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Re: Regulation of Seaweed as a Food Source

Date: March 27, 2019

This product was prepared by the National Sea Grant Law Center under award number NA14OAR4170065 from the National Oceanic and Atmospheric Administration, U.S. Department of Commerce. This material is also based upon work supported by the National Agricultural Library, Agricultural Research Service, U.S. Department of Agriculture under Subaward no. UA AES 05687-03 from the National Agricultural Law Center, University of Arkansas. The statements, findings, conclusions, and recommendations are those of the author and do not necessarily reflect the views of NOAA, U.S. Department of Commerce, or the USDA.

Advisory Request Summary

Last year, Connecticut Sea Grant asked the National Sea Grant Law Center (NSGLC) to research potential models for the state of Connecticut to look for as guidance in its regulation of the sale of seaweed in its whole form, which implicates food safety issues. On the federal level, the U.S. Food & Drug Administration (FDA), located in the Department of Health and Human Services, regulates food safety through the authority given to it by Congress. However, the U.S. Department of Agriculture (USDA) is in charge of the food safety of meat, poultry, and processed eggs. USDA is also in charge of setting federal organic standards. However, neither FDA or USDA has regulated the sale of seaweed in its whole form. As such, you asked the NSGLC to look into two potential models for regulation at the state level: seafood Hazard Analysis Critical Control Point (HACCP) plans or the federal Food Safety Modernization Act (FSMA).

Currently, Connecticut is using the HACCP plan that the states uses to regulate seafood for the regulation of seaweed. The regulator for seafood HACCP as applied to the harvest of shellfish produced in Connecticut is the Connecticut Department of Agriculture Bureau of Aquaculture (CT DOAG). HACCP applied to kelp intended to be sold as a *raw agricultural commodity* under a *seaweed producer license* is also regulated by the CT DOAG. HACCP applied to kelp that is *packaged or processed* under a *food manufacturing license* is regulated by the Connecticut Department of Consumer Protection Food and Standards Division (CT DCP), which currently regulates those who make and sell food in the state and runs the state inspection program for “retail and wholesale food manufacturers that operate, transport or store food in Connecticut.”¹

¹ *Food Program*, CONN. DEPT. OF CONSUMER PROT., <https://portal.ct.gov/DCP/Food-and-Standards-Division/Food--Standards/Foods-Program>.



In considering the models that Connecticut could use for its regulatory program, NSGLC also conducted research into whether other states regulated farmed seaweed as a food source.² While several states have implemented regulations governing facets of seaweed aquaculture that Connecticut could look to for initial direction in expanding its seaweed industry, no state has adopted a formal method of food safety inspection for farmed seaweed. Our summary of the current federal regulatory structure for seaweed, as well as seafood HACCP plans and the FSMA is below.

Background

Seaweed has traditionally had many uses, including as both food sources and food additives. Currently, East Asia is the leader in seaweed and kelp production. However, there is a budding seaweed and kelp aquaculture and wild harvest industry in the United States, which presents both economic benefits and novel legal considerations. In particular, there are issues regarding the respective regulation of seaweed products by the FDA and USDA, as neither has regulated the sale of seaweed in its whole form as a food product. Without federal guidance on the food safety risks of seaweed in its whole form, states are unsure how to proceed with their own laws and regulations, impeding the growth of the industry.

Seaweed is a type of marine macroalgae that is classified as either a green, red, or brown algae.³ For instance, sugar kelp is an edible type of seaweed that is part of the brown algae family. In comparison, blue-green algae, which causes harmful algal blooms, is a cyanobacteria and not a marine algae.⁴ Seaweed can be either wild harvested or commercially cultivated, but farming produces more than 90% of the world's demand. In the U.S., wild harvest occurs in states like Alaska, Maine, and Washington. Additional states in the U.S. also cultivate seaweed, including multiple states in the Northeast such as Connecticut and Rhode Island. Macroalgae is typically cultivated using either off-bottom line farming or floating line aquaculture. In off-bottom line farming, seaweed and kelp are grown in shallow parts of the ocean on lines stretched between wooden stakes anchored to the sea bed. With floating line, seaweed and kelp are grown from lines anchored directly to the sea floor, instead of to wooden stakes as in the off-bottom method. Most food species are cultivated using the floating line method, which is suitable for deep ocean areas or areas with weak currents.

Regulatory Uncertainty

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 basis for FDA to regulate food under the Food, Drug and Cosmetic Act (FDCA) and FSMA. While the FDA has wide authority to regulate food that circulates in interstate commerce,

² The states included in this inventory were Maine, New Hampshire, New York, Massachusetts, Rhode Island, New Jersey, Alaska, Washington, Oregon, and California.

³ Ajit Kandale et al., *Marine Algae: An Introduction, Food value and Medicinal uses*, 4 JOURNAL OF PHARMACY RESEARCH 219 (2011), https://www.researchgate.net/publication/234002702_Marine_algae_An_Introduction_Food_value_and_Medicinal_uses.

⁴ *Marine Algae*, MARINE EDUC. SOC'Y OF AUSTRALASIA, http://www.mesa.edu.au/marine_algae/.



states have the authority to regulate food sold in restaurants and retail stores found within the state. 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. The Connecticut Department of Consumer Protection and Connecticut Department of Health have both adopted the 2013 version of the FDA Food Code, and there are plans in the state to adopt the 2017 version.⁵

With respect to the sale of seaweed in its whole form as a food product, there are no federal regulations or guidance. In such cases, states can act to fill the regulatory gap. However, there are federal regulations and other actions related to other uses of seaweed.

Both the FDA and USDA have promulgated regulations that could greatly impact the success of kelp and seaweed products when put to market. First, the FDA's current regulations can help aquaculturists 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 full form. Second, the USDA's organic regulations are applicable to seaweed in some instances, but, again, not when referring to whole marine algae products.

The FDA currently has several regulations controlling the legal consumption of seaweed and kelp products in the United States. The FDA considers kelp "generally recognized as safe" (GRAS), 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.⁶ Food additives are subject to FDA's premarket review and approval, unless the substance is given a GRAS designation.⁷

The FDA has set forth maximum daily amounts of kelp additive (including giant kelp, oarweed, and sugar kelp) that certain subsets of people should be able to ingest without consuming too much iodine. For most people, the daily amount is 225 micrograms.⁸ 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 curvie.⁹

⁵ ADOPTION OF THE FDA FOOD CODE BY STATE AND TERRITORIAL AGENCIES RESPONSIBLE FOR THE OVERSIGHT OF RESTAURANTS AND RETAIL FOOD STORES, U.S. FOOD & DRUG ADMIN. 5 (2017), <https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM577858.pdf>. See also *2017 Food Code Frequently Asked Questions*, CONN. DEPT. OF PUBLIC HEALTH, https://portal.ct.gov/-/media/Departments-and-Agencies/DPH/dph/environmental_health/food_protection/2018-Uploads/Food_new-questions-for-website--081718-CA-CC--FINAL.pdf?la=en.

⁶ 21 U.S.C. § 321(s).

⁷ *Generally Recognized as Safe (GRAS)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/ingredientpackaginglabeling/gras/>.

⁸ 21 C.F.R. § 172.365.

⁹ *Id.*



Besides these general regulations, the FDA adopted specific regulations for brown and red algae.¹⁰ 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.

USDA regulates the organic classification of farmed kelp and other algae, but only when used as an ingredient in livestock feed, fertilizer, or food for human consumption. The USDA permits four nonorganic substances taken from farmed marine plants and algae to be allowed in products labeled "organic" when the algal product is not otherwise commercially available in organic form.¹¹ The USDA also allows farmed aquatic plant extracts to be used in organic crop production as plant or soil amendments in certain circumstances.¹²

Overview of HACCP and FSMA

In considering a potential model for Connecticut to use in the future, you asked us to examine two potential models: (1) regulation using the HACCP model that Connecticut is currently pursuing; and (2) regulation based on the federal FSMA. Generally speaking, regulation of seafood under a HACCP plan requirement involves an internal analysis of potential hazards and an enforceable, written plan to address any hazards that are likely to occur. Regulation of a general food product under the FSMA similarly requires the responsible agent of a food processing facility to analyze potential hazards and create a written plan including preventative control measures for each potential hazard. A general overview of each program is provided below.

Hazard Analysis Critical Control Point Plans

The FDA has adopted regulations for the development of seafood HACCP plans.¹³ The seafood HACCP regulations require a seafood processor to 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 these hazards."¹⁴ 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."¹⁵ A fishery product is defined as "any human food product in which fish is a characterizing ingredient."¹⁶ Finally, food safety hazards are "any biological,

¹⁰ *Id.* §§ 184.1120, 1121.

¹¹ 7 C.F.R. § 205.606.

¹² *Id.* § 205.601(j)(1).

¹³ 21 C.F.R. § 123.6(g).

¹⁴ *Id.*

¹⁵ *Id.* § 123.3.

¹⁶ *Id.*



chemical, or physical property that may cause a food to be unsafe for human consumption.”¹⁷ Although seaweed is not explicitly included here, a state could choose to extend the model to apply to the regulation of seaweed.

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.¹⁸ 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.”¹⁹

A fish or fishery product processor’s failure to have and implement a compliant HACCP plan renders that processor’s products adulterated.²⁰ Under the federal FDCA, a food can be considered adulterated “if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.”²¹ Adulterated products cannot be introduced into interstate commerce.²²

Seafood HACCP Requirements

There are some general requirements for a seafood HACCP plan, each of which are discussed more fully below.

Analyze process for potential hazards. First, the seafood processor must conduct an internal analysis to determine any safety hazards that are reasonably likely to occur and note any potential preventative measures. This could mean hazards in the processing plant environment or in the harvest environment. “Reasonably likely to occur” means that a prudent fish or fishery product processor would implement preventative controls because “experience, illness data, scientific reports, or other information” shows that a hazard is likely to occur without those controls.²³

Write and implement a HACCP Plan whenever one or more hazard is reasonably likely to occur. The written HACCP plan should address the identified hazard(s) and be written specifically to each location where the fishery product is processed by that processor and for each kind of product.²⁴

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.* § 123.6(g).

²¹ *Id.* § 342(a)(4).

²² *Id.* § 331(a).

²³ *Id.* § 123.6(a).

²⁴ *Id.* § 123.6(b).



Address minimum required factors in HACCP plan. The plan should include at minimum a list of all of the food safety hazards reasonably likely to occur (thus requiring controls), a list of the critical control points for each identified food safety hazard, a list of the critical limits that must be met at each of the critical control points, the procedures that will be used to monitor critical control points, any corrective action plans, a list of verification procedures (in accordance with § 123.8(a)), and a recordkeeping system for documenting critical control point monitors.²⁵ Furthermore, consider the following issues of note:

- When discerning likely-to-occur safety hazards, processors should consider natural toxins, microbiological contamination, chemical contamination, pesticides, drug residues, decomposition (in certain species), parasites, physical hazards, and unapproved use of additives; and
- The list of critical control points should include those designed to control hazards potentially introduced both inside and outside the processing plant environment, including before, during, and after harvest.

Sign and date the HACCP plan. Either a high-level official of the processor or the most responsible individual onsite of the processing facility must do this at initial acceptance of the plan, upon any modification, and upon verification of the plan under § 123.8(a)(1).²⁶

Applicability of other Provisions.

HACCP plans may, but are not required to, include sanitation controls. Sanitation is covered by § 123.11(b), which lists eight sanitation conditions and practices that all processors must monitor sufficiently; therefore, it is not necessary to list this required monitoring in a HACCP plan.²⁷ Among others, these include the safety of water that comes into contact with the food and the protection of food from adulteration from various contaminants.²⁸

Food Safety Modernization Act

The FSMA came into law 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 the FSMA include a legislative mandate to prevent food safety issues, mandated inspection and testing protocols, and enhanced response authority. Since the FSMA was enacted, the FDA has finalized seven major rules under the act, including the Produce Safety Rule, which is discussed in more detail below due to its potential application to seaweed. It should be noted that the FSMA is applicable only to food facilities “engaged in manufacturing, processing, packing, or holding food for consumption...”.²⁹

Major Provisions

²⁵ *Id.* § 123.6(c).

²⁶ *Id.* § 123.6(d).

²⁷ *Id.* § 123.6(f).

²⁸ *Id.* § 123.11(b).

²⁹ *Id.* § 170.3(n).



Inspection of records. The FSMA requires that processors, manufacturers, packagers, etc. of food produce records for the Secretary of the Department of Health and Human Services (HHS Secretary), which is the department of the federal government where the FDA sits, when he reasonably believes an article of food is adulterated and requests the records in writing. The provision allows the HHS Secretary to require by regulation that food processors maintain, for up to two years, records of the immediate prior source and subsequent recipient of the food.³⁰

Registration of food facilities. The FSMA requires that all food facilities (“any facility engaged in manufacturing, processing, packing, or holding food for consumption...”) register with the HHS Secretary. Registration must include general information about the physical facility, contact information for the registrant, and the category or categories of food processed in the facility, and the registration must be renewed biennially.³¹ Although seaweed is not listed in the food categories, fish and vegetables are.³²

Hazard analysis and risk-based preventative controls. The agent in charge of a food facility must evaluate potential hazards, implement controls to reduce the risk of such hazards, and monitor and keep records of the performance of the controls.³³ This section further provides the specifics of exemptions and exceptions related to certain kinds of facilities, sizes of businesses, and/or types of products. Specific requirements of the hazard analysis include:

- The hazard analysis must be written and must include natural, unintentional hazards as well as hazards that may be intentionally introduced.
- The preventative 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. The required monitoring should assure these outcomes are achieved.
- 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.
- The agent in charge of the facility must personally verify that the control measures are adequate, effective, documented, and in accordance with these provisions.
- The facility must maintain records of monitoring preventative controls for at least two years; the records must include instances of nonconformance, use of corrective action, and effectiveness of the controls and corrective actions.
- The agent in charge of the facility must prepare a written plan that documents all of the procedures by which the facility complies to this section; this document must be available to the HHS Secretary’s agent by oral or written request.

³⁰ 21 U.S.C. § 350(c).

³¹ *Id.* § 350d.

³² 21 C.F.R. § 170.3(n).

³³ 21 U.S.C. § 350(g).



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. Additionally, the HHS Secretary may require reanalysis to respond to new scientific understanding. Further, the FSMA provides for the HHS Secretary 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.³⁴ 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.

Sanitary transportation practices. Transporters of food products under the FSMA must follow the HHS Secretary's regulatory requirements for safe transportation of food in order to be compliant.³⁵

Protection against intentional adulteration. The HHS Secretary has the role of assessing the vulnerability of food systems to intentional adulteration, such as terrorist attacks. The agent in charge of a food facility is responsible for considering the HHS Secretary's determinations in his written hazard analysis and preventative control plan.³⁶

Collection of fees. The HHS Secretary has the authority to collect fees from the responsible party for each domestic food facility annually to cover inspection costs and to cover recall costs in the event that the facility does not comply with a mandatory recall.³⁷

The remaining sections of the FSMA are generally related to the role of the HHS Secretary, rather than requirements of the agent in charge of a food facility. A processor would still need to be familiar with the remainder of the provisions as they may have an implied effect on the hazard analysis and prevention documents that the facility is required to produce and maintain.

The Produce Safety Rule

In 2015, under the FSMA, 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 establishes mandatory science-based, minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. These standards are designed to work effectively for food safety across the wide diversity of produce farms.³⁸ What this means is that farms covered by the rule will be held to certain standards designed to reduce the presence of potentially dangerous bacteria in the food supply, with

³⁴ *Id.* § 2201.

³⁵ *Id.* § 350e.

³⁶ *Id.* § 350i.

³⁷ *Id.* § 379j.

³⁸ Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. 74353 (Nov. 27, 2015), <https://www.federalregister.gov/documents/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption> [hereinafter Produce Safety Rule].



the ultimate goal of reducing the number of illnesses caused by contaminated produce. Consider the following key elements of the rule that could be applicable to seaweed:

- The rule has requirements for agricultural water quality and testing designed to detect contamination.
- Farm workers handling covered produce and/or food contact surfaces must be trained on the importance of health and hygiene.
- There are standards related to equipment, tools, and buildings to prevent problems, such as poor sanitation, from contaminating produce.

It should be noted that produce is not divided into different categories (i.e. fruits, vegetables, tree nuts, etc.). They only two categories that exist are: (1) foods that are covered by this rule; and (2) foods that are not covered by this rule. Therefore, the same rules apply to greens as would apply to tree nuts. Generally, the PSR is intended to apply to produce that will be eaten raw, and the FDA provided a non-exhaustive list of produce that is covered by the rule.³⁹ While seaweed or algae is not currently on this list, the list could be amended in the future.

While it was drafting the PSR, the FDA received comments as to whether the term “produce” included a list of other commodities, including algae. In response, the agency 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.”⁴⁰ The agency went on to discuss how algae differ 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.”⁴¹ However, the agency mentioned how algae that are used for food will continue to be covered under the federal FDCA and applicable implementing regulations. 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.”⁴²

PSR Requirements

Generally, the PSR requires 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.”⁴³ The PSR contains various provisions including:

Subpart “C” – Personnel Qualifications and Training

³⁹ 21 CFR §112.1.

⁴⁰ Produce Safety Rule, *supra* note 38, at 74385.

⁴¹ *Id.*

⁴² *Id.*

⁴³ 21 CFR §112.11.



This subpart covers the requirements regarding qualifications and training for personnel who handle/contact covered produce or food contact surfaces. These requirements apply to all personnel, including temporary, part-time, seasonal, and contracted personnel.

Subpart “D” – Health and Hygiene

This subpart covers potential contamination of covered produce by personnel and other visitors. It contains various provisions regarding specific measures to take when personnel are ill, as well as hygienic practices that must be used by personnel.

Subpart “E” – Agriculture Water

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).⁴⁴

The general requirement under this subpart is that “all agricultural water must be safe and of adequate sanitary quality for its intended use.”⁴⁵ In furthering this requirement, 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.

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. Such criteria are as follows:

It must be ensured that there is no detectable generic E. coli in 100 milliliters of agricultural water and that untreated surface water is 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.

⁴⁴ *Id.* §112.3.

⁴⁵ *Id.* §112.41.



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.

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.

Subpart "I" – Domesticated and Wild Animals

This subpart covers requirements of domesticated and wild animals in instances where a covered activity takes place outdoors or in a partially-enclosed building where there is a reasonable probability that animals will contaminate covered produce.

These requirements do *not* apply when a covered activity takes place in a fully-enclosed building or to fish used in aquaculture operations. Thus, it appears that fish used in a mixed-use system to grow seaweed would not be covered by these requirements.

Subpart "K" – Growing, Harvesting, Packing, and Holding Activities

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.

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.

Subpart "L" – Equipment, Tools, Buildings, and Sanitation

This subpart covers equipment, tools, buildings, and standards and requirements regarding operation, maintenance, and sanitation. In regard to buildings, it covers requirements for hand-washing stations, toilet facilities, sewage, pests, and trash disposal.

Subpart "M" – Sprouts

This subpart covers all sprouts, except for soil or substrate-grown sprouts harvested without their roots. It contains requirements regarding seeds and beans and mentions various testing requirements, as well.



Produce Safety Rule Application to Aquaponics or Hydroponics

Although it is not clear how seaweed operations would be classified by the FDA, the NSGLC examined whether the PSR addressed aquaponics or hydroponic operations. A review of the notice and comment record for the rule uncovered several references to these topics. The relevant comments are discussed below.

One Comment (Comment 17) asked the agency to exempt aquaponic farming from the PSR, specifically the subparts related to Agriculture Water (Subpart E) and Domesticated and Wild Animals (Subpart I). The agency's response addressed each subpart.⁴⁶

In response to Subpart E: Agriculture Water, the agency stated that aquaponic farms should *not* be excluded from the rule. 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.⁴⁷

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."⁴⁸ 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."⁴⁹

In response to Subpart I: Domesticated and Wild Animals, the agency stated this subpart only applied to outdoor areas and partially-enclosed areas. The requirements under this subpart do not apply when a covered activity takes place in a full-enclosed building or to fish used in aquaculture operations.

Another comment (Comment 18) asked that the agency exempt aquaponic and hydroponic farming of produce other than sprouts from the requirements under Subpart M- Sprouts. In response, the agency added a new section which clarified the scope of this subpart. Now, aquaponic and hydroponic systems used to grow covered produce other than sprouts are not subject to the requirements under Subpart M. In addition, the agency went on to define "spent sprout irrigation water" as "water that has been used in the growing of sprouts."⁵⁰ Following this definition, the agency stated, "the term 'spent sprout irrigation water,' and the requirements for testing spent sprout irrigation water in subpart "M," *only* apply to the water used for

⁴⁶ Produce Safety Rule, *supra* note 38.

⁴⁷ *Id.* at 74366.

⁴⁸ *Id.* (emphasis added).

⁴⁹ *Id.* (emphasis added).

⁵⁰ *Id.* at 74367.



growing sprouts, and *not* to water used in an aquaponic or hydroponic operation growing produce other than sprouts.”⁵¹ However, the agency went on to “encourage” aquaponic and hydroponic operations to consider voluntarily implementing the requirements under Subpart M.

A further comment (Comment 19) asked the agency to consider establishing additional regulations specifically applicable to aquaponic and hydroponic operations that produce crops other than sprouts. The agency responded by stating it had not established additional standards applicable to aquaponic or hydroponic production of crops other than sprouts.⁵²

Conclusion

There are several key differences between the seafood HACCP and the FSMA regulatory schemes. Both regulatory schemes require internal analysis by the processing facilities, but the FSMA seems to give more direction as to what hazards exist and must be addressed. Further, it is not clear who the regulating entity would be if Connecticut chooses the FSMA model. The regulator could be the CT DCP.⁵³ The CT DCP Foods Division currently regulates individuals who make and sell food in the state and runs the state inspection program for “retail and wholesale food manufacturers that operate, transport or store food in Connecticut.”⁵⁴ However, the CT DOAG implements the Produce Safety Rule in the state and therefore could also have regulatory authority.

As for the applicability of the Produce Safety Rule, the rule currently does not include any provisions specifically addressing seaweed, aquaponics, or hydroponics. However, that is not to say that these operations are excluded from the rule. As noted above, during the administrative process the agency responded to a comment explicitly stating that the PSR does, in fact, still apply to aquaponic and hydroponic operations despite the lack of specific regulations for such operations. The agency left the door open to addressing the issue in the future.

While the PSR has various subparts, there are provisions that would be applicable to seaweed operations, including:

- Subpart “C” – Personnel Qualifications and Training;
- Subpart “D” – Health and Hygiene;
- Subpart “K” – Growing, Harvesting, Packing, and Holding Activities; and
- Subpart “L” – Equipment, Tools, Buildings, and Sanitation.

⁵¹ *Id.*

⁵² *Id.*

⁵³ See *Who Regulates our Food?*, UNIV. OF CONN. COLL. OF AGRIC., HEALTH AND NATURAL SCIENCES, http://cag.uconn.edu/nutsci/nutsci/foodsafety/Home_Page/Who_Regulates_our_Food.php.

⁵⁴ *Id.*; see also *Food Program*, CONN. DEPT. OF CONSUMER PROT., <https://portal.ct.gov/DCP/Food-and-Standards-Division/Food--Standards/Foods-Program>.



The agency also stated during the administrative process that the requirements of Subpart I: Domesticated and Wild Animals do not apply to fish used in aquaculture operations. The most complicated subpart to adapt would most likely be Subpart E: Agriculture Water. While the agency did provide some response in regard to how agricultural water is handled in aquaponic operations, applying this to something like seaweed might be somewhat different.

Some of the keys differences between HACCP and FSMA are described in the table below.

HACCP/FSMA Comparison		
	HACCP	FSMA
Plan Requirements	Preventative control plans are written separately per identified hazard and for each point in a process where a hazard may be best controlled, and include critical limits necessary to control the hazard, monitoring requirements, corrective actions, recordkeeping, and verification requirements.	Written plan is more comprehensive and detailed, including preventative controls, methods for monitoring them, and corrective actions for when the controls fail. Using FSMA subjects a facility to a greater degree of regulation with regards to making their records available to and registering with its regulatory agency.
Plan Revisions	Does not specify a frequency for reanalyzing hazards and writing a new plan. Under the requirements for HACCP as applied to shellfish, hazards must be re-analyzed when a change to the process or product is proposed, or new state or federal regulations are adopted.	Requires the facility to reanalyze hazards at least every three years or when a significant change occurs or the regulatory agency gives notice of a change in scientific understanding.
Fees	Does not mention a fee for assuring compliance.	Facilities will be charged an annual fee for inspections and face potential fees if they fail to comply with a mandatory recall.
Regulator	CT DOAG: kelp intended to be sold as a raw agricultural commodity under a seaweed producer license CT DCP: kelp that is packaged or processed under a food manufacturing license	Unclear. For other food products, the current jurisdiction is: CT DOAG: implements the PSR in the state CT DCP: regulates those who make and sell food in the state. Runs state inspection program for “retail and wholesale food manufacturers that operate, transport or store food in Connecticut”



Finally, the lack of certainty about hazards from seaweed will be an issue for both regulatory regimes. Regulators will have to determine whether there are similar hazards to shellfish or if there are additional concerns that should be considered. Therefore, neither model may not capture all the specific issues with seaweed at this time. However, this challenge may arise more under HACCP, as the FSMA provides more of a structure. Until food safety hazards with seaweed are better understood, HACCP may present more compliance challenges for industry.