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PREVENTIVE CONTROLS FOR HUMAN FOOD: AN OVERVIEW

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Preventive Controls for Human Food: An Overview

Summary

The safety of the food that we process and serve to the public is very important. Keeping our food safe in the production, packaging, and distribution and until it reaches the consumer is critical. The Food Safety Modernization Act (FSMA) Preventive Controls for Human Food (PCHF) rule focuses on the preventive approach in enhancing the safety of our food system. The rule provides the food processors numerous tools and options to implement controls that can help ensure the safety of the food in acquiring the raw ingredients, processing the raw ingredients, and packaging and distributing them to the consumer or to secondary and tertiary processors. The four major preventive controls that the processers can utilize include: process, allergen, sanitation, and supply chain preventive controls. Each of these preventive controls provide ways to ensure that the various hazards including; biological, physical, chemical and radiological hazards are controlled or minimized effectively. The various tools will assist us in maintaining the safety of the food as it changes hands across the supply chain.

Introduction

This publication provides a basic overview of the FSMA PCHF rule with an emphasis of the development of the food safety plan that is the major requirement of this rule. The FSMA – Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food rule (21 CFR Part 117) consists of 7 major subparts (FSMA n.d.). These include, Subpart A – General Provisions; Subpart B – Current Good Manufacturing Practice; Subpart C – Hazard Analysis and Risk-based Preventive Controls; Subpart D – Modified Requirements; Subpart E – Withdrawal of a Qualified Facility Exemption; Subpart F – Requirements Applying to Records That Must be Established and Maintained; and Subpart G – Supply-chain Program.

The FSMA PCHF Rule was implemented by the Food and Drug Administration (FDA) in September of 2016, with different compliance dates for processors of different sizes (FSMA n.d.). The PCHF rule is a significant rule in that it provides processors with various tools to enhance their food safety systems. Under this rule, the covered facilities **must establish and implement a food safety system** that includes an analysis of hazards and risk-based preventive controls (FDA n.d.). The rule sets requirements for a written food safety plan that includes: hazard analysis; preventive controls (if at least one hazard is identified requiring a preventive control); oversight and management of preventive control(s); and a recall plan (if at least one hazard is identified requiring a preventive control) (FDA n.d.). These are the essential requirements of the rule. The other items of the food safety plan such as company overview; food safety team, product, and process description; and a flow chart showing the flow the processing in the production facility are also recommended to be included in the food safety plan (FSPCA n.d.).

Food passes through many different hands as it travels from the farm to the consumer. Food encounters various food safety hazards as it moves along the supply chain. Food safety hazards can be broadly classified into, **biological** hazards which include the various harmful microorganisms, **chemical** hazards which include chemicals that are naturally occurring, chemicals that are added into the formulation, and the chemicals that are used for cleaning and sanitation, **physical** hazards which can include metal, plastic, or glass pieces, and **radiological** hazards which can include radioactive materials that can adversely affect human health.

The PCHF rule focuses on the risk-based prevention of food safety hazards. To help understand this concept, let's look at the conceptual processing facility in Figure 1. As a **first step** in the process of developing the food safety plan, **emphasis should be given to a thorough analysis of the hazards** associated with the raw and processed ingredients coming into the facility; people entering into the facility (including the regular employees as well as all the visitors) and the environment in and around the processing facility. The food safety hazards are often unique to each facility.

Within the production facility, it is very important to have prerequisite programs in place that help mitigate the spread of the hazards. The current Good Manufacturing Practices (cGMPs) as described in the rule Part 117 Subpart B are the practices that all the food processing facilities have to comply with. These are the basic practices that help reduce the contamination of the food through the handling of raw materials and processed foods.

As the food is processed and converted into the finished product, it is typically subjected to an appropriate unit operation(s) that may help eliminate or minimize the hazards identified through the hazard analysis. In the example provided (Figure 1), the product is subjected to a cooking process which helps eliminate the identified biological hazard. Thus in this

example, the processor is applying a **process preventive control** to the product. Immediately after the process preventive control is applied to help eliminate or minimize the hazard(s) the product is moved on to the packaging process. Typically, there is a time gap before the food product is packaged. During this time gap, the product is exposed to the environment and has the potential to be contaminated again through various avenues, such as employee handling, coming in contact with the un-treated products or ingredients, or through the environment. A significant emphasis is given in the PCHF rule to help reduce any cross-contact for the processed product before it is packaged. Various practices, including **sanitation preventive controls** can be used to prevent cross-contact. If the product being processed is a ready-to-eat (RTE) product, then the regulation recommends that the processor has environmental monitoring programs in place to help avoid re-contamination of the processed products.

Further, the processor has to ensure that the right package is used to pack the product. The packaging should have all the appropriate information about the product, so that the consumer has clear information about what is in the package. It is specifically critical to include information about all the allergens present in the product. This is one of the **allergen preventive controls**. The other information that can be on the packaging pertaining to the food safety should include, storage conditions for the product and appropriate use instructions.

It is important that the processor follow all the labeling guidelines provided by the FDA. In cases where the processor has identified a hazard that requires a preventive control, but they do not apply the control, the processor has to have a supply chain control program in place. In the supply chain preventive control program, the processor has to inform their customer (who can be a secondary processor) about the hazard and that it still needs to be eliminated or minimized as well as get a written assurance that their customer acknowledges this information and will address the hazard in their processing facility.

Preventive Controls

Preventive controls are the measures required to ensure that hazards requiring a preventive control will be minimized or prevented. They include process, allergen, and sanitation controls, as well as supply-chain controls and a recall plan (FSMA n.d.; FDA n.d.).

The **process preventive controls** are the only ones which require the processors to validate the controls. This validation has to be based on sound scientific principles. While all other preventive controls do not require validation, the processors can validate them as well, if they want to. The **allergen preventive controls** allow the processors to ensure that the

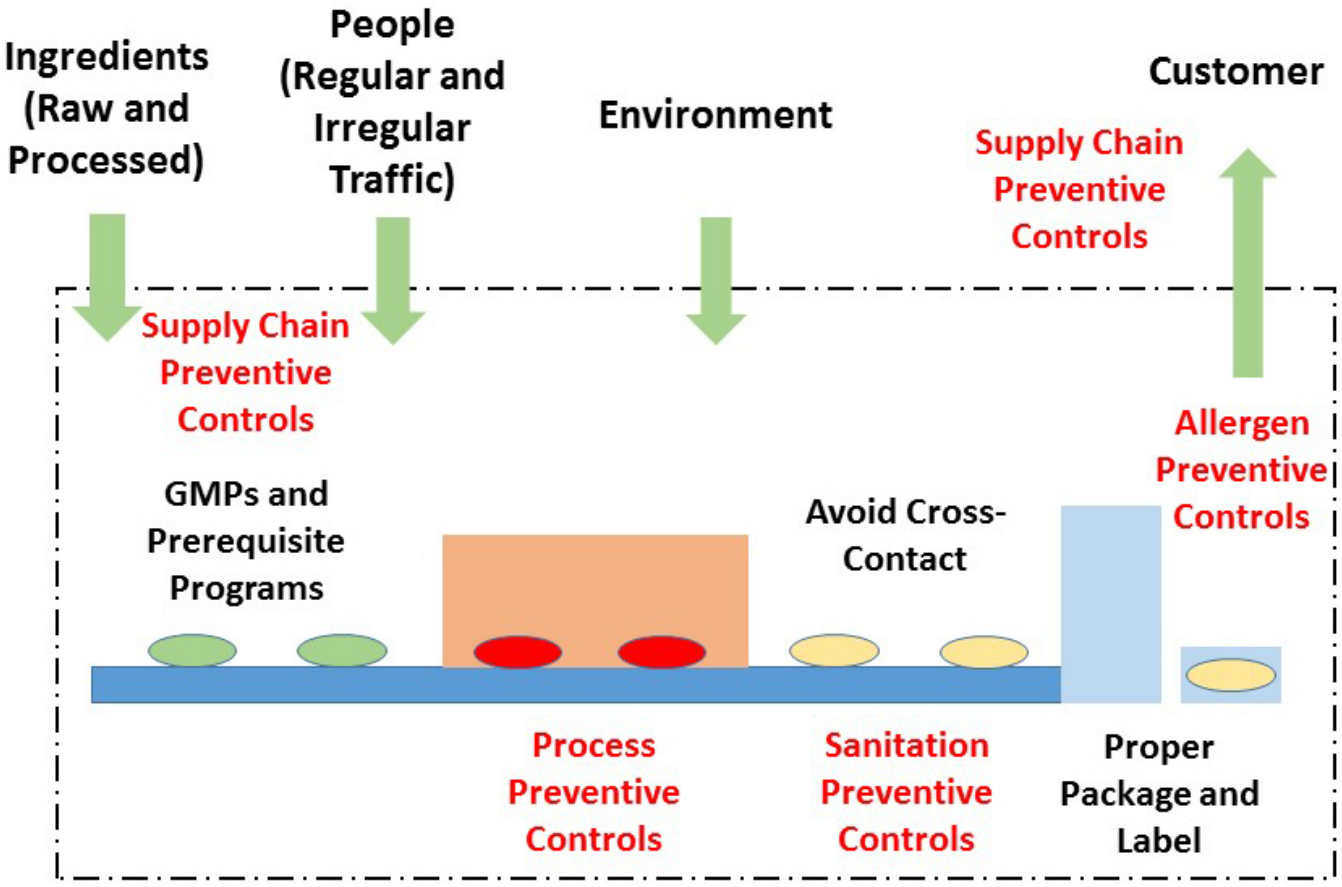

Figure 1. Overview of a food production facility with different preventive controls.

foods leaving their facility have all the important information about the allergens present in the product, so that the consumer knows what they are consuming. This should help reduce a very significant number of recalls associated with allergens. The **sanitation preventive controls** provide a great opportunity for the processors to help avoid any cross-contact after the product has been given the appropriate process to eliminate the hazards of concern. This preventive control helps with the overall food safety system by maintaining sanitary and clean conditions in the whole production facility. Finally, the **supply chain preventive controls** come in handy to ensure that the identified hazard is eliminated or minimized either in the upstream facility or the downstream facility, if that particular hazard is not addressed in the processors facility. This will assist in more open communication between the suppliers, receiving facilities, and the customers.

In the FSMA-PCHF, there is a significant emphasis on the preventive controls. By having different types of preventive controls, the processors can implement them in various stages of their production process. By taking this holistic approach of minimizing and eliminating hazards across the whole supply chain of the food, we can ensure that the food is safe for the consumer. Figure 2 shows a depiction of how the preventive controls can play a role in the overall food safety plan of the facility.

Developing a Food Safety Plan

Having a written food safety plan that is specific to the production facility is a major requirement of the PCHF rule. As mentioned above, there are certain components of the food safety plan that are essential, including written hazard analysis; preventive control(s) if any hazard is identified which needs to be controlled or eliminated; procedures for monitoring, corrective actions and verifications; and a recall plan (FSMA n.d.; FDA n.d.; FSPCA n.d.). If no hazards are identified, the plan should still contain a written hazard analysis. The other components of the food safety plan, such as the description of the food safety team, product and process descriptions, and flow charts can help in proper assessment of the hazards and the implementation of the overall food safety plan.

Figure 3 provides one of the potential ways to go about developing the food safety plan. The figure provides a flow chart with the sequential steps for developing the food safety plan. As previously mentioned, the first five steps shown are not essential components, but we recommend these as they help the rest of the process. The hazard analysis step is a critical part of the food safety plan, as the rest of the steps depend on this.

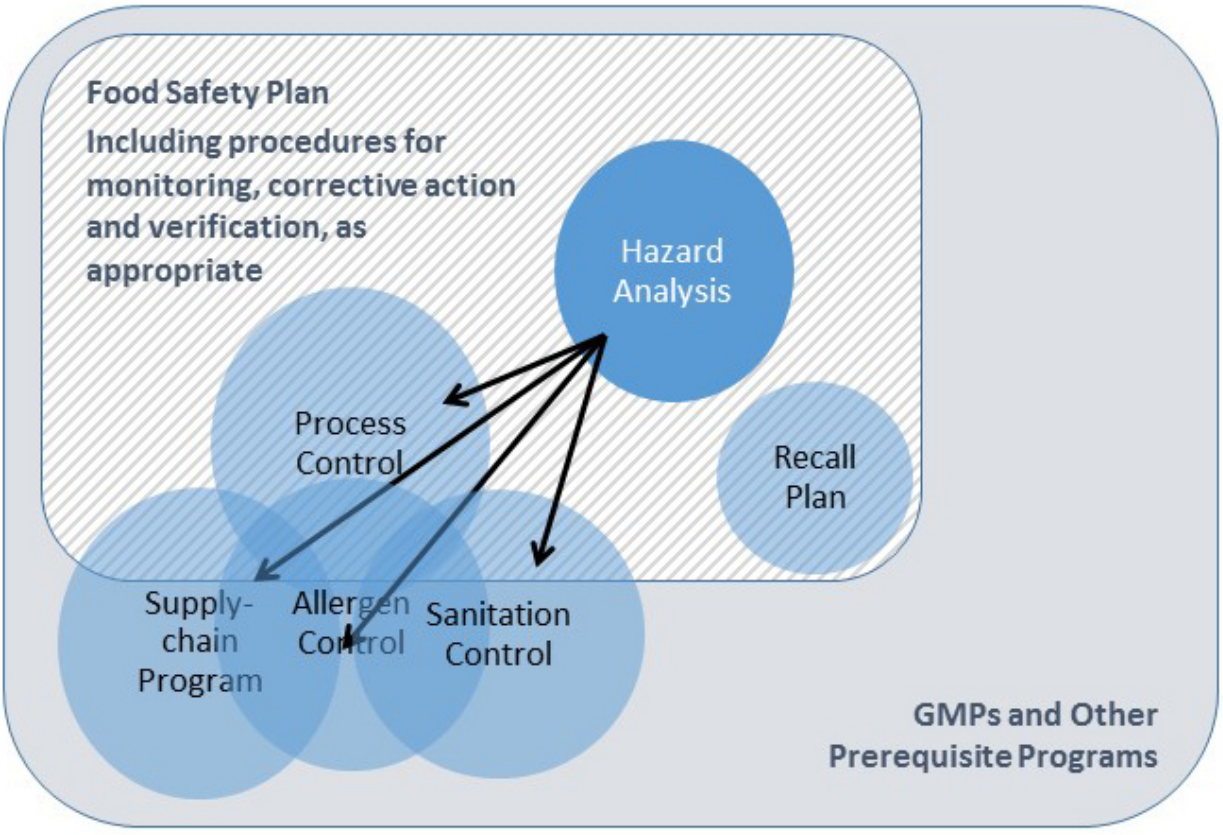

Figure 2. Preventive controls as a part of the food safety plan (FSPCA n.d.).

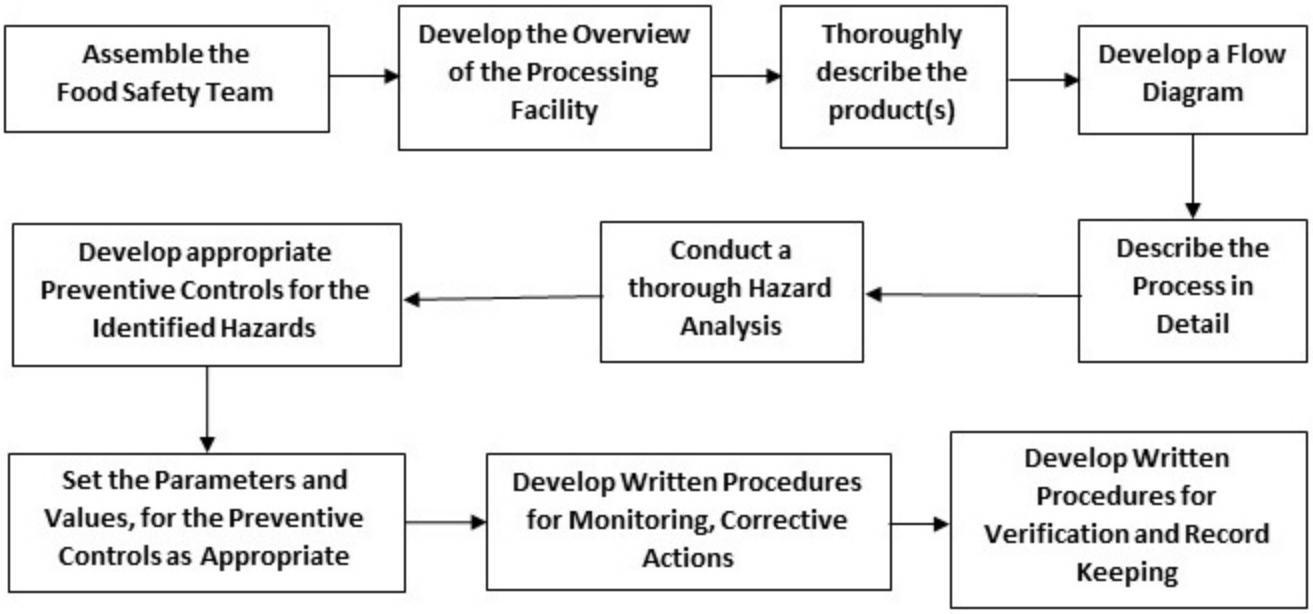

Figure 3. Process flow of developing a food safety plan.

Along with these, it is important to develop a **recall plan**. This enables the processors to be ready with an action plan if any of their products have to be recalled due to their production deviations or errors, or their supplier's production deviations or errors.

Finally, it is required by this rule that the processors conduct a re-analysis of their food safety plan at least once every three years. However, the re-analysis may be triggered before the three years' time due to corrective actions or changes in the suppliers, product, ingredients, or equipment. It is important to understand that the content and implementation of the food safety plan is a dynamic process over time.

Conclusion

The FSMA-PCHF rule is a major update to the food safety system by the FDA. The rule is described in Part 117 of the Title 21 of the CFR. This rule was designed to assist food processors in elevating the food safety system across the whole supply chain. It is a risk-based food safety system. The various preventive controls (process, sanitation, allergens, and supply chain) are designed to address the various hazards that are commonly encountered in the food processing operations. A food safety plan enables communication between suppliers, receivers, and customers throughout the supply chain. This holistic approach to food safety will enable producers to strengthen the safety of the food supply.

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