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From: Catherine Janasie, National Sea Grant Law Center, Research Counsel II

Re: Regulation of Dried or Dehydrated Seaweed (NSGLC-24-04-05)¹

Date: September 30, 2024

Advisory Summary

As part of the Seaweed Food Safety Working Group’s discussions, questions have been raised regarding the regulatory status of dried or dehydrated seaweed in the United States. Seaweed growers are drying and dehydrating seaweed and receiving different regulatory directions from their state agencies, with some states saying the dried seaweed needs to be regulated as a processed food. Growers use various methods to dry and dehydrate their product, including air drying in a barn, commercial dehydrators, and personal food dehydrators that sit on a kitchen counter.

The food safety framework in the United States is described more fully below. Generally, seaweed that is dried or dehydrated by a “farm” under the U.S. Food & Drug Administration’s (FDA) regulations is only subject to the Federal Food, Drug, and Cosmetic Act (FDCA). Seaweed that is dried or dehydrated by an entity other than the farm, as well as other processed seaweed, is subject to the Food Safety Modernization Act (FSMA). Such operations are subject to FSMA’s registration requirements, as well as the FDA’s Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Rule.

This memo provides an overview of the federal food safety framework as it applies to dried or dehydrated seaweed. It is important to note that seaweed operations must comply with any additional food safety requirements implemented by their applicable state agencies. For more information on the federal requirements related to seaweed food safety and how some

¹ This product was prepared by the National Sea Grant Law Center under award number NA22OAR4170089 from the National Oceanic and Atmospheric Administration, U.S. Department of Commerce. The statements, findings, conclusions, and recommendations are those of the authors and do not necessarily reflect the views of NOAA or the U.S. Department of Commerce.

states are implementing these requirements, see [Seaweed Food Safety: Comparing Compliance with Preventive Controls for Human Foods and Seafood HACCP](#).

Food Safety Introduction

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.² 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.³ 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.⁴

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 1.900-1.934.⁵ This standard could be important when considering the transportation of seaweed from the farm to a farmers market, restaurant, or similar location.

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

² 21 U.S.C. § 342(a)(4).

³ 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.*

⁴ *Id.*

⁵ *Id.*

legislative mandate to prevent food safety issues, mandatory inspection and testing protocols, and enhanced response authority. Under FSMA, the responsible agent of a food processing facility is required to analyze potential hazards and create a written plan that includes preventative control measures for each potential hazard. Since FSMA was enacted, the FDA has finalized seven major rules to implement the Act, including 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.

Raw Seaweed

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.⁶ Like other raw agricultural commodities, the FDA therefore considers the growing and harvesting of seaweed to be “farm” activities. This distinction is important because activities that fit within FDA’s definition of a “farm” are not considered food processing that would be subject to further requirements beyond the FDCA’s adulteration prohibition mentioned above. As discussed more below, some activities that may be thought of as processing can still fall within the farm definition, such as drying.⁷

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 raising of animals (including seafood), or any combination of these activities.”⁸ 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.”⁹

Seaweed Dried or Dehydrated on the Farm

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

⁶ Email on file with author.

⁷ 21 C.F.R. § 1.227.

⁸ *Id.*

⁹ *Id.*

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.”¹⁰ 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.¹¹

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

¹⁰ *Id.* § 117.3.

¹¹ Email correspondence with Emanuel Hignutt, on file with the author.

Seaweed not Dried/Dehydrated by the Farm and other Processed Seaweed

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.”¹² 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.

Specifically, FSMA is applicable to food facilities that “engaged in manufacturing, processing, packing, or holding food for consumption...”.¹³ The FDA has published detailed definitions for each of these terms in the agency’s regulations implementing FSMA, which are covered in Table 2 below.

Table 2- Definitions of Manufacturing, Processing, Packing, or Holding Food for Consumption¹⁴

Activity	Definition
Manufacturing/ Processing	<p>Making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients.</p> <ul style="list-style-type: none"> Examples include: baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, <i>drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins)</i>, 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.

¹² 21 U.S.C. § 321(gg).

¹³ 21 U.S.C. § 350d.

¹⁴ 21 C.F.R. § 1.227.

	<ul style="list-style-type: none"> As discussed above, for farms, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.¹⁵ This includes drying/dehydrating done on the farm as part of these activities.
Packing	<p>Placing food into a container other than packaging the food. The definition also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)). It does not include activities that transform a raw agricultural commodity into a processed food.</p>
Holding	<p>Storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and <u>drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)</u>).</p> <ul style="list-style-type: none"> 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. As discussed above, for farms, activities that are part of harvesting, packing, or holding are exempted under the farm definition.¹⁶ This includes drying/dehydrating done on the farm as part of these activities.

¹⁵ 21 C.F.R. § 1.227.

¹⁶ 21 C.F.R. § 1.227.

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.¹⁷

For more information on the requirements of Part 117 and qualified facilities, see [Seaweed Food Safety: Comparing Compliance with Preventive Controls for Human Foods and Seafood HACCP](#).

Conclusion

In conclusion, seaweed that is dried or dehydrated by a farm is only subject to the FDCA. Seaweed that is dried or dehydrated by an entity other than the farm, as well as other processed seaweed, is subject to FMSA. Such operations must register with the FDA and comply with Part 117. However, as discussed above, many seaweed operations will likely be qualified facilities under the FDA’s regulations and face modified requirements under Part 117. Finally, this memo only discusses federal requirements. Seaweed operations may face additional requirements from their applicable state agencies.

¹⁷ 21 C.F.R. § 117.3.