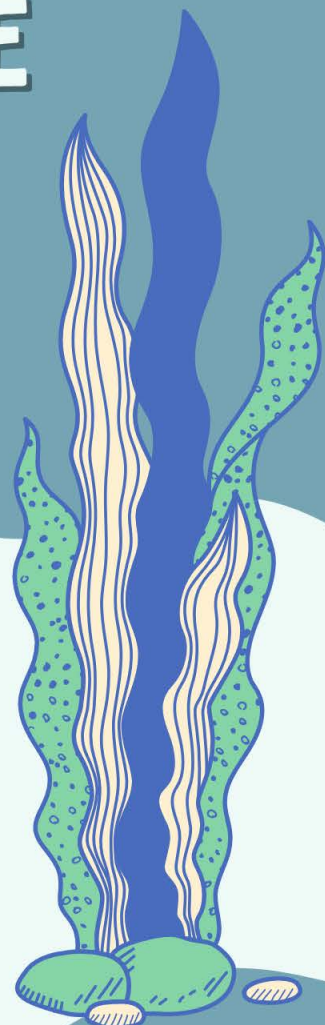


SEAWEED AND THE FDA PREVENTIVE CONTROLS RULE

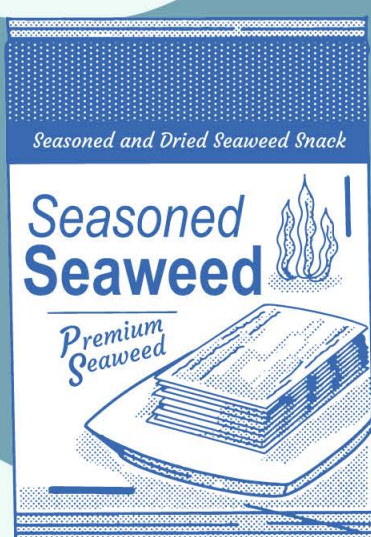


THE PREVENTIVE CONTROLS RULE APPLIES TO FACILITIES

Facilities are any operation that manufactures/processes, packs, or holds food in the US. Facilities must register with the FDA.

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.



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.

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.

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.

