



Seaweed Food Safety: Federal Considerations

Informational Webinar sponsored by the National Sea Grant Law Center
August 27, 2020

Developing Policy Consensus to Facilitate State Regulation of Seaweed as a Food Product

- ▶ 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.
 1. Conduct legal research to identify and assess potential models;
 2. Convene a collaborative learning workshop; and
 3. Develop a model law, regulation, or guidance document for the sale of seaweed in its whole form as food.
- ▶ Collaborative workshop to be held virtually January 2021, TBD. Invitation only for state program managers and federal regulatory agencies.



AGENDA

- Purpose & Agenda
- Basic Skills in MURAL
- Guidance for US Domestic Seaweed: Why Is It Needed?
- Q&A
- FSMA Preventive Controls for Human Foods
- Q&A
- 3:00 - BREAK
- USDA Regulation of Seaweed
- Q&A
- Breakout Instructions
- Breakout Discussions
- Review
- Wrap-up

Guidance for U.S. Domestic Seaweed: Why is it Needed?



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8/27/2020

With a new farmed crop come questions...from Regulators

- How do we protect public health - how do we know it's safe for human consumption and can therefore enter the market?
- What are potential hazards associated with fresh seaweed and other seaweed products?
- What are appropriate controls for these hazards?
- How should fresh seaweed be sold?
- What do industry need to know about safe handling and processing of seaweed?



N. Balcom, CT Sea Grant

from Industry



- How do I harvest /handle fresh seaweed?
- Can I dry kelp in a greenhouse?
- How long is its shelf life?
- Do I need to refrigerate it? At what temp and for how long?
- Can I sell it at a farmer's market?
- Can I sell it by the pound? By the single blade? Bagged and sealed?
- Can I freeze it? For how long?
- How should I prepare it for freezing to maintain quality and shelf life?
- Can I / how do I turn it into a value-added product?
- Are there hazards I should be concerned about? What control measures do I use?
- Who regulates seaweed as a food product?
- Will I have to undergo inspection? If so, by whom?

from Consumers

- Is this safe to eat? How do I know?
- Is anyone regulating these new products?
- How should I store my new purchase of fresh kelp?
- How long should it/does it last?



from Trainers

- How incorporate seaweed into standard seafood HACCP training? *(CT state agencies went with what existed / they knew, requiring seafood HACCP training and seaweed HACCP plans (FDA Seafood HACCP Reg 21 CFR Part 123))*
- How do we address the training disconnect of teaching principles with no identified potential hazards or controls developed for seaweed to reference? How can we help industry fill information gaps so they can develop and implement appropriate HACCP plans?
- If, as now surmised, seaweed falls under Preventive Controls:
 - What do PC trainers need to know about seaweed? Who will teach them?
 - Should they recommend industry follow PC guidance for lettuce?
 - What information do they need to provide trainees on risks and controls and where will it come from?
- When will more research be available on potential hazards and preventive control measures for fresh seaweed products and value-added products?
- How can we better assist this new industry beyond *“this is the best information we can offer at this time and unfortunately you need to figure out the rest”*?

My View

- Development of regulatory safe handling and processing guidance will:
 - **assist regulators** by establishing consistent expectations and consistent enforcement, replacing current patchwork
 - **assist industry** by removing uncertainty; help them avoid product loss and potential recalls; help them regularize production and marketing of domestic seaweed products
 - **assist trainers** by providing pertinent information they need on potential hazards, control measures and regulations
 - **assure consumers** that public health is being protected so they support new domestic industry with their \$\$\$\$
 - remove “guesswork”
- One major food safety incident could severely harm the prospects of a domestic national industry that holds a lot of promise



A. Concepcion, CT Sea Grant

FSMA Preventive Controls for Human Foods (PCHF)

With Emphasis on Seaweed

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Seaweeds Definitions

- Large, multicellular marine algae
- Not classified as “plants”
- Not defined as “produce”
- **Seaweed is a Raw Agricultural Commodity**



Uses of Seaweeds

- **Food**
- Feed
- Fertilizer
- Medicine
- Phycocolloids
 - Alginates
 - Carrageenans
 - Agars
- Cosmetics
- Textile
- Paper
- Leather
- Biofuels



Farm Definition – 21 CFR 1.2227

- “...an operation devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities.”
- Farms are not required to register with FDA
 - Exempt from 21 CFR Part 117
- Must comply with general requirements of Federal Food, Drug and Cosmetics Act



CGMP & PCHF Rule - 21 CFR Part 117

- Modernizes longstanding current good manufacturing practice (CGMP) requirements
- Establishes new FSMA requirements for hazard analysis and risk-based preventive controls (HA/PC requirements)

HA/PC Requirements

- Apply to facilities that have to register with FDA.
 - Facility is engaged in the manufacturing/processing, packing, or holding of food for consumption in the United States
 - Farms do not have to register
- The farm definition was updated when the final CGMP & PC rule was published.
 - Some manufacturing/processing activities are within the farm definition

Manufacturing/Processing

- *Manufacturing/processing* means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients.
- Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), 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.



Food Safety Plan

- Hazard analysis
- Preventive controls
- Procedures for monitoring the preventive controls
- Corrective action procedures
- Verification procedures
- Supply-chain program
- Recall plan

Food Safety Plan – Hazard Analysis



- Hazard identification must consider known or reasonably foreseeable biological, chemical and physical hazards.
 - These could occur naturally, be unintentionally introduced, or be intentionally introduced for economic gain.
- Hazard evaluation must consider severity of illness/injury and probability of occurrence in absence of preventive controls

Food Safety Plan – Preventive Controls

- Measures required to ensure that hazards are significantly minimized or prevented. These include:
 - Process controls
 - Food allergen controls
 - Sanitation controls
 - Supply-chain controls
 - Recall plan



Food Safety Plan – Preventive Controls

- Include controls at critical control points (CCPs), if any, and controls other than those at CCPs that are appropriate for food safety
- Flexibility for how preventive controls are managed

Preventive Control Management Components



- Monitoring
- Corrective Actions
- Verification



Food Safety Plan - Verification

- Includes (as appropriate to the facility, food and nature of the preventive control):
 - Validation of preventive controls
 - Verification of monitoring and corrective actions
 - Calibration of process monitoring and verification instruments
 - Product testing, environmental monitoring
 - Records review

Supply-Chain Program

- A receiving facility must establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which a hazard has been controlled before receipt.
 - For example, a fresh-cut produce processor that does not have a control for microbial pathogens (e.g., kill step) for the product being manufactured would conduct supplier verification activities (i.e., onsite audit of the farm it purchased from) to verify compliance with the produce safety standards.



PC Qualified Individual

- A qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Exemptions

- Foods subject to Hazard Analysis & Critical Control Points (HACCP) regulations (i.e., seafood and juice)
- Dietary supplements
- Alcoholic beverages
- Food subject to low-acid canned food regulations (microbiological hazards only)



Qualified Facilities

- Very small businesses are qualified facilities exempt from the requirements for hazard analysis and risk-based preventive controls (but have some 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



Questions?

[FSMA Technical Assistance Network \(TAN\) | FDA](#)



U.S. FOOD & DRUG
ADMINISTRATION

USDA Regulation of Seaweed

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USDA APHIS and Aquatic Plants

- Animal and Plant Health Inspection Service (APHIS) regulates aquatic plants under the Plant Protection Act.
- APHIS regulates nonvascular plants, including green algae. Requires:
 - Phytosanitary certificate from exporting country; and
 - Import permit (PPQ Form 587 application) for shipments of 13 or more articles.
- Aquatic plants subject to inspection at port of entry.
- Must be free of quarantine pests.



Prohibited Algae

- APHIS only prohibits one alga - the Mediterranean strain of *Caulerpa taxifolia*.
 - Aka “killer algae”
- Listed as a Federal Noxious Weed.
- PPQ Form 526 permit needs to be submitted for importation or interstate movement.



USDA Organic Program

- Administered by the Agricultural Marketing Service (AMS).
- Federal regulatory program that develops and enforces uniform national standards for organically-produced agricultural products sold in the U.S.
- National Organic Program (NOP) – public/private partnership that accredits third-party organizations to certify that farms and businesses meet the national organic standards.



USDA Organic and Macroalgae

- USDA regulates the classification of farmed kelp and other algae as organic, but:
 - Not when for sale in whole form; and
 - Only as an ingredient in livestock feed, fertilizer, or food for human consumption.



NOP 5027- The Use of Kelp in Organic Livestock Feed

- Provides for the use of kelp in organic livestock feed, but the kelp must be certified organic.
- Only existing route to certification is through the USDA's wild harvest provisions.
- Kelp must be harvested in:
 - Designated areas; and
 - A manner not destructive to the environment.



Thank You! Questions?

NSGLC Seaweed Website:

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

Contact Me:

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Small Group Discussions

Purpose: Gather the knowledge in the room

Discuss

1. What are the gaps in federal regulations you learned about today?
2. How can states fill in what's missing from the federal framework?

Developing Policy Consensus to Facilitate State Regulation of Seaweed as a Food Product

- ▶ Building essential knowledge and learning from stakeholders to inform model regulations
- ▶ Schedule:
 - August 27, 2 PM CST: Federal Considerations - **THANK YOU!**
 - September 23, 2 PM CST: State Efforts
 - October 22, 2 PM CST: Industry Barriers and Challenges

