

## Food Safety Modernization Act (FSMA) Preventative Controls for Human Foods

The [Food Safety and Modernization Act \(FSMA\) Preventative Controls for Human Foods \(PCHF\) Rule](#) was implemented in 2016 by the Food and Drug Administration (FDA). The PCHF rule outlines what processors must do to develop effective food safety programs that ensure safe and wholesome food production. Facilities covered under the PCHF rule must establish and implement a food safety system. The food safety system includes a variety of prerequisite programs and a written food safety plan.

The written food safety plan MUST include a hazard analysis; preventive controls (when significant hazards are identified); oversight and management of preventive control(s); and a recall plan (when significant hazards are identified).

Seaweed is considered a [Raw Agricultural Commodity](#) and is subject to the PCHF rule when processed, unless exempt (Exemption details provided in NYSG Seaweed Regulatory Guide). This guide outlines the requirements of the PCHF rule, if not exempt.

### Hazard Analysis

The hazard analysis is essentially the risk assessment/evaluation that facilitates the identification of potential biological, chemical, and physical hazards, and determines if controls are required to prevent those hazards from occurring in products. Detailed instructions and resources on how to conduct a hazard analysis can be found in Chapter Two of [FDA's Draft Guidance for industry](#).

### Preventative Controls

When potentially significant hazards are identified through the hazard analysis, facilities MUST develop and implement written preventive controls for those hazards to significantly minimize or prevent them from occurring. There are four categories of preventative controls that may be warranted depending on the facility.

**Process controls** are controls specific to a facility's (or operation's) procedures, practices, and processes as a product enters and moves through the facility (i.e., cooking, refrigeration, cutting, drying etc.).

» Process controls should specify the parameters (i.e., minimum or maximum values) necessary to control each hazard identified and be listed in the food safety plan.

**Food allergen controls** represent the specific procedures, practices, and processes in place to prevent allergen cross-contact within a facility and to ensure all food allergens are correctly labeled.

**Sanitation Controls** are the procedures, practices, and processes in place to make sure the facility is maintained in a sanitary manner. Effective sanitation controls will reduce or eliminate the chances of foods being contaminated with environmental pathogens or through cross-contact with food allergens.

» Facilities producing ready-to-eat foods (i.e., seaweed salad) MUST implement environmental monitoring procedures if preventative controls are necessary to prevent contamination with an environmental pathogen (i.e. *Listeria monocytogenes*). These environmental monitoring procedures will be a critical component of a food safety plan's verification procedures.

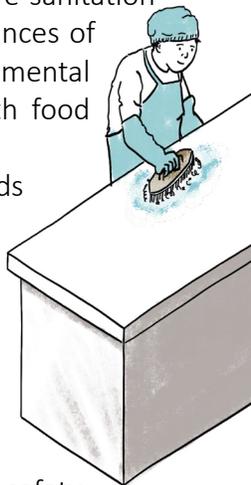


Illustration by  
G. Pederson

**Supply Chain Controls** are the procedures, practices, and processes in place to make sure that the products sourced are safe. These controls are part of the Risk-Based Supply Chain Program reviewed on the next page.

**Other Controls** that do not fit within the process, food allergen, supply chain, or sanitation controls categories may be necessary to ensure the safety of the food(s) being produced. Based on scientific evidence, historical data, and personal knowledge, producers should identify any additional hazards that might affect the safety of their product(s) and should implement controls to minimize or prevent them.

## Oversight and Management

A facilities food safety plan MUST outline how each preventative control implemented will be monitored; the actions that will be taken if the required parameters are not met (corrective actions); the verification steps necessary to ensure that the controls in place are effectively controlling the hazard (i.e., validation); and the records that will be kept documenting that this control is regularly implemented and effective.

**Monitoring procedures** should be designed and regularly documented to ensure that the preventive controls in place are routinely implemented, as appropriate to prevent hazards. For example, monitoring of a drying process to ensure the product reaches a water activity below 0.85 would require strict adherence to and monitoring of the time-temperature requirements outlined in a scheduled process.

**Corrections** should be made throughout processing to address any minor or isolated issues that occur during production that do not directly impact product safety but could if not corrected in a timely manner. These minor corrections, commonly related to sanitation, do not need to be documented or written into a food safety plan.

**Corrective actions** must be taken to address any issues that occur during production that could cause food safety hazards to be present. Corrective actions must be documented in records and should prevent future occurrences, evaluate the safety of the affected products, and prevent unsafe foods from entering commerce.

**Verification activities** must be implemented to ensure that preventative controls are effectively minimizing potential food safety hazards. Verification activities must be documented in records and typically include process controls that are scientifically validated to control the identified hazards; calibration and accuracy checks of equipment used during processing; and regular review of monitoring and corrective action records as applicable. Some or more than those listed here could be necessary but will depend on the facilities specific process and products.

**Records** must be maintained for all monitoring, corrective action, and verification activities.

## Risk-Based Supply Chain Program

A Risk-Based Supply Chain Program must be in place when processors identify a hazard(s) related to ingredients received from a supplier and they rely on the supplier to control that hazard. The supply chain program must include verification activities and be implemented to ensure the ingredients sourced are safe.

## Recall Plan

A Recall Plan is required whenever a hazard that requires a preventive control is identified. The recall plan must be written and describe all the steps necessary to effectively recall unsafe products from the market. At minimum, the plan must identify who will be responsible for:

- » Notifying the buyers of the food being recalled, including how to return or dispose of the affected food;
- » Notifying the public about the potential food hazards;
- » Conducting effectiveness checks; and
- » Appropriately disposing of the recalled product.

## Additional Resources

An effective food safety system relies, not only on the implementation of a PCHF compliant Food Safety Plan but also a foundation of Good Manufacturing Practices (GMP's) and properly trained personnel. Additional resources that may be helpful are linked below:

- » [FSMA Rules & Guidance for Industry](#)
- » [Training & Materials on Preventive Controls for Human Food \(FSPCA\)](#)
- » [FDA Food Safety Plan Builder](#)
- » [FDA's Key Facts about Preventative Controls for Human Food](#)
- » [The Technical Assistance Network \(TAN\)](#)

NOTE: This resource was adapted from FDA's Key Facts about Preventative Controls for Human Foods document and the other resources linked above.