



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.

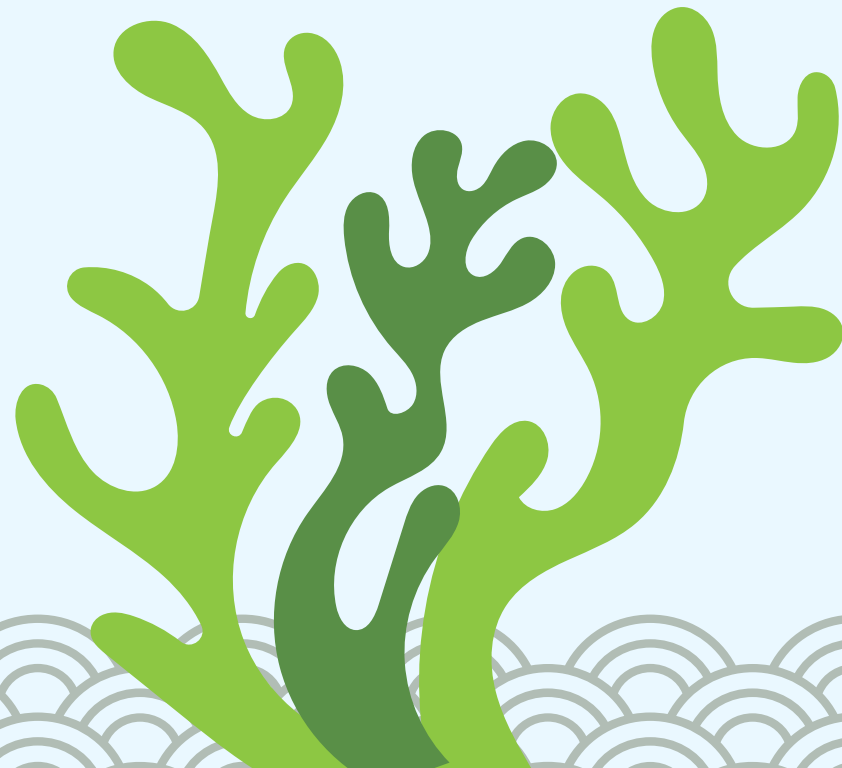


FDA Classification of Seaweed

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.

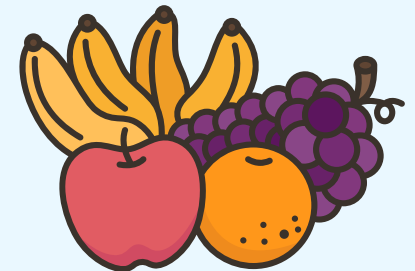
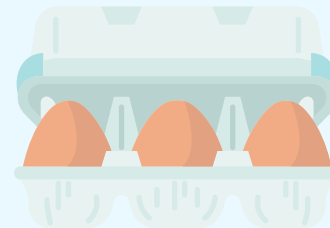
It does not include food that has been processed or manufactured.



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



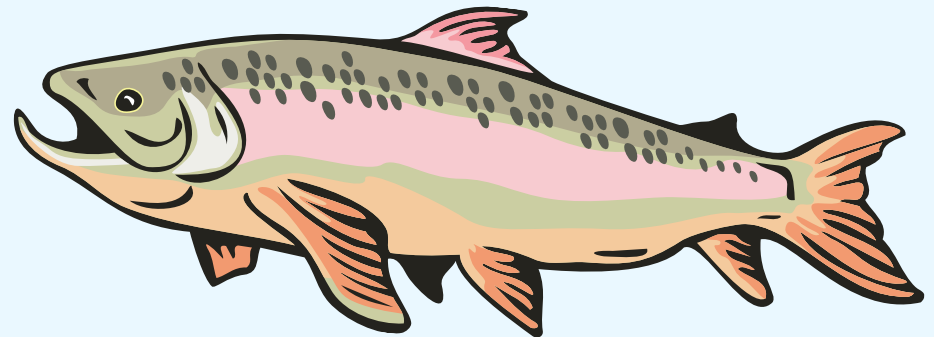
Seaweed is not covered by the **Produce Safety Rule (PSR)**.

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

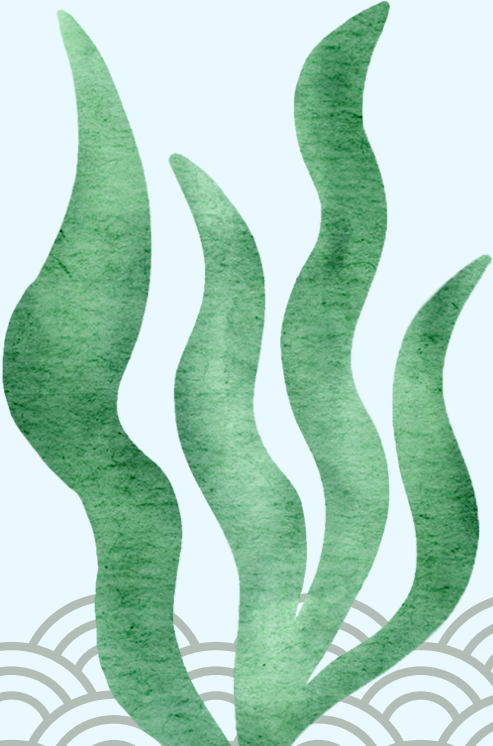
FDA does *not* consider seaweed to be seafood

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



FDA Classification of Seaweed

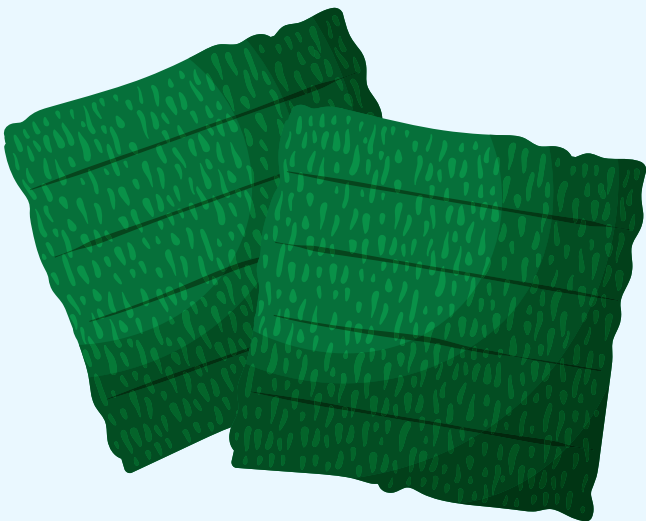
The Food Safety Modernization Act (FSMA) and its related rules *may* apply to seaweed.



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.



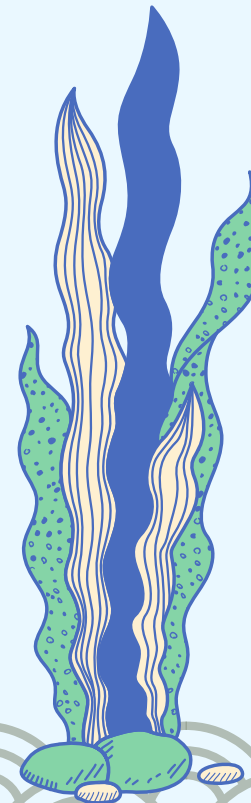
Seaweed operations may be exempt based on the **type of seaweed product produced** or face modified requirements due to the **monetary value of the seaweed products sold**.

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

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

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.

Ex: a business that sells seaweed and shellfish would count all food sales.



Seaweed and the FDA Preventive Controls Rule

2nd Way to be a Qualified Facility

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.



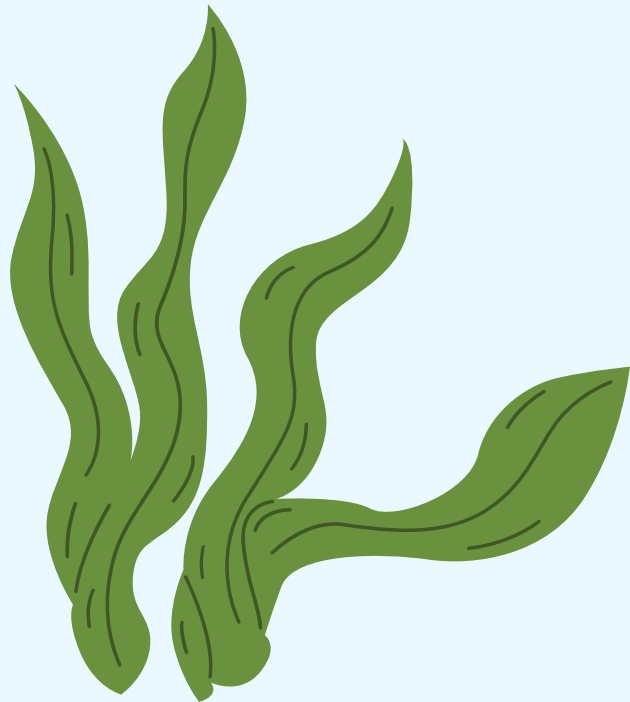
Regulation of Raw Seaweed

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

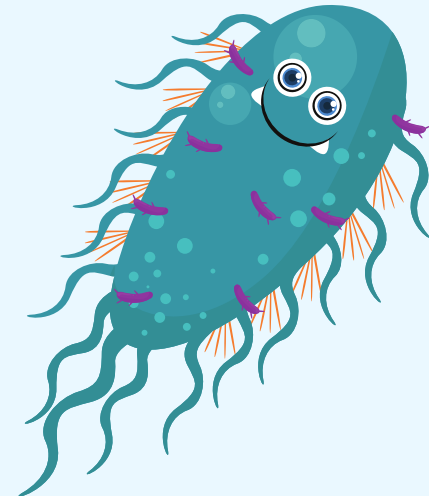


Raw seaweed is a raw agricultural commodity and not covered by FSMA. The FDCA Adulteration Provision prohibits the seaweed from being handled in a way that makes it unsafe to eat.

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

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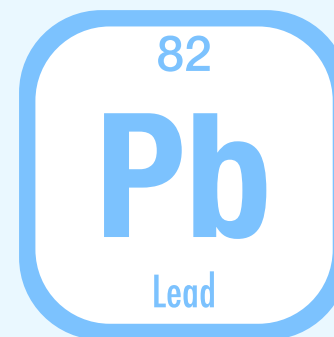


Food containing **poisonous** or **harmful** substances that could make people sick is also adulterated. Food that is **filthy**, **rotting**, or is otherwise **unfit** to be eaten, is another example.

The FDCA Adulteration Provision

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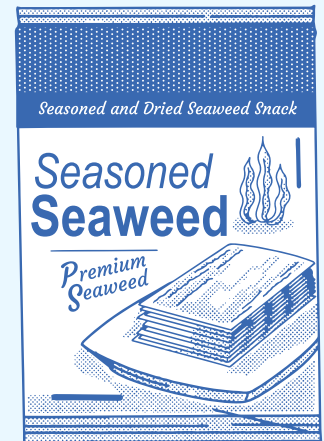
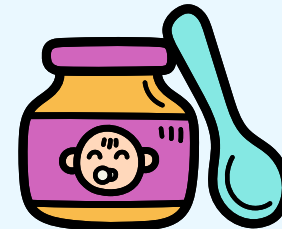
Foods with **naturally occurring poisonous** or **harmful substances** that exceed regulatory limits are prohibited.



The FDCA Adulteration Provision

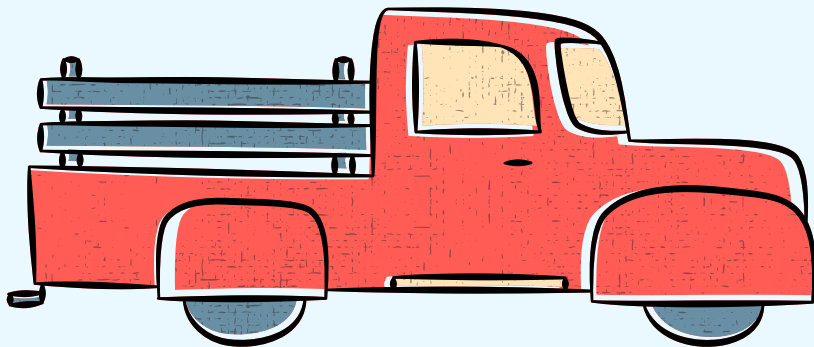
The Federal Food, Drug, and Cosmetic Act (FDCA) prohibits the introduction of adulterated food into interstate commerce.

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:

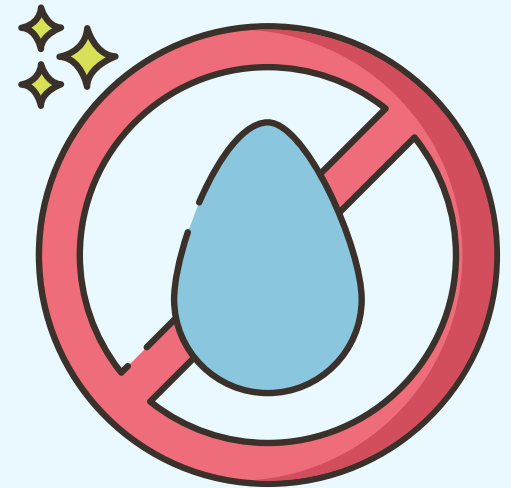
- ✓ **FDA Preventive Controls**
- ✓ **Seafood HACCP**
- ✓ **Produce Safety Rule**
- ✓ **other best handling practices**



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.

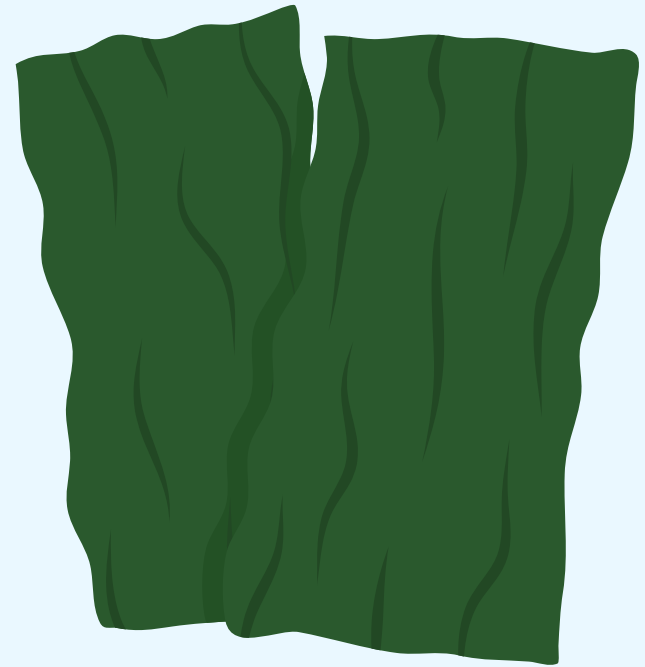
- The adulteration provision still applies.
- States may also add additional requirements.



Regulation of 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.



Acknowledgments

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- Questions? Please contact Catherine Janasie at cjanasie@olemiss.edu