NSGLC/CT Sea Grant Seaweed Food Safety Project

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Seaweed Food Safety: Industry Panel
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Project Overview

- In 2019, the NSGLC & CT Sea Grant received funding from the NOAA National Sea Grant College Program to enhance coordination and cooperation among states to build policy consensus as to the preferred approaches for regulating the sale of seaweed in its whole form for food.
- Project Objectives:
  1) *conducting legal research to identify and assess potential models*;
  2) convening a collaborative learning workshop to engage stakeholders; and
  3) developing a model law, regulation, or guidance document for the sale of seaweed in its whole form as food.

Project Timeline

Planning Committee

- Jeremy Ayers, Division of Environmental Health, Alaska Department of Environmental Conservation
- Steven Bloodgood, FDA Center for Food Safety and Applied Nutrition
- Jason Bolton, University of Maine Cooperative Extension
- Kristin DeRosia-Banick, Connecticut Department of Agriculture
- Michael Graham, Moss Landing Marine Laboratories
- Emanuel Hignutt, Jr., Office of Food Safety, FDA Center for Food Safety and Applied Nutrition
- Randy Lovell, California Department of Fish and Wildlife
- Jennifer Perry, University of Maine
- Caird Rexroad, Agricultural Research Service, USDA
- Mark Tedesco, Long Island Sound Office, U.S. Environmental Protection Agency
- Anoushka Concepcion, Connecticut Sea Grant
- Jaclyn Robidoux, Maine Sea Grant

Completed Research

http://nsglc.olemiss.edu/projects/regulatingseaweed/index.html

Legal Research

- Presentation: *Determining the Best Method of State Regulation of Seaweed as a Food Product*
- Article: *Navigating the Kelp Forest: Current Legal Issues Surrounding Seaweed Wild Harvest and Aquaculture*
- Advisory Request re Regulation of Seaweed as a Food Source
- Inventory of State Laws Affecting Commercial Seaweed Aquaculture

FDA GRAS GENERALLY RECOGNIZED AS SAFE

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Food Safety 101

- Federal Food, Drug, and Cosmetic Act (FDCA) prohibits the introduction into interstate commerce of any food that is “adulterated or misbranded.” (21 U.S.C. 331).

- Basic strategies to protect against adulterated food:
  - HACCP:
    - FDA- Required for: Seafood, Juice
    - FDA- Voluntary for: Dairy Grade A
    - USDA FSIS- Meat and Poultry
  - Food Safety Plan

- “Farms” must comply with general requirements of FDCA.

Table 1-1 Comparison of Elements of a HACCP Plan and a Food Safety Plan

Element	HACCP Plan	Different in Food Safety Plan
Hazard Analysis	Biological, chemical, physical hazards	Chemical hazards include radiological hazards, consideration of economically motivated adulteration (21 CFR 117.130(b)(1)(ii))
Preventive Controls	CCPs for processes	Process CCPs + controls at other points that are not CCPs (21 CFR 117.135(a)(2))
Parameters and values	Critical limits at CCPs	Parameters and minimum/maximum values (equivalent to critical limits for process controls) (21 CFR 117.135(c)(1))
Monitoring	Required for CCPs	Required as appropriate for preventive controls (21 CFR 117.145)
Corrective actions and Corrections	Corrective actions	Corrective actions or corrections as appropriate (21 CFR 117.150(a))
Verification (including validation)	For process controls	Verification as appropriate for all preventive controls; validation for process controls; supplier verification required when supplier controls a hazard (21 CFR 117.155, 117.160)
Records	For process controls	As appropriate for all preventive controls (21 CFR 117.190)
Recall plan	Not required in the plan	Required when a hazard requiring a preventive control is identified (21 CFR 117.139)

Source: FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry

Regulatory Gaps

How to regulate macroalgae? What models to look at for guidance?

Are seaweed farms “farms” for purposes of FDA regulation? Are they “processors”?

Where do seaweed operations fit in?

Federal Food, Drug and Cosmetics Act (FDCA)

- "Farms" are defined as "an operation devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities."
  - Regulatory definition does include some manufacturing/processing activities.
  - "Drying/dehydrating **raw agricultural commodities** to create a distinct commodity ... packaging and labeling such commodities, without additional manufacturing/processing" (such as slicing)

Food Safety Modernization Act (FSMA)

- FSMA is applicable only to ***food facilities*** "engaged in *manufacturing, processing*, packing, or holding food for consumption…"
- *Manufacturing/processing* = making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients.
    - Ex: cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity, freezing labeling, packaging, trimming, washing, or waxing.

FSMA Requirements

- A major requirement for food facilities under FSMA include Hazard Analysis and Risk-Based Preventive Controls
    - Exempt, with modified requirements: Average less than $1M per year in sales of human food plus the market value of human food manufactured, processed, packed or held without sale.
- *How many seaweed facilities fit under this exemption?*

Cultivated sugar kelp. Credit: Stephen Schreck, PSRF

Best model?

- With a lack of existing regulations for macroalgae, where should we look for guidance?
  - Seafood?
  - Plants?
  - Produce?

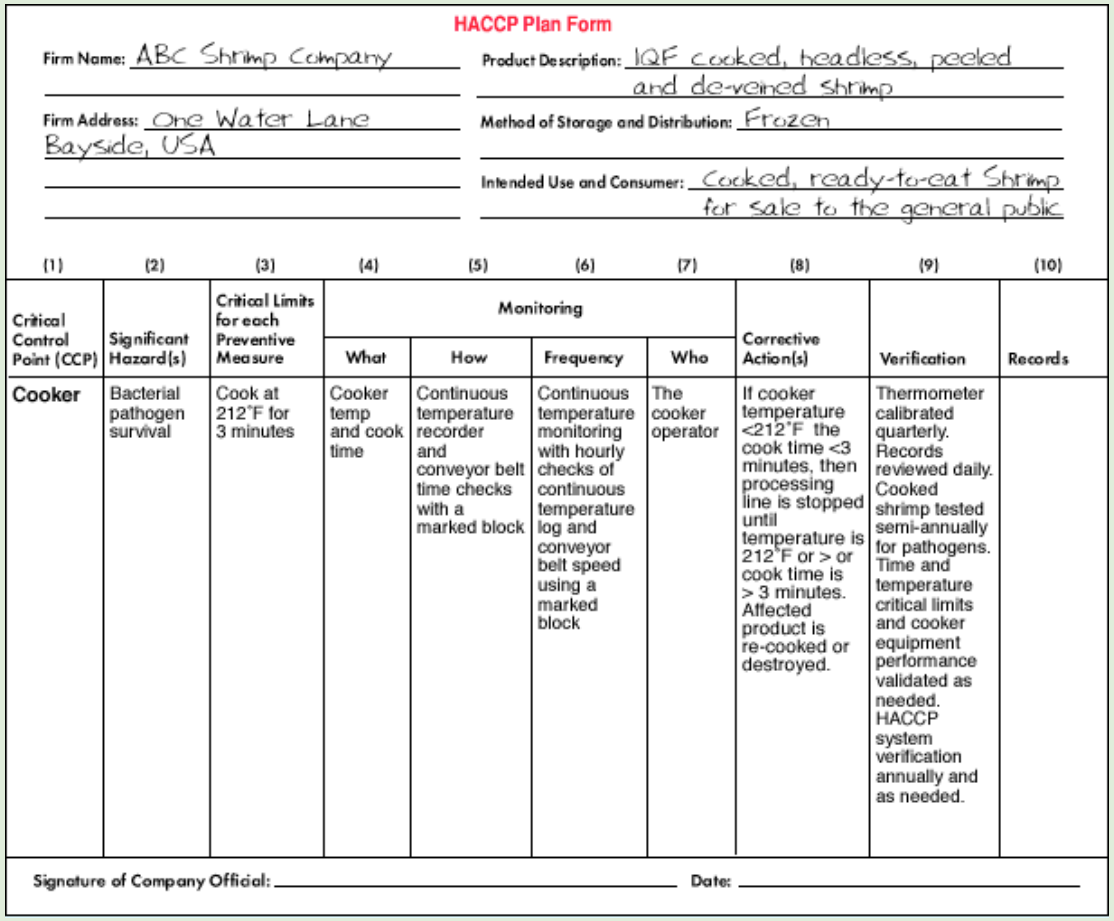
Important Note

Legal Definitions ≠ Scientific Classifications

Tomato = Vegetable (but it's a fruit)

Seafood HACCP Plans

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



HACCP Plan Form

Firm Name: ABC Shrimp Company

Firm Address: One Water Lane, Bayside, USA

Product Description: IQF cooked, headless, peeled and de-veined shrimp

Method of Storage and Distribution: Frozen

Intended Use and Consumer: Cooked, ready-to-eat Shrimp for sale to the general public

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Preventive Measure	Monitoring				Corrective Action(s)	Verification	Records
			What	How	Frequency	Who			
Cooker	Bacterial pathogen survival	Cook at 212°F for 3 minutes	Cooker temp and cook time	Continuous temperature recorder and conveyor belt time checks with a marked block	Continuous temperature monitoring with hourly checks of continuous temperature log and conveyor belt speed using a marked block	The cooker operator	If cooker temperature <212°F the cook time <3 minutes, then processing line is stopped until temperature is 212°F or > or cook time is > 3 minutes. Affected product is re-cooked or destroyed.	Thermometer calibrated quarterly. Records reviewed daily. Cooked shrimp tested semi-annually for pathogens. Time and temperature critical limits and cooker equipment performance validated as needed. HACCP system verification annually and as needed.	

Signature of Company Official: _____ Date: _____

FSMA Produce Safety Rule

- Standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.
- Goal: reduce the presence of potentially dangerous bacteria in the food supply
- Produce = “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.”
  - ***BUT*** USDA may address algae in future: “[a]s appropriate, we may consider issuing guidance on the topic of algae production for human food use in the future.”

Best model?

Best regulator?

Input from our industry survey can help inform our analysis.

Thank you!
Questions?

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