



Seaweed Food Safety: Regulatory Overview

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Federal Food Safety Overview

All food for human consumption is subject to the Federal Food, Drug, and Cosmetic Act (FDCA)

A major component of the FDCA is the prohibition on introducing adulterated food into interstate commerce.



Federal Food Safety Overview

Congress passed the Food Safety Modernization Act (FSMA) to strengthen food safety regulation in the United States.

FSMA is applicable to food facilities that “engaged in manufacturing, processing, packing, or holding food for consumption.



FDA Classification of Seaweed

Seaweed is a “raw agricultural commodity”

A **raw agricultural commodity** - also referred to as a **RAC** - includes any food in its raw or natural state.

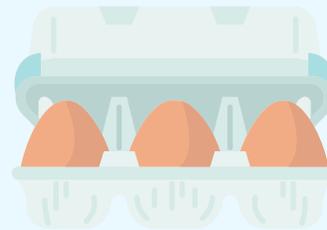
It does not include food that has been processed or manufactured.



FDA Classification of Seaweed

Examples of raw agricultural commodities

- fruit
- vegetables
- grains
- nuts
- eggs
- raw milk
- meats



FDA Classification of Seaweed

FDA does *not* consider seaweed to be produce



Seaweed is not covered by the **Produce Safety Rule (PSR)**.

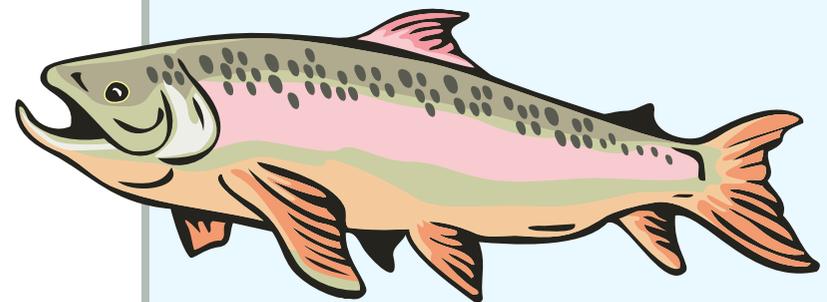
The PSR's list of covered produce does not currently include seaweed or algae, though the list could be amended in the future.

FDA Classification of Seaweed

FDA does *not* consider seaweed to be seafood

The Seafood HACCP regulations do not include algae in the definition of fish or fishery product.

- Fish - “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.”
- Fishery Product - “any human food product in which fish is a characterizing ingredient.”



FDA Classification of Seaweed

The Food Safety Modernization Act (FSMA) and its related rules *may* apply to seaweed.

A stylized illustration of seaweed with several long, wavy, green blades. The seaweed is positioned on the left side of the slide, partially overlapping a decorative border at the bottom. The border consists of a repeating pattern of light green, overlapping semi-circles that resemble waves or a scalloped edge.

FDA's 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, is the rule that *potentially* applies to seaweed.

FDA Classification of Seaweed

Some seaweed may be exempt from FSMA and FDA's Preventive Controls Rule.



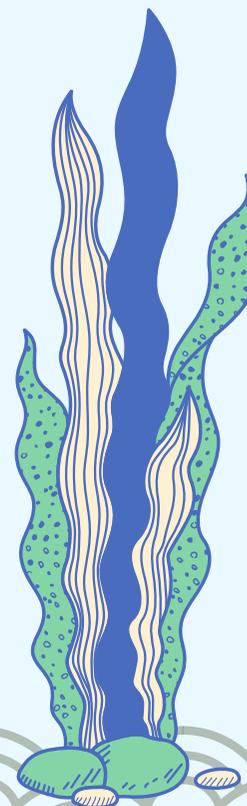
Seaweed operations may be exempt based on the **type of seaweed product produced** or face modified requirements due to the **monetary value of the seaweed products sold**.

Seaweed and the FDA Preventive Controls Rule

FSMA and the Preventive Controls Rule Apply to Facilities

Facilities are any operation that **manufactures/processes, packs,** or **holds** food in the US.

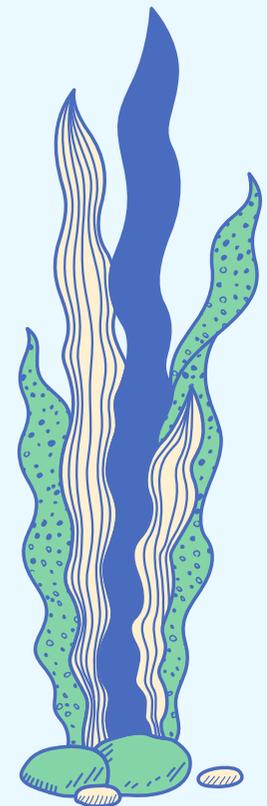
Facilities must register with the FDA.



Seaweed and the FDA Preventive Controls Rule

Preventive Controls for Human Food Rule Subparts

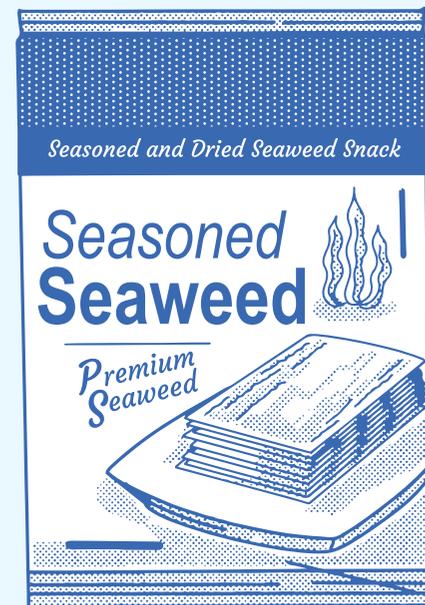
	A	B	C	D	E	F	G
Subparts	General Provisions	Current Good Manufacturing Practices	Hazard Analysis and Risk-Based Preventive Controls	Modified Requirements <i>(for qualified facilities)</i>	Withdrawal of a Qualified Facility Exemption	Requirements Applying to Records that Must be Established and Maintained	Supply-Chain Program
Description	Provides an overview of the regulation, definitions of terms used, exemptions and training requirements.	Outlines general best practices for ensuring facilities/ operations operate in a sanitary manner.	Covers the requirements of the food safety plan required to prevent or eliminate significant food safety hazards.	Modified requirements that must be met by qualified facilities since they are exempt from Subparts C and G.	Outlines instances where facilities/ operations may lose their qualified facility status and the process for withdrawal of this status.	Covers general recordkeeping requirements	Outlines the required supply chain program for any preventive controls identified as necessary for products/ ingredients being received.



Seaweed and the FDA Preventive Controls Rule

Applicability

Facilities have to comply with all the requirements of the Preventive Controls Rule. But smaller facilities, known as **Qualified Facilities**, are subject to modified requirements.



Seaweed and the FDA Preventive Controls Rule

1st Way to be a Qualified Facility

“Very small business”

A business that grossed less than \$1M/year for the previous 3 years in food sales. FDA Guidance states the \$1M cap applies to all food sales for the operation.



Seaweed and the FDA Preventive Controls Rule

1st Way to be a Qualified Facility

Example 1: XYZ Seaweed Company has never sold more than \$800,000 worth of product per year thus qualifies as a very small business and is a Qualified Facility.

Example 2: Sea Food, Co. sells \$1 million worth of raw kelp, and \$200,000 worth of processed seaweed patties. Sea Food, Co. is NOT a Qualified Facility.

Example 3: Food From the Sea Inc. sells \$1.5 million worth of shellfish and \$200,000 worth of processed seaweed patties. Food from the Sea Inc. is NOT a Qualified Facility.

Seaweed and the FDA Preventive Controls Rule

2nd Way to be a Qualified Facility

“Qualified End Users”

Have direct sales in the same state or within 275 miles to consumers, restaurants, and others that sell food directly to consumers. These food sales must be less than \$500k/yr and greater than sales to other purchasers.



Seaweed and the FDA Preventive Controls Rule

2nd Way to be a Qualified Facility

Example: XYZ Seaweed Company sells \$400,000 worth of its blanched kelp to restaurants in town. This is a Qualified Facility because all their products are being sold to a qualified end user (restaurant within 275 miles) and less than \$500,000.

Seaweed and the FDA Preventive Controls Rule

Qualified Facility Requirements

Operation Type	Registration	Subpart A <i>General Provisions</i>	Subpart B <i>Current Good Manufacturing Practices</i>	Subpart C <i>Hazard Analysis/PC</i>	Subpart D <i>Modified Requirements (for qualified facilities)</i>	Subpart E <i>Withdrawal of a Qualified Facility Exemption</i>	Subpart F <i>Records</i>	Subpart G <i>Supply-Chain Program</i>
Farm	No	No	No	No	No	No	No	No
Facility	Yes	Yes	Yes	Yes	No	No	Yes	Yes
Qualified Facility	Yes	Yes	Yes	No	Yes	Yes, if losing Qualified Facility status	Yes	No

Regulation of Raw Seaweed

Farms are Exempt if:

The farm harvests, packs, and holds the seaweed as either a **raw agricultural commodity** - meaning in its natural state - or **dried without any other processing**.



Regulation of Raw Seaweed

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The farm harvests, packs, and holds the seaweed as either a **raw agricultural commodity** - meaning in its natural state - or **dried without any other processing**.



Example: A Farm that dries seaweed, a raw agricultural commodity, would remain within the definition of a Farm as long as they are also not cutting or producing a value-added product (i.e. salsa).

Regulation of Raw Seaweed

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The farm harvests, packs, and holds the seaweed as either a **raw agricultural commodity** - meaning in its natural state - or **dried without any other processing**.

*States may add additional requirements:
CT- Seafood HACCP*



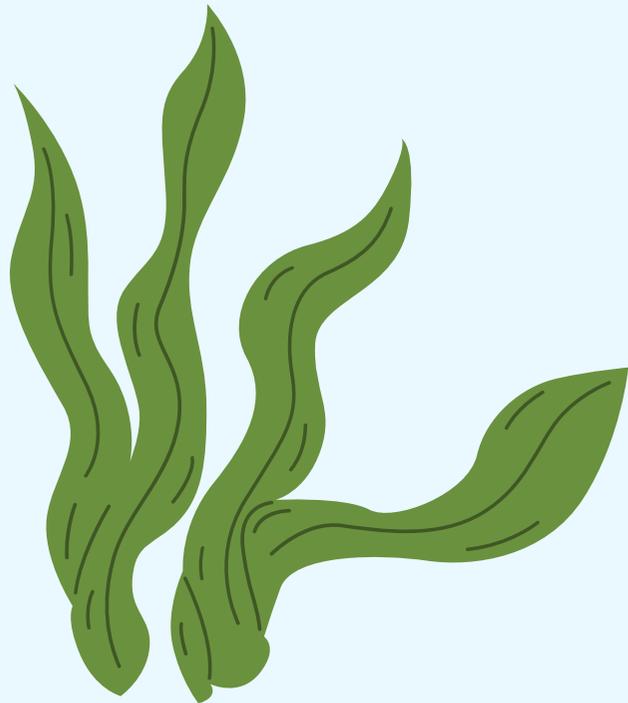
Regulation of Raw Seaweed

Types of Farms:

- *Primary Production Farm*
- *Secondary Activities Farm*



Regulation of Raw Seaweed

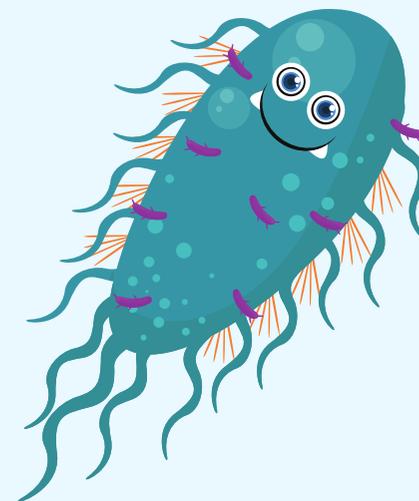


Raw seaweed is a raw agricultural commodity and not covered by FSMA. The FDCA Adulteration Provision prohibits the seaweed from being handled in a way that makes it unsafe to eat.

The FDCA Adulteration Provision

The Federal Food, Drug, and Cosmetic Act (FDCA) prohibits the introduction of adulterated food into interstate commerce.

Food can be adulterated if it is **prepared, packed, or held** under unsanitary conditions. Think of food that has been handled in a way that a bacteria like E. coli or Salmonella grows.



The FDCA Adulteration Provision

The Federal Food, Drug, and Cosmetic Act (FDCA) prohibits the introduction of adulterated food into interstate commerce.



Food containing **poisonous** or **harmful** substances that could make people sick is also adulterated. Food that is **filthy**, **rotting**, or is otherwise **unfit** to be eaten, is another example.

The FDCA Adulteration Provision

The Federal Food, Drug, and Cosmetic Act (FDCA) prohibits the introduction of adulterated food into interstate commerce.

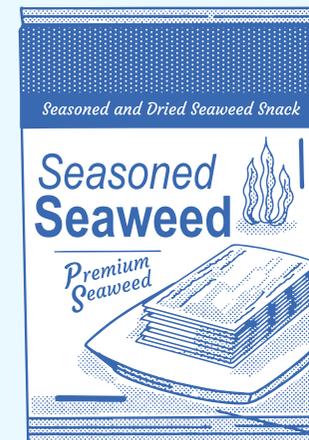
Foods with **naturally occurring poisonous** or **harmful substances** that exceed regulatory limits are prohibited.



The FDCA Adulteration Provision

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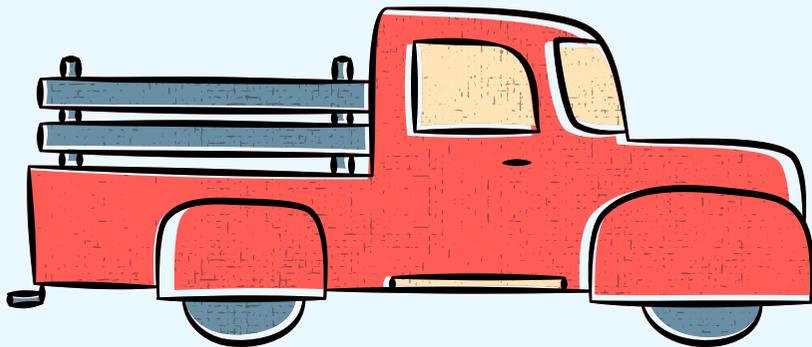
But these limits don't exist for all foods. For example, **baby food** and **bottled water** both have a lead limit, but **whole seaweed** does not.



The FDCA Adulteration Provision

The Federal Food, Drug, and Cosmetic Act (FDCA) prohibits the introduction of adulterated food into interstate commerce.

Food is also adulterated if it is **transported** in a way that does not comply with the FDA regulations for sanitary transportation practices.



The FDCA Adulteration Provision

The Federal Food, Drug, and Cosmetic Act (FDCA) prohibits the introduction of adulterated food into interstate commerce.

Depending on the type of food, producers can prevent adulteration by following:

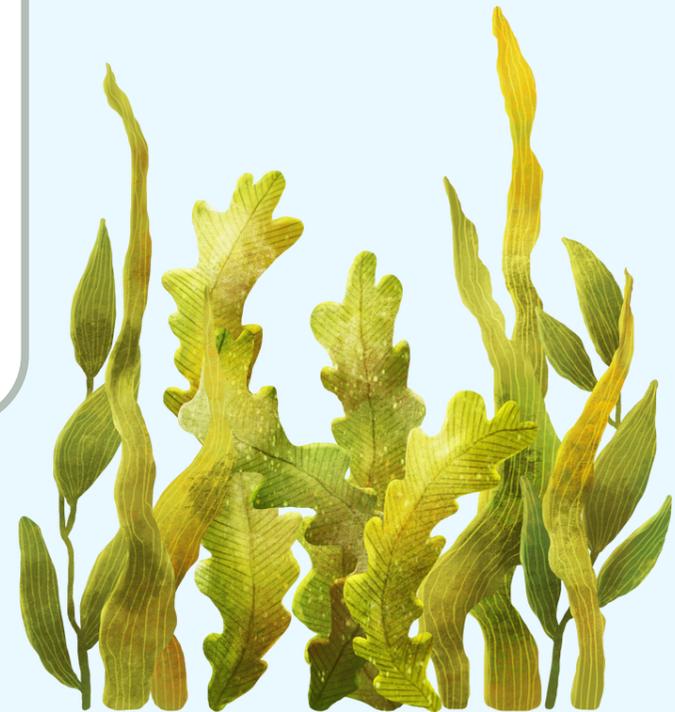
- ✓ **FDA Preventive Controls**
- ✓ **Seafood HACCP**
- ✓ **Produce Safety Rule**
- ✓ **other best handling practices**



Regulation of Dried Seaweed

Under federal law, a farm that dries/dehydrates seaweed does not need to register under the FMSA or the Preventive Controls Rule.

- The adulteration provision still applies.
- States may also add additional requirements.



Regulation of Dried Seaweed

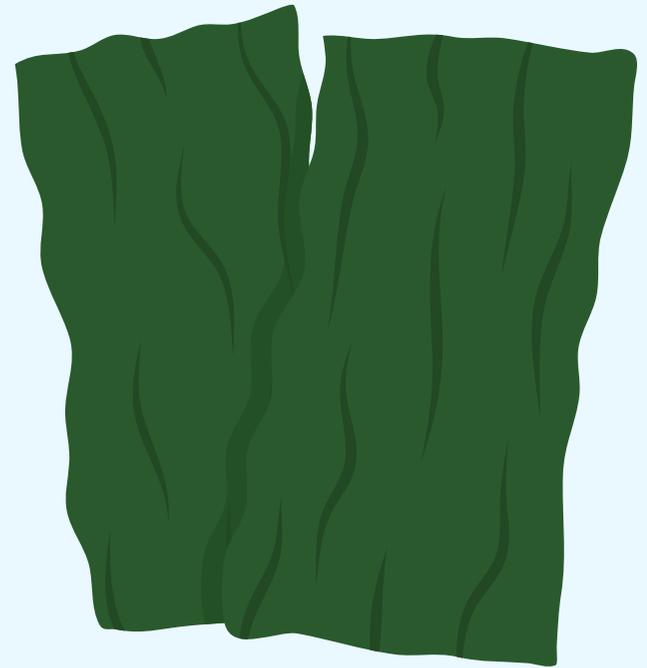
Classification of Drying/Dehydrating RACs:

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

Regulation of Processed Seaweed

All other processed seaweed is regulated under FSMA, including:

- Seaweed that is dried/dehydrated by an entity other than farm that grew it
- Other types of processed seaweed, such as pickled seaweed.



Thank you!

Questions?

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