98] 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.[99] 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

[94] 21 C.F.R. § 117.80.
[95] *Id.* § 117.93.
[96] *Id.* § 117.110.
[97] *Id.*
[98] *Id.*
[99] 21 C.F.R. § 117.126.

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.[100]

- *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.[101]

[100] *Id.*
[101] *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.[102] 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.[103] 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.

1. Hazard Analysis

Through Hazard Analysis, a facility must identify and evaluate "known or reasonably foreseeable hazards" that require preventive controls.[104] All facilities must complete a written hazard analysis, even if the facility ultimately determines that there are no hazards that require implementing preventive controls.[105]

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.[106] 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.[107] Finally, the facility must consider any hazards that naturally occur or are

[102] *Id.* § 117.150.
[103] 21 U.S.C. § 2201.
[104] 21 C.F.R. § 117.130(a).
[105] *Id.*
[106] *Id.*
[107] *Id.*

introduced unintentionally or intentionally for economic gain.[108]

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."[109] 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).[110]

2. Preventive Controls

If required by the facility's hazard analysis, the facility must create and implement written preventive controls.[111] The preventive controls must ensure that the hazards "will be significantly minimized or prevented" and the food will not be

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[108] *Id.* § 117.130(b).
[109] 21 C.F.R. § 117.130(c).
[110] *Id.*
[111] *See id.* (part 117 does provide circumstances for when a facility is not required to implement preventive controls).

adulterated.[112] Preventive controls can include controls at any critical control points (CCPs) and other controls that are necessary for food safety.[113] 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.[114]

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

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.[115] 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.

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

[112] *Id.* § 117.135(a).
[113] *Id.* § 117.135(b).
[114] 21 C.F.R. § 117.135(c).
[115] CONCEPCION, *supra* note 31 at ii.

The FDA issued regulations in 1995 that require processors of fish and fishery products to develop and implement HACCP systems for their operations.[116] 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."[117] Food safety hazards are defined as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption."[118] 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.[119]

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.[120] Specifically, processing does not mean: "(i) Harvesting or transporting fish or fishery products, without otherwise engaging in processing; (ii) Practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel; (iii) The operation of a retail establishment."[121]

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

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[116] Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, 60 Fed. Reg. 65096 (December 18, 1995) (to be codified 21 C.F.R. parts 122, 1240).
[117] 21 C.F.R. § 123.6.
[118] *Id.*
[119] FOOD & DRUG ADMIN., *Fish and Fishery Products Hazards and Controls Guidance,* CTR. FOR FOOD SAFETY AND APPLIED NUTRITION, OFF. OF FOOD SAFETY, June 2022.
[120] *Id.*
[121] *Id.*

required for juice processors and encouraged for dairy plants and retail and food service.[122]

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."[123] A fishery product is defined as "any human food product in which fish is a characterizing ingredient."[124]

i. 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.[125]

Other states are also treating seaweed as a seafood, but have not gone as far as Connecticut in requiring Seafood HACCP. New York encourages seaweed growers who qualify as Qualified Facilities to use HACCP, stating "while food safety science for seaweed is still developing applying the principles included in a HACCP plan could ensure that all potential hazards are eliminated or controlled to acceptable levels."[126] For example, there are no seaweed processors in Massachusetts, so seaweed is a seasonal commodity sold raw and fresh.[127] 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

[122] *Hazard Analysis Critical Control Point (HACCP)*, FOOD & DRUG ADMIN., (Jan. 29, 2018).
[123] 21 C.F.R. § 123.3.
[124] *Id.*
[125] CONCEPCION, *supra* note 31.
[126] N.Y. DEP'T OF AGRIC. AND MKT., *supra* note 91.
[127] Robidoux & Chadsey, *supra* note 7.

dealer. From there, the wholesalers distribute the seaweed to restaurants.[128]

ii. 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.

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.[129] 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.[130] 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

[128] *Id.*
[129] EUR. PARL. DOC. (NO 852) (2004).
[130] *Id.*

> 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.[131]

The Commission has published a guidance document on implementing procedures based on the HACCP principles, particularly in certain food businesses.[132] Likewise, sector-specific guides developed by the EU and a register of available national guides to good hygienic practices (GHP) are also available.[133] 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.[134] 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, 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

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[131] *Id*. at 15.
[132] *See Food Hygiene*, EUROPEAN COMM'N, https://food.ec.europa.eu/safety/biological-safety/food-hygiene_en (last visited Nov. 9, 2022).
[133] *See Guidance Platform*, EUROPEAN COMM'N, https://food.ec.europa.eu/safety/biological-safety/food-hygiene/guidance-platform_en (last visited Nov. 9, 2022).
[134] FOOD SAFETY AUTH. OF IR., https://www.fsai.ie/faq/haccp.html (last visited Dec. 23, 2022).

requirement for any registered food facility or manufacturer in Ireland.[135] 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.[136]

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).[137] 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.[138] 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.[139] 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.[140]

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[135] *See About Us*, IRISH SEAWEEDS, https://irishseaweeds.com/about-us/ (last visited Nov. 12, 2022).
[136] *See* EMERALD ISLE ORGANIC IRISH SEAWEED, https://emeraldisleseaweed.com/ (last visited Nov. 9, 2022).
[137] *See* 食品衛生法 [Food Sanitation Act] Act No. 233 of 1947, (Japan), *amended by* Act No. 46 of 2018 art 3 para 1.
[138] *Id.*
[139] *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 https://www.mhlw.go.jp/english/topics/foodsafety/consideration/dl/summary_of_the final report.pdf (December 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), https://www.foodnavigator-asia.com/Article/2019/01/09/International-requirements-How-Japanese-food-manufacturers-can-benefit-from-global-food-safety-guidelines.
[140] Summary of the Final Report, *supra* note 139; 21 U.S.C. § 321(r).

B. 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).[141] 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.[142] 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, or handling."[143] States participating in the NSSP agree to adopt and enforce the Model Ordinance.[144]

The NSSP Model Ordinance requires states to conduct sanitary surveys of shellfish growing areas to assess water quality and determine their suitability for harvest.[145] 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

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[141] *National Shellfish Sanitation Program (NSSP)*, FOOD & DRUG ADMIN. (Oct. 29, 2020), https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp.
[142] *Id.*
[143] FOOD & DRUG ADMIN., GUIDE FOR THE CONTROL OF MOLLUSCAN SHELLFISH (2019), https://www.fda.gov/media/143238/download.
[144] Lisa Schiavinato & Catherine Courtier, *Molluscan Shellfish Aquaculture in Federal Waters of the Exclusive Economic Zone (EEZ): Agencies, Industry, and Academia Working Together on Compliance and Permitting Requirements*, SEA GRANT CAL. (Jan. 01, 2019), https://caseagrant.ucsd.edu/our-work/e-documents/molluscan-shellfish-aquaculture-in-federal-waters-of-the-us-exclusive-economic-zone.
[145] *Id.*

be met before harvest.[146] 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.[147]

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.[148] 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. Farmed seaweed is regulated as produce by the Maine Department of Agriculture, Conservation and Forestry.[149] The next chapter provides an overview of the FDA's Produce Safety Rule.

V. Treating Seaweed as a Plant: the Produce Safety Rule

In 2019, the Maine Supreme Court likened rockweed, a kind of seaweed, to a plant.[150] In the decision, the Maine Supreme Court refused to consider harvesting seaweed in the intertidal zone as a form of fishing, citing the fundamental

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[146] *See* FOOD & DRUG ADMIN., *supra* note 23.
[147] Schiavinato & Catherine Courtier, *supra* note 144, at 14.
[148] ME. STAT. tit. 12, §6001 (2021) (The Maine Department of Marine Resources also regulates seaweed aquaculture in Maine. Aquaculture is defined to mean the cultivation of marine organisims, which defined to include "any animal, plant or other life that inhabits waters below head of tide.").
[149] Private Communication with Maine Sea Grant Staff on file with author.
[150] Ross v. Acadian Seaplants, 206 A.3d 283 (Me. 2019).

biological differences between fish and rockweed, as rockweed draws nutrients from the air and seawater using a photosynthetic process and, once attached to the intertidal substrate, does not move."[151] 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 for states 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).[152] 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.[153] 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.[154] Produce included on this list is not

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[151] *Id.* at 291.

[152] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. 74353 (Nov. 27, 2015) (to be codified at 21 C.F.R. §112) [hereinafter *Produce Safety Rule*].

[153] *Id.*

[154] 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 uniq 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,

subdivided into 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.[155]

Neither seaweed nor 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.[156] 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."[157] The agency went on to discuss how algae differ from and are not considered produce.[158] 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."[159] However, the agency mentioned that algae that are used for food will continue to be covered under the FDCA and its applicable implementing regulations.[160] 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.[161] The agency left open the opportunity to address algae in the future, stating, "[a]s appropriate, we may consider issuing guidance on

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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).

[155] *Id.*

[156] Produce Safety Rule, *supra* note 152.

[157] *Id.* at 74385.

[158] *Id.*

[159] *Id.*

[160] *Id.*

[161] Produce Safety Rule, *supra* note 152.

the topic of algae production for human food use in the future."[162]

A. Produce Safety Rule Requirements

The PSR standards are designed to work effectively for food safety across the wide diversity of produce farms.[163] 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."[164] 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").
- 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-*

[162] *Id.*
[163] *Id.*
[164] 21 C.F.R. §112.11.

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").[165]

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.[166] Further, during covered activities, growers must handle harvested covered produce in a manner that protects against contamination with known or reasonably foreseeable hazards.[167] 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.[168]

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).[169]

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[165] *Id.* § 112.
[166] *Id.* § 112.113.
[167] *Id.*
[168] *Id.* § 112.115.
[169] 21 C.F.R. §112.3.

The general requirement under this subpart is that "all agricultural water must be safe and of adequate sanitary quality for its intended use."[170] 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 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."[171]

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.[172]

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

[170] *Id.* §112.41.
[171] *Id.* §112.42.
[172] *Id.* §112.44(a).

- 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.[173]

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.[174]

B. 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, biological soil amendments of animal origin, and animals as covered produce grown using non-aquaponic systems.[175]

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."[176] In contrast, "when covered produce is grown in an

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[173] *Id.* §112.44(b).
[174] 21 C.F.R. §112.48.
[175] Produce Safety Rule, *supra* note 152, at 74366.
[176] *Id.* (emphasis added).

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."[177]

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.[178]

VI. Conclusion

The growth of the seaweed aquaculture industry in the United States is raising challenging questions about how to ensure products are safe to eat when most operations are exempt from the federal framework. States are taking action to fill the gaps, but they are pursuing different approaches. This could make it difficult for products to cross state lines and cause problems as businesses grow. There is a need for states and federal governments to work together.

There are multiple factors that states must consider when adopting a regulatory model. First, seaweed is biologically very different from fish, shellfish, and produce. However, the regulatory models used to ensure that those products are safe to eat may be informative from a regulatory perspective as state frameworks are developed to govern the emerging seaweed industry.

Second, states must consider which agency or agencies should have authority for implementing the seaweed food safety program. Importantly, the model a state chooses to implement can vastly affect which state agency is in charge of licensing or approving the sale of seaweed as a food source. 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.

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[177] *Id.* (emphasis added).
[178] *Id.*

Third, states must consider the regulatory burden associated with implementing the chosen seaweed food safety framework. States may choose particular paths because they are familiar with a regulatory framework, even if that framework is not the best option scientifically. For instance, if many seaweed growers in a particular state are diversifying their shellfish farms by adding seaweed, then both the farmer and the regulator are already familiar with Seafood HACCP and the National Shellfish Sanitation Program.

Fourth, states must consider how their chosen model will affect businesses as they grow and expand. How hard would it be for a qualified facility following Seafood HACCP pursuant to state regulation to shift to Hazard Analysis and Preventive Controls if the business sells enough product to lose their qualified facility exemption?

Finally, food safety hazards are being actively researched. States will have to do a delicate balance to not provide overly-burdensome regulations while the science is still developing while also providing for food safety protocols. Likewise, states will have the burden of updating their regulations as the science on seaweed food safety continues to emerge.