



This document is a companion to the slide deck entitled *Seaweed Food Safety: Regulatory Overview*, which provides an overview of the federal food safety framework as it applies to seaweed. This document and the slides were both produced with funding from the [National Seaweed Hub](#) under NOAA Award No. NA22OAR4170629.

The text below provides additional context and background information for each slide that may be helpful for individuals wishing to share the slide deck in presentation settings. For more information on the federal requirements related to seaweed food safety and how some states are implementing these requirements, see [Seaweed Food Safety: Comparing Compliance with Preventive Controls for Human Foods and Seafood HACCP](#). Questions can be directed to Catherine Janasie, Senior Research Counsel, National Sea Grant Law Center, at [cjanasie@olemiss.edu](mailto:cjanasie@olemiss.edu).

### **Federal Food Safety Overview (Slides 1-2)**

On the federal level, all food for human consumption is subject to the Federal Food, Drug, and Cosmetic Act (FDCA), including the prohibition on introducing adulterated food into interstate commerce. The adulterated food prohibition applies to harvested seaweed intended for consumption as food, including that it not be “prepared, packed, or held under insanitary conditions.”<sup>1</sup> The adulteration prohibition is described more fully below.

Under the Food Safety Modernization Act (FSMA), food facilities that need to register with the FDA are also subject to 21 CFR Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Rule. However, there are certain exemptions to these requirements that may result in few seaweed operations in the United States being subject to the full requirements of Part 117. FSMA and the Preventive Controls rule are described more fully below.

### **FDA Classification of Seaweed (Slide 3)**

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.<sup>2</sup> Like other raw agricultural commodities, the FDA therefore considers the growing and harvesting of seaweed to

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<sup>1</sup> 21 U.S.C. § 342(a)(4).

<sup>2</sup> Email on file with author.

be “farm” activities. This distinction is important because activities that fit within FDA’s definition of a “farm” are not considered food processing that would be subject to further requirements besides the adulteration prohibition (described more fully below). Some activities that may be thought of as processing can still fall within the farm definition, such as drying.<sup>3</sup> If an operation goes beyond harvesting and drying, such as by blanching, freezing, or cutting the seaweed, it would be considered a “food facility.”

Important to note: Seaweed does not fit into the FDA’s definition of “fish or fishery product,” which would subject it to Seafood HACCP requirements, or the definition of produce, which would subject it to the Produce Safety Rule.

*Note on the Produce Safety Rule (PSR):* In 2015, the FDA adopted Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, known as the Produce Safety Rule (PSR). The PSR, which went into effect in 2016, establishes mandatory science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.<sup>4</sup> Neither seaweed or algae is currently on the list of produce covered by the PSR, although the list could be amended in the future. In fact, the FDA explicitly addressed the inclusion of seaweed within the scope of the PSR when responding to public comments as part of the PSR rulemaking process. While it was drafting the PSR, the FDA received comments inquiring whether the term “produce” included a list of other commodities, including algae. In response, the FDA defined produce to include, “fruits (the harvestable or harvested part of a plant developed from a flower) and vegetables (harvested part of any plant or fungus), which by definition does not include algae.”<sup>5</sup> The agency mentioned that algae that are used for food will continue to be covered under the FDCA and its applicable implementing regulations. As mentioned in previous chapters, the FDA has asserted that seaweed sold in its whole form will be regulated as a raw agricultural commodity under the FDCA. The agency left open the opportunity to address algae in the future, stating, “[a]s appropriate, we may consider issuing guidance on the topic of algae production for human food use in the future.”<sup>6</sup>

## **Seaweed and the Preventive Controls Rule (Slides 9 - 12)**

Congress enacted the FSMA 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,

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<sup>3</sup> 21 C.F.R. § 1.227.

<sup>4</sup> [Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption](#), 80 Fed. Reg. 74353 (Nov. 27, 2015) [hereinafter Produce Safety Rule].

<sup>5</sup> Produce Safety Rule, *supra* note 3, at 74385.

<sup>6</sup> *Id.*

and enhanced response authority. Under FSMA, the responsible agent of a food processing facility is required to analyze potential hazards and create a written plan that includes preventative control measures for each potential hazard. Since FSMA was enacted, the FDA has finalized seven major rules to implement the Act, including 21 CFR Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Rule, sometimes referred to as Part 117 or the Preventive Controls Rule.

Specifically, FSMA is applicable to food facilities that “engaged in manufacturing, processing, packing, or holding food for consumption...”<sup>7</sup> The FDA has published detailed definitions for each of these terms in the agency’s regulations implementing FSMA.

Operations that qualify as a food facility need to register with the FDA and are also subject to Part 117. However, many seaweed operations in the United States are likely to face modified requirements under Part 117, as they could be considered qualified facilities. 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.

The second route is based on direct sales to consumers and other “qualified end users,” which includes restaurants and retail food establishments in the same state or within 275 miles that sell food directly to consumers. To meet this requirement, the value of 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.<sup>8</sup>

### **Regulation of Raw Seaweed (Slides 13 - 14)**

Like other raw agricultural commodities, the FDA considers the growing and harvesting of seaweed to be “farm” activities. This distinction is important because activities that fit within FDA’s definition of a “farm” are not considered food processing that would be subject to further requirements beyond the FDCA’s adulteration prohibition (described below). As discussed more below, some activities that may be thought of as processing can still fall within the farm definition, such as drying.<sup>9</sup>

Farms are not subject to Part 117. The definition of farm is complicated and divided into two subcategories: “primary production” farms and “secondary activities” farms. 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

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<sup>7</sup> 21 U.S.C. § 350d.

<sup>8</sup> 21 C.F.R. § 117.3.

<sup>9</sup> 21 C.F.R. § 1.227.

raising of animals (including seafood), or any combination of these activities.”<sup>10</sup> 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.”<sup>11</sup>

### **The FDCA Adulteration Provisions (Slides 15 - 20)**

On the federal level, all food for human consumption is subject to the FDCA, including the prohibition on introducing adulterated food into interstate commerce. The adulterated food prohibition applies to harvested seaweed intended for consumption as food.<sup>12</sup> The FDCA prohibits activities involving the movement of adulterated food in interstate commerce. The statute lists the different circumstances where a food could become adulterated.<sup>13</sup> Relevant to seaweed is the category of poisonous or unsanitary ingredients in food, which includes, among other items, the following:

- Poisonous or deleterious substances that make the food injurious to health, though a food is not adulterated if the potentially harmful substance is not added to the food and the amount is not usually injurious to health.
- Added poisonous or deleterious substance, pesticide chemical residue, unsafe food additives, or new animal drugs that are unsafe under the Act.
- Food that consists in whole or in part of filthy, putrid, or decomposed substances, or is otherwise unfit to be eaten.
- Food that is prepared, packed, or held in conditions where it can become “contaminated with filth” or rendered injurious to health.”
- Food that is held in a container that could be injurious to health.<sup>14</sup>

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.<sup>15</sup> This

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<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> 21 U.S.C. § 342(a)(4).

<sup>13</sup> 21 U.S.C. § 342. Other categories of adulterated food that are not discussed in this paper include color additives that do not meet the standards of the FDCA, confections containing alcohol or nonnutritive substances, oleomargarine that is unfit as food, limits on dietary supplements or ingredients, and certain imported food that does not meet the standards of the FDCA. *Id.* Additional adulterated food categories include food “(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.” *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

standard could be important when considering the transportation of seaweed from the farm to a farmers market, restaurant, or similar location.

### **Regulation of Dried Seaweed (Slide 21)**

If seaweed is dried or dehydrated on either a primary production farm or secondary activities farm, it is exempt from FSMA requirements, as these activities are covered by the farm definition. This seaweed is still subject to the FDCA's adulteration prohibition. As discussed more below, if the drying/dehydration is not done as part of the farm operation, it is processed food and the entity who is drying or dehydrating the seaweed must comply with FSMA and Part 117 in particular.

Farms are allowed to perform "harvesting," "packing," and "holding" activities that are incidental to the farming operations and take place on the farm without jeopardizing their status as a farm. In addition, the registration requirement specifically states: "For farms..., manufacturing/processing does not include activities that are part of harvesting, packing, or holding."<sup>16</sup> The activities directly related to drying and dehydrating are classified in Table 1 below. The FDA has indicated that there is no regulatory difference between drying or dehydrating seaweed or a temporal requirement to when the drying or dehydration needs to happen for it to be covered by the farm definition.<sup>17</sup>

**Table 1- Classification of Drying/Dehydrating RACs**

Harvesting	Drying/dehydrating RACs on a farm when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating grains in the growing area on a farm) is a harvesting activity
Holding	Drying/dehydrating RACs for purposes of safe or effective storage when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa) is a holding activity
Manufacturing/Processing	Drying/dehydrating RACs to create a distinct commodity (such as drying/dehydrating grapes to produce raisins) is a manufacturing/processing activity

<sup>16</sup> *Id.* § 117.3.

<sup>17</sup> Email correspondence with Emanuel Hignutt, on file with the author.

## **Regulation of Processed Seaweed (Slide 22)**

Seaweed that is dried or dehydrated by an entity other than a primary production farm or secondary activities farm is covered by FSMA. Additionally, FSMA covers other types of processed seaweed, including additional processing done by the farm, such as slicing. Under the FDCA, processed food is defined as “[a]ny 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.”<sup>18</sup> Except for the exception described above related to a farm operation drying or dehydrating seaweed, each of the listed processing activities subject an operation to the requirements of FSMA.

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<sup>18</sup> 21 U.S.C. § 321(gg).