Safefood 360°

Safefood 360° provides food safety management software for industry leading food processing plants

WHITEPAPER

Developing a Food Safety Plan Under FSMA

CONTENTS

QUICK SUMMARY

This whitepaper will cover the suggested methodology to be employed when developing a PCP plan. This includes how to develop your plan in accordance with FSMA's Final Rule for Preventive Controls for Human Food.

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INTRODUCTION

A need for a Food Safety Plan has arisen due to the new Food Safety Modernization Act 2011. A Food Safety Plan, often referred to as a PCP Plan builds on a HACCP plan and gives specific attention to preventive controls. This whitepaper covers how to build a plan capable of identifying and controlling food safety hazards relevant to their products and processes. We have used the core document developed by the FDA, "Preventive Controls for Human Food" to ensure alignment with legal and commercial requirements. We have developed this content in appropriate areas and use the Safefood 360° food safety management platform to illustrate how the requirements are met.

1 HISTORY & BACKGROUND

1.1 History

In 2009, the U.S. Congress and the Obama Administration proposed new food safety measures. This came about due to a rise in foodborne illness cases. In 2009, 714 people got sick and nine died from a Salmonella outbreak in peanut butter from the Peanut Corporation of America. This prompted a recall of their peanut butter products and the company filed for bankruptcy as a result. The threat of bioterrorism due to events such as 9/11 was also a concern prompting new food safety measures. In 2011, the Congress passed the Food Safety Modernization Act (FSMA). The Food & Drug Administration (FDA) then set about turning the bill into rules and regulations. A series of final rules have been put in place.

Figure: List of the FDA Final Rule

Final Rules
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals
Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications
Focused Mitigation Strategies To Protect Food Against Intentional Adulteration
Sanitary Transportation of Human and Animal Food

On September 17, 2015, the FDA established the regulation "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" (PCHF Rule). The final rule became effective on November 16, 2015. The regulation is in Title 21 of the Code of Federal Regulations, Part 117 (21 CFR Part 117). The rule created new requirements for the production of human food by registered food facilities and revises previous requirements.

1.2 Requirements of the PCHF Rule

The PCHF Rule requires:

- A written Preventive Controls Plan (PCP)
- A hazards analysis
- Preventive controls
- Monitoring
- Corrective actions and corrections
- Verification
- Supply-chain program
- Recall Plan

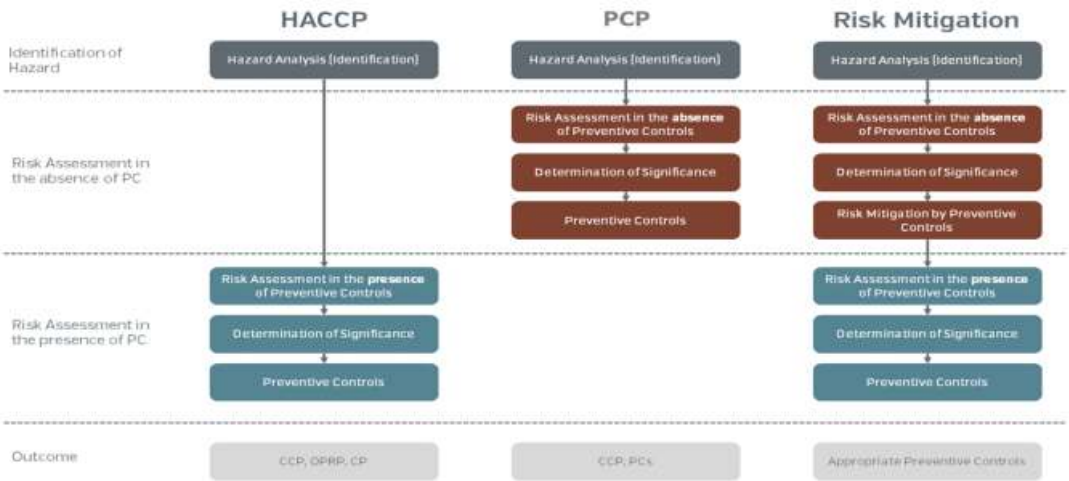
A Preventive Control Plan (PCP) must be prepared by one or more Preventive Controls Qualified Individual (PCQI). The PCP must include a written hazard analysis and preventive controls. The hazard analysis needs to identify and evaluate, based on experience and data, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at a facility to determine whether there are any hazards requiring a preventive control. The plan must include written procedures for monitoring, corrective actions, and verification.

1.3 The difference between HACCP & PCP

HACCP (Hazard, Analysis, Critical, Control Point) is a food safety system originally created in the 1960s by NASA to ensure the safety of food to be consumed by astronauts. HACCP is based on 7 principles, which involve determining what the potential hazards are, how to recognize if they are exceeding acceptable levels, and what to do if acceptable levels are exceeded. While a HACCP plan identifies hazards and how to control them if they occur, a PCP aims to prevent the hazards from occurring in the first place, and it also takes into consideration vulnerabilities and threats. A PCP is different in that:

- Radiological hazards and economically motivated adulteration are identified as chemical hazards (21 CFR 117.130(b))
- While a HACCP & PCP both have Critical Control Points (CCP) for processes, the PCP
- also has controls at points which aren't CCPs (21 CFR 117.135(a))
- CCP's in a HACCP have critical limits but a PCP has values and parameters (21 CFR
- 117.135(c))
- CCP's in a HACCP require monitoring whereas in a PCP monitoring is needed as required
- for preventive controls (21 CFR 117.145)
- Corrective actions are required by both HACCP & PCP, but a PCP requires corrections were needed (21 CFR 117.150(a))
- Process controls require and verification and validation in a HACCP, however in a PCP preventive controls are verified, process controls are validated and when a hazard is controlled by a supplier verification is needed (21 CFR 117.190)
- In a HACCP records are needed for process controls however in a PCP preventive controls require records as appropriate (21 CFR 117.190)
- A recall plan is not part of a HACCP, however in a PCP if a hazard requires a preventive control a recall plan should be included (21 CFR 117.139)
- The following graph depicts the key differences between HACCP and PCPs and the role of risk mitigation.

Figure: Difference between HACCP & PCP



2 PCP PLAN OVERVIEW

2.1 Contents of a PCP Plan

Facilities must establish and implement a food safety system that includes an analysis of hazards and implementation of risk-based preventive controls (21 CFR Part 117, subpart C). The rule requires a written food safety plan for all covered facilities unless an exemption applies. The written plan must include (21 CFR 117.126):

- A Hazard Analysis
- Preventive Controls
- A risk-based supply chain program, if appropriate
- A recall plan, if there are any hazards associated with the food
- Procedures for monitoring the implementation of the Preventive controls
- Procedures for verifying that the Preventive controls are consistently implemented and are effectively minimizing or preventing the identified hazards

PCP Plans require full planning for controls beyond the traditional CCP.

Figure: PCP Plan Overview

2.2 Hazard Analysis & Preventive Controls

Developing a PCP involves determining where preventive controls are needed and this begins with a hazard analysis to identity hazards requiring preventive controls. Preventive controls include:

- Critical Control Points – Thermal processing, freezing, chemical preservation, and other lethal processes.
- Operational Prerequisites (oPRPs) - Metal detection, detection & scanning, filtering, sieving and refrigeration.
- General Prerequisites (oPRPs) - Cleaning and sanitizing plant, equipment, employee facilities, as well as managing calibration, maintenance, personal hygiene, and contamination controls.

However, under 21 CFR 117, a PCP plan does require some specific preventive controls.
Supply Chain Controls

3 PRELIMINARY STEPS IN DEVELOPING A PCP

3.1 Scope of the PCP Plan

Under 21 CFR 117, a PCP Plan is specific to a facility and preventive controls are specific a product and process. When defining the scope of your plan, you should determine what the PCP plan will address, i.e., the specific product and process and which part of the food chain is applicable. For example, products sold to retail may have different considerations compared to products sold to the food service industry. The PCP plan must also include reference to any regulatory requirements.

Figure: Scope of a PCP Plan

3.2 Appoint PCQI

Under 21 CFR 117.180 a "Preventive Control Qualified Individual" or PCQI must be appointed to manage the PCP plan. Under 21 CFR 117.3, a PCQI is defined as "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 as recognized by the FDA or is otherwise qualified through job experience to develop and apply a food safety system." Under 21 CFR 117.180(a), the responsibilities of the PCQI include:

- Developing or overseeing the preparation of the PCP plan,
- Validating the preventive controls,
- Review of records,
- Reanalysis of the food safety plan.

A facility must have one or more persons appointed as PCQI. A PCQI does not need to be an employee of the facility. Although it is not required by the PCHF rule to have a PCP plan team, its recommended that a team be assembled. While the PCQI will prepare the PCP plan, it is important to have additional team members from different processes within a facility who are involved in daily activities, e.g., production manager, and who have food safety knowledge. List out your team members, their positions, and identify who is the PCQI.

Figure: PCP Plan Team

3.3 Risk Assessment Model & Decision Tree

A risk assessment model and decision tree model can be used to help you in your hazard analysis.

Risk Assessment Model

Under 21 CFR 117.130(c)(1)(i), you will need to assess if a hazard was to occur, what would the severity of the illness or injury be. Also, with no preventive controls what would be the probability the hazard occurring. Risk assessment models are used to assist in determining which hazards are significant if no preventive controls are put in place.

Figure: Risk Assessment Model Example

Decision Tree Model

Typically, decision tree models may be used to determine the appropriate control. Decision trees comprise a sequence of questions which when answered determine the appropriate control. In this example there are potentially 9 questions to answer. Within these questions all the essential elements to be considered have been included.

Figure: Decision Tree Example

No.	Question	Yes Decision	Monitor?	No Decision	Monitor?
1	Can the food type (determined and documented) be consumed without application of an appropriate control?	Preventive Control Not Required	No	Go to 2	
2	Do we rely on an internal appropriate control to ensure that the indentified hazard will be significantly minimized or prevented?	Go to 4		Go to 3	
3	Do we rely on the customer or an entity subsequent to the customer, who is subject to the requirements for PCHF rule to ensure that the identified hazard will be significantly minimized or prevented; or where not subject to PCHF rule provide assurance it is manufacturing, processing, or preparing the food in accordance with applicable food safety standards?	Preventive Control Not Required - Document disclosure of hazard required - Obtain annually customer assurances	No	Stop purchase and distribution of product until requirements are addressed	No
4	Is this Step specifically designed to prevent or eliminate the hazard or reduce it to an acceptable level?	CCP - Preventive Control - CCP	Yes	Go to 5	
5	Could contamination occur or increase to an unacceptable level?	Go to 6		Preventive Control Not Required	No
6	Will a subsequent Step eliminate or reduce the hazard to an acceptable level?	Preventive Control Not Required	No	Go to 7	
7	Is the hazard addressed under a Preventive Control - General?	Go to 8		Go to 9	
8	Will this Step of the hazard workflow be used to define and monitor the Preventive Control - General?	PRP - Preventive Control - General	Yes	Stop	No
9	Is the Preventive Control specific to this Step?	sPRP - Preventive Control - Specific - This Step	Yes	Modify	No

Question 1: Can the food type (determined & documented) be consumed without application of an appropriate control?

In this question, we address the requirement of the rule (21 CFR 117.130(c)(2)) which states that the company must determine the nature of the food product and specifically if the food product can be consumed without control measures, e.g., nuts in their natural shell. If you are producing

shelled nuts to be used as an ingredient in another product, you may answer "No" that this is a product that cannot be consumed without controls.

Question 2: Do we rely on an internal appropriate control to ensure that the identified hazard will be significantly minimized or prevented?

This question addresses whether there are any internal controls in your process such as cooking which will reduce or prevent the hazard from occurring.

Question 3: Do we rely on the customer or an entity subsequent to the customer, who is subject to the requirements for PCHF rule to ensure that the identified hazard will be significantly minimized or prevented: or where not subject to PCHF rule provide assurance it is manufacturing, processing, or preparing the food in accordance with applicable food safety standards?

This question addresses the circumstances where you do not apply the preventive control and you rely upon an entity later in the supply chain to address the hazard (21 CFR 117.136(a)):

- You determine & document the type of food, e.g., coffee beans, can't be consumed without a control.

- You rely on your customer, who is subject to PCHF rule, to ensure the hazard is minimized or prevented and you should disclose that the food is not processed to control the hazard and also obtain annually written assurance from your customer that they have established and are following requirements.
- Your customer is not subject to the PCHF rule and they must provide assurance.
- You rely on your customer to provide assurance the food will be processed to control the hazard by an entity subsequent to you and your customer.
- You document the implementation of a system at a subsequent distribution step to control hazards in your food product.

Question 4: Is this step specifically designed to prevent or eliminate the hazard or reduce it to an acceptable level?

This question addresses the fact the step itself could be designed specifically for the identified hazard in order to prevent or minimize the hazard. If the answer is "Yes" the outcome in the step is a CCP or other appropriate preventive control.

Question 5: Could contamination occur or increase to an unacceptable level?

If contamination with a hazard in excess of acceptable levels is unlikely then there is no need for a control measure.

Question 6: Will a subsequent Step eliminate or reduce the hazard to an acceptable level?

This question addresses the fact that there may be downstream controls in place to control the hazard, e.g., metal detection within your process.

Question 7: Is the hazard addressed under a Preventive Control - General?

This question asks if the hazard is prevented or minimized by a General Preventive Control (i.e., a control not specific to a particular process step. For example in a receiving step for refrigerated ingredients there may be a hazard such as salmonella, which is controlled by a supply chain control,

e.g., Certs of Analysis provided by supplier.

Question 8: Will this Step in the Hazard Workflow be used to define and monitor the Preventive Control - General?

This question is asking if the step will monitor the General Preventive Control. Sometimes control measures are not carried out at the same step where the hazard arises; however, if the step is actually going to monitor the control these details need to be defined.

Question 9: Is the Preventive Control specific to this step?

This question is asking if there is a preventive control specific to the step. The outcome by selecting "Yes" is that that the control is an Operational Pre-Requisite Program (oPRP).

3.4 Hazard Evaluation Considerations

21 CFR 117.130 (c)(2) specifies that during the hazard analysis a number of factors should be taken into consideration. The factors should be considered when evaluating hazards as they could impact the finished product and in turn the safety of the intended consumer. These factors include:

- **Formulation of the food:** How the food is formulated, e.g., pH or water activity that could provide conditions favorable to pathogens.
- **Condition, function, and design of the facility and equipment:** The design or structure of the facility/equipment, e.g., the design of a piece of equipment may make cleaning difficult and increase the risk of a hazard.
- **Ingredients and raw materials:** Ingredients from supplier may introduce hazards such as food allergens and pathogens known to be associated with a specific food.
- **Transportation Practices:** How the product is transport could influence the presence of pathogens, e.g., bulk product versus packaged product.
- Manufacturing/processing procedures: Processing method may increase potential for hazards.
- **Packaging & labeling activities:** Packaging type may create an environment which supports the growth of pathogens.
- **Storage and distribution:**
- **Intended or reasonably foreseeable use:**
- **Sanitation including employee hygiene:** Do employees handle raw & cooked products. How often are surfaces cleaned to avoid pathogen growth.

The PCQI can collect data on the product in regard to the above factors and record the data as part of the PCP plan and use it to help identify any hazards.

Figure: Product Data

Product Data

Checklist

Item	Description
Product name(s) & Formulation	Raw meat, water, salt, dextrose, sugar, phosphates, nitrites, acids & spices.
The condition, function, and design of the facility and equipment	Purpose designed facility for the production of cooked meats including reception areas, temperature control storage, packaging storage, low risk areas, cooking and cooling facilities, high risk areas, packing and labeling and final product storage
Raw materials and other ingredients	Raw meat is sourced locally. Other ingredients are sourced from a variety of countries including domestically and abroad.
Physical, Biological & Chemical Properties	pH - 6.2, Water Activity - 0.97
Manufacturing / processing procedures	Curing, cooking and cooling
Packaging and packaging activities	Vacuum Packaged. 60 days from the date of packing at stated storage conditions. Keep refrigerated at maximum 5°C. Consume with 3 days of purchase.
Storage and distribution conditions	Maximum temperatures: Storage: 5° C ; Distribution: 5C°.
Intended or reasonably foreseeable use	Fully cooked, not shelf stable, ready to eat product. It will be sold at retail service/self service or food service.
Sanitation, including employee hygiene	The process maintains a sanitation program covering production area, contact prep surfaces, production equipment, storage and containers and personal hygiene facilities.

3.5 Flow Diagram

A flow diagram is not required by the PCHF rule. However, the flow diagram is an important tool to help describe the process. When creating the flow diagram it is important to include all the process steps under the facility's control and show each step in the sequence and the relationship between each step. When developing a flow diagram, you are organizing the information for the hazard analysis so hazards can be identified at each step. Information which can be included in the flow diagram includes:

- All ingredients and materials used
- Sequence of all process operations, where raw materials & ingredients enter the flow
- Time/temperature
- Flow conditions for liquids and solids
- Product recycle/rework
- Waste disposal

Once the flow diagram has been developed it should be verified to ensure no steps have been missed as these steps are the framework for conducting the hazard analysis.

3.6 Process Steps

The flow diagram does not give a detailed description of each step and therefore a written description explaining what is happening at each step can be developed. It is not required by the rule to give a detailed process step description; however, it is important to know exactly what is happening at each process step.

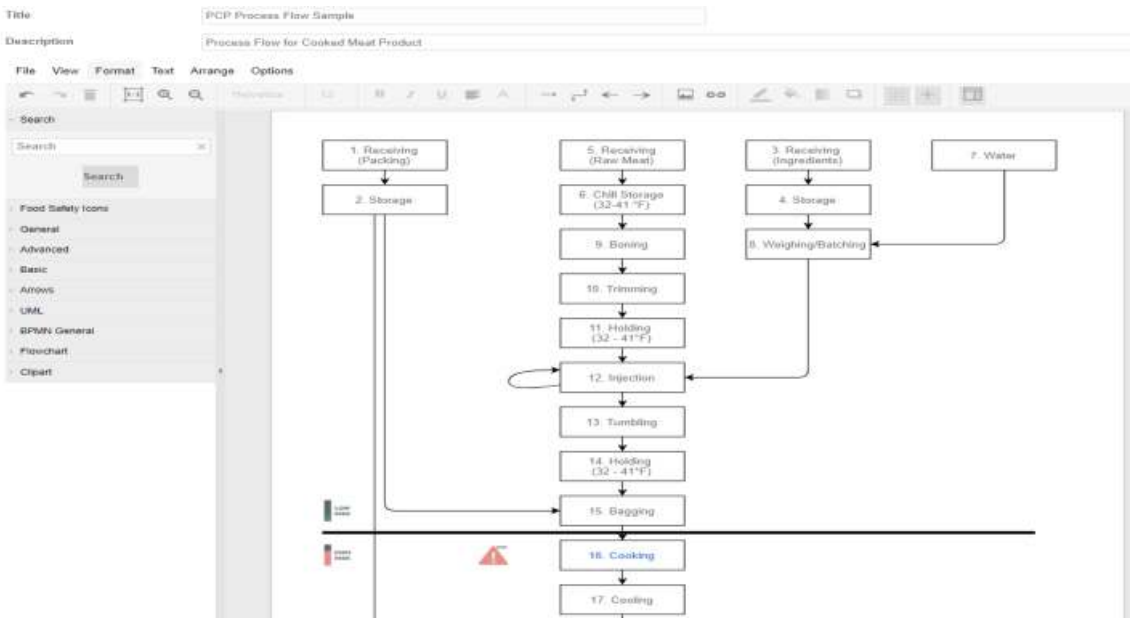
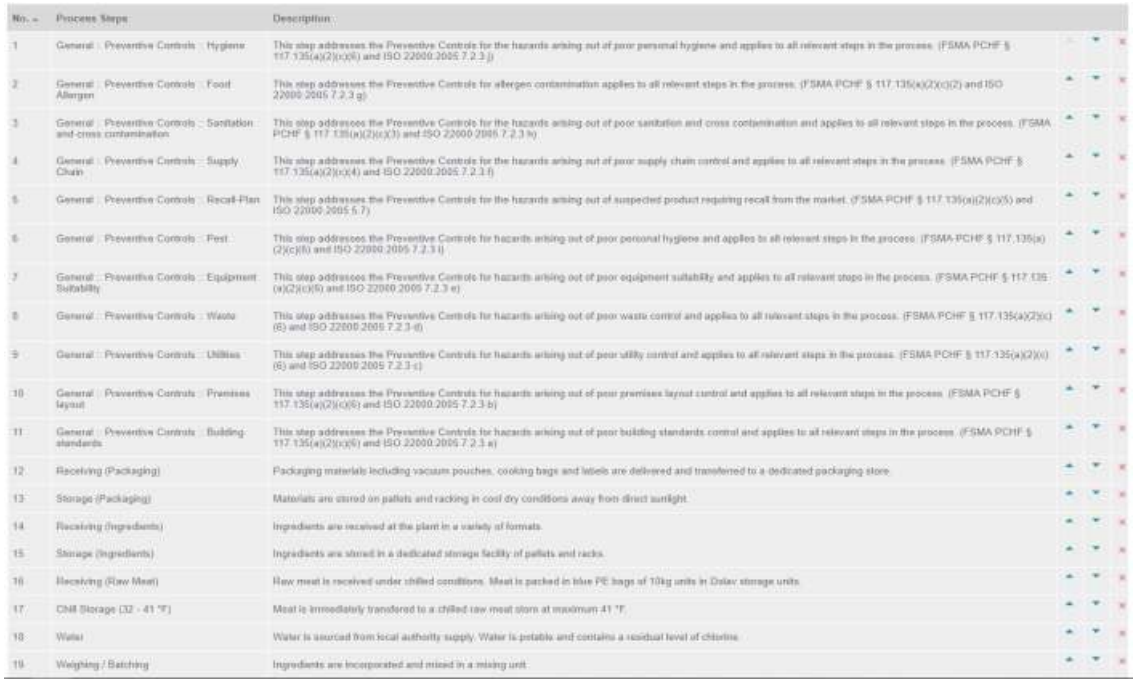


Figure: Process steps including Preventive controls



No.	Process Steps	Description
1	General :: Preventive Controls :: Hygiene	This step addresses the Preventive Controls for the hazards arising out of poor personal hygiene and applies to all relevant steps in the process. (FSMA PCHF § 117.135(a)(2)(c)(6) and ISO 22000:2005 7.2.3 j)
2	General :: Preventive Controls :: Food Allergen	This step addresses the Preventive Controls for allergen contamination applies to all relevant steps in the process. (FSMA PCHF § 117.135(a)(2)(c)(2) and ISO 22000:2005 7.2.3 g)
3	General :: Preventive Controls :: Sanitation and cross contamination	This step addresses the Preventive Controls for the hazards arising out of poor sanitation and cross contamination and applies to all relevant steps in the process. (FSMA PCHF § 117.135(a)(2)(c)(3) and ISO 22000:2005 7.2.3 h)
4	General :: Preventive Controls :: Supply Chain	This step addresses the Preventive Controls for the hazards arising out of poor supply chain control and applies to all relevant steps in the process. (FSMA PCHF § 117.135(a)(2)(c)(4) and ISO 22000:2005 7.2.3 f)
5	General :: Preventive Controls :: Recall Plan	This step addresses the Preventive Controls for the hazards arising out of suspected product requiring recall from the market. (FSMA PCHF § 117.135(a)(2)(c)(5) and ISO 22000:2005 5.7)
6	General :: Preventive Controls :: Pest	This step addresses the Preventive Controls for hazards arising out of poor personal hygiene and applies to all relevant steps in the process. (FSMA PCHF § 117.135(a)(2)(c)(6) and ISO 22000:2005 7.2.3 i)
7	General :: Preventive Controls :: Equipment Suitability	This step addresses the Preventive Controls for hazards arising out of poor equipment suitability and applies to all relevant steps in the process. (FSMA PCHF § 117.135(a)(2)(c)(6) and ISO 22000:2005 7.2.3 e)
8	General :: Preventive Controls :: Waste	This step addresses the Preventive Controls for hazards arising out of poor waste control and applies to all relevant steps in the process. (FSMA PCHF § 117.135(a)(2)(c)(6) and ISO 22000:2005 7.2.3 d)
9	General :: Preventive Controls :: Utilities	This step addresses the Preventive Controls for hazards arising out of poor utility control and applies to all relevant steps in the process. (FSMA PCHF § 117.135(a)(2)(c)(6) and ISO 22000:2005 7.2.3 c)
10	General :: Preventive Controls :: Premises layout	This step addresses the Preventive Controls for hazards arising out of poor premises layout control and applies to all relevant steps in the process. (FSMA PCHF § 117.135(a)(2)(c)(6) and ISO 22000:2005 7.2.3 b)
11	General :: Preventive Controls :: Building standards	This step addresses the Preventive Controls for hazards arising out of poor building standards control and applies to all relevant steps in the process. (FSMA PCHF § 117.135(a)(2)(c)(6) and ISO 22000:2005 7.2.3 a)
12	Receiving (Packaging)	Packaging materials including vacuum pouches, cooking bags and labels are delivered and transferred to a dedicated packaging store.
13	Storage (Packaging)	Materials are stored on pallets and racking in cool dry conditions away from direct sunlight.
14	Receiving (Ingredients)	Ingredients are received at the plant in a variety of formats.
15	Storage (Ingredients)	Ingredients are stored in a dedicated storage facility of pallets and racks.
16	Receiving (Raw Meat)	Raw meat is received under chilled conditions. Meat is packed in blue PE bags of 10kg units in Dolav storage units.
17	Chill Storage (32 - 41 °F)	Meat is immediately transfered to a chilled raw meat store at maximum 41 °F.
18	Water	Water is sourced from local authority supply. Water is potable and contains a residual level of chlorine.
19	Weighing / Batching	Ingredients are incorporated and mixed in a mixing unit.

3.7 Resources

In developing or modifying your PCP, it is important to identify the sources of information referenced. Collect information from sources that are credible. This can include government agencies, technical experts & publications. The FDA (www.fda.gov) is an excellent source for guidance on FSMA

Figure: Regulatory information

4 HAZARD ANALYSIS & PREVENTIVE CONTROL DETERMINATION

4.1 Identify Potential Hazards

Following the preliminary steps, next is hazard identification. According to 21 CFR 117.3, a hazard is defined as "any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury." All reasonably foreseeable biological, chemical, and physical hazards should be considered. These hazards could be present because they occur naturally, are unintentionally introduced, or are intentionally introduced for economic gain (if they affect the safety of the food).

In identifying potential hazards, it is important to consider the product data as previously mentioned in section 3.4.

Biological Hazards

21 CFR 117.130(b)(1)(i) states you must conduct a hazard analysis to help identify known or foreseeable biological hazards including microbiological hazards such as environmental pathogens, parasites and other pathogens.

Figure: Examples of Biological Hazards

Examples of Biological Hazards (bacteria)	
Bacteria (spore-forming)	Bacteria (non-spore-forming)
Clostridium botulinum *Clostridium perfringens* *Bacillus cereus*	*Brucella abortis* *Brucella suis* *Campylobacter spp.* *Pathogenic Escherichia coli (E.coli 0157:1-17, EHEC, EIEC, ETEC, EPEC)* *Listeria monocytogenes* *Salmonella spp. (S. typhimurium, S. enteriditis)* *Shigella (S. dysenteriae)* *Staphylococcus aureus* *Streptococcus pyogenes* *Vibrio cholerae* *Vibrio parahaemolyitcus* *Vibrio vulnificus*

Figure: Examples of Biological Hazards

Examples of Biological Hazards (viruses)	
Viruses	Protozoa and parasites
Hepatitis A and E *Norwalk virus group* *Rotavirus*	*Cryptosporidium parvum* *Diphyllobothrium latum* *Entamoeba histolytica* *Giardia lamblia* *Ascaris lumbricoides* *Taenia solium* *Taenia saginata* *Trichinella spiralis*

Most biological hazards are microorganisms. Microorganisms are too small to see and are present everywhere in air, water, animal fur, skin, etc. Many microorganisms are beneficial.
However, under certain conditions microorganisms can cause illness through the consumption of food and these can be called foodborne pathogens. According to regulation 21 CFR 117.3, a pathogen means a "microorganism of public health significance." Pathogens can cause illness by infection or intoxication after the food is eaten. Infections are caused by consuming the live pathogen, which will then grow in the body and cause illness. Intoxication is caused by consuming toxins produced by bacteria.

Some pathogens like Salmonella can be a hazard in the food when consumed but other pathogens require growth to a level where they will cause illness. Therefore, knowledge of bacterial pathogens and the conditions that make them hazardous to humans is important to be aware of when developing preventive controls.

Potential controls for bacterial pathogens:

- Prevent them from arising in the first place, e.g., good hygiene practices
- Eliminate or kill them, e.g., Cooking or irradiation
- Control their growth by not allowing them the conditions that influence their growth such as water, pH levels, temperature, oxygen, e.g., Storage at correct temperature

Chemical Hazards

21 CFR 117.130(b)(1)(ii) states you must conduct a hazard analysis to help identify known or foreseeable chemical hazards such as food allergens, mycotoxins, toxic chemicals and radiological hazards. Radiological hazards now need to be considered as a chemical hazard. Radiological hazards rarely occur in the food chain but when they occur and it's over a period of time they can present a significant risk. Sources include contaminated soil, water or air, ingredients with radionuclides, and packaging materials. They may also arise from accidental contamination, e.g., in 2011, radioactivity was found in milk and vegetables produced in an area where a nuclear power plant was damaged by tsunami.

Potential controls for chemical hazards:

- Supply chain controls – Most chemical hazards can be controlled by ensuring suppliers have appropriate controls in place and understanding where ingredients are coming from.
- Sanitation controls – Good sanitation controls can reduce allergen contamination.
- Allergen controls – Labelling ingredients with allergen information.
- Process controls – Relevant for chemicals in food formulation.

Figure: Chemical Hazards Examples

Examples of Chemical Hazards	
Naturally occurring chemicals Allergens Mycotoxins (e.g. aflatoxin) Scombrotoxin (histamine) Ciguatoxin Mushroom toxins Shellfish toxins • Paralytic shellfish poisoning (PSP) • Diarrhoeic shellfish poisoning (DSP) • Neurotoxic shellfish poisoning (NSP) • Amnesic shellfish poisoning (ASP) • Pyrrolizidine alkaloids • Phytohaemagglutinin	Added chemicals Polychlorinated biphenyls (PCBs) Agricultural chemicals • Pesticides • Fertilizers • Antibiotics • Growth hormones Prohibited substances • Direct • Indirect Toxic elements and compounds • Lead • Zinc • Cadmium • Mercury • Arsenic • Cyanide • Food additives • Vitamins and minerals Contaminants • Lubricants/paints • Cleaners • Sanitizers • Coatings
From packaging materials Plasticizers Vinyl chloride Printing/coding inks Adhesives Lead Tin	Radiological Hazards Strontium-96 Iodine-131 Cesium-137

Physical Hazards

21 CFR 117.130(b)(1)(ii) states you must conduct a hazard analysis to help identify known or foreseeable physical hazards such as glass, plastic, metal, wood, and stones. A physical hazard is any potentially harmful extraneous matter not normally found in food. These hazards can cause choking and other health issues to the consumer. Common sources of glass in food include light fixtures, jars, thermometers, and gauge covers. Common sources of metal in food could be from metal to metal contact in processing equipment, wire meshes, and screens.

Potential controls for physical hazards include:

- Metal Detection
- Good Manufacturing Practices
- Supply Chain Controls

Figure: Physical Hazards Examples

Material	Injury potential	Sources
Glass	Cuts, bleeding; may require surgery to find or remove	Bottles, jars, light fixtures, utensils, gauge covers, etc.
Wood	Cuts, infection, choking; may require surgery to remove	Field sources, pallets, boxes, building materials
Stones	Choking, broken teeth	Fields, buildings
Metal	Cuts, infection; may require surgery to remove	Machinery, fields, wire, employees
Insulation	Choking; long-term if asbestos	Building materials
Bone	Choking	Improper processing
Plastic	Choking, cuts, infection; may require surgery to remove	Packaging, pallets, equipment
Personal effects	Choking, cuts, broken teeth; may require surgery to remove	Employees

Economically Motivated Hazards

21 CFR 117.130(b)(2)(iii) states known or reasonably foreseeable hazards that may occur in food due to intentional adulteration for economic gain should be considered. Adulteration affects food quality and product integrity. It is recommended to consider circumstances with a history of adulteration for economic gain that could cause illness. In 2008, approximately 300,000 babies in China became ill due to milk powder adulterated with melamine and caused six deaths.

Figure: Examples of cases where food has been adulterated for economic gain

Food & Hazard	Details
Milk :: Melamine	Milk may be watered down and melamine added to raise the apparent protein content and hide dilution. Melamine is an organic base chemical, and is known to pose a health threat.
Turmeric :: Lead chromate	Due to high demand for spices such as turmeric they are adulterated with lead chromate to mimic its appearance. In 2016 seven brands of turmeric were recalled in USA due to elevated lead levels.
Paprika :: Lead oxide	In 1994 ground paprika was adulterated with lead oxide in order to enhance its colour and it resulted in over 50 people in Hungary being poisoned.

4.2 Hazard Evaluation

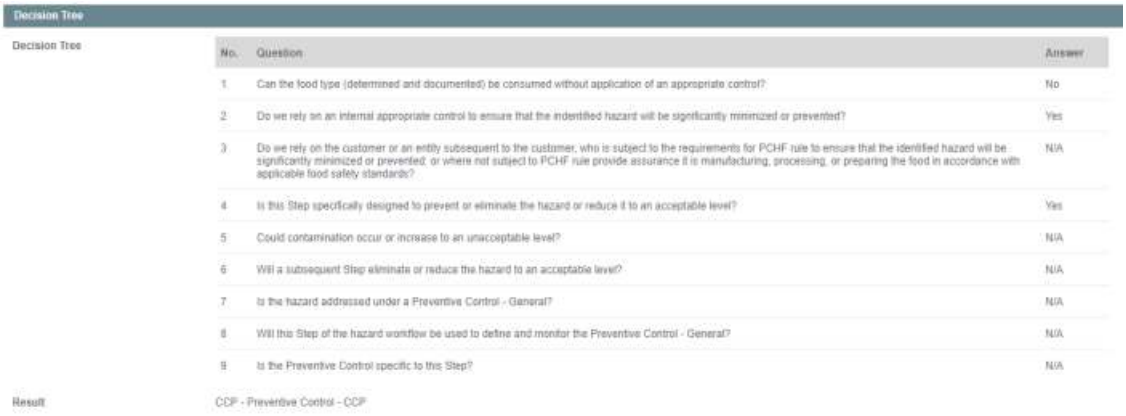
After identifying the hazards at each process step, the hazard needs to be evaluated for likelihood of occurrence and severity of the illness. Severity of the hazard will depend on a number of factors such as whether symptoms are mild, severe or who the target consumer is (elderly and infants are more vulnerable). The likelihood of the hazard occurring requires considering factors such as

historic incidents of foodborne illness, recalls on products, previous laboratory results on products & complaints from consumers. Likelihood of a hazard will vary from facility to facility and depending on different factors, for example:

- Operational programs, e.g., personal hygiene
- Preparation methods
- Transportation conditions
- Storage conditions
- Preparation of product before consumed

Evidence to support the risk outcome should also be included in the PCP. If a hazard is identified as significant, preventive controls are required. The term "Preventive Controls" is defined by regulation 21 CFR 117.3 as "those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of analysis." Using a decision tree, the PCQI can determine what, if any, controls are required.

Figure: Decision tree



Decision Tree

Decision Tree

No.	Question	Answer
1	Can the food type (determined and documented) be consumed without application of an appropriate control?	No
2	Do we rely on an internal appropriate control to ensure that the indentified hazard will be significantly minimized or prevented?	Yes
3	Do we rely on the customer or an entity subsequent to the customer, who is subject to the requirements for PCHF rule to ensure that the identified hazard will be significantly minimized or prevented; or where not subject to PCHF rule provide assurance it is manufacturing, processing, or preparing the food in accordance with applicable food safety standards?	N/A
4	Is this Step specifically designed to prevent or eliminate the hazard or reduce it to an acceptable level?	Yes
5	Could contamination occur or increase to an unacceptable level?	N/A
6	Will a subsequent Step eliminate or reduce the hazard to an acceptable level?	N/A
7	Is the hazard addressed under a Preventive Control - General?	N/A
8	Will this Step of the hazard workflow be used to define and monitor the Preventive Control - General?	N/A
9	Is the Preventive Control specific to this Step?	N/A

Result: CCP - Preventive Control - CCP

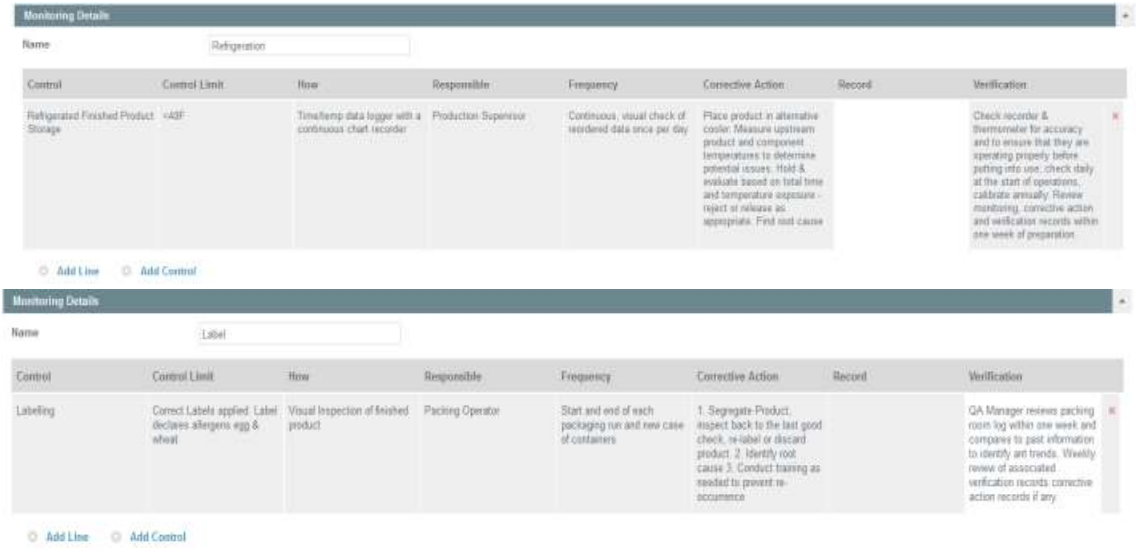
4.3 Preventive Controls

21 CFR 117.135 requires preventive controls to be implemented where a hazard has been identified as requiring a control. Controls are required at critical control points and any other control as appropriate for food safety. 21 CFR 117.3 defines a preventive control as "Those risk based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understand of safe food manufacturing, processing, packaging or holding at the time of the analysis."

Preventive controls may include:

- Process preventive controls - In 21 CFR 117.135(c)(1), when operations such as heat processing are taking place, the parameters need to be controlled. Control of such parameters include procedures, processes, and practices.
- These controls are identified at a specific step such as Critical Control Points (CCP).

Figure: Process control examples for Cooking & Refrigeration



- **Food allergen Preventive controls** - Allergen Preventive controls include procedures for managing allergens and preventing cross-contamination and accurate labelling.

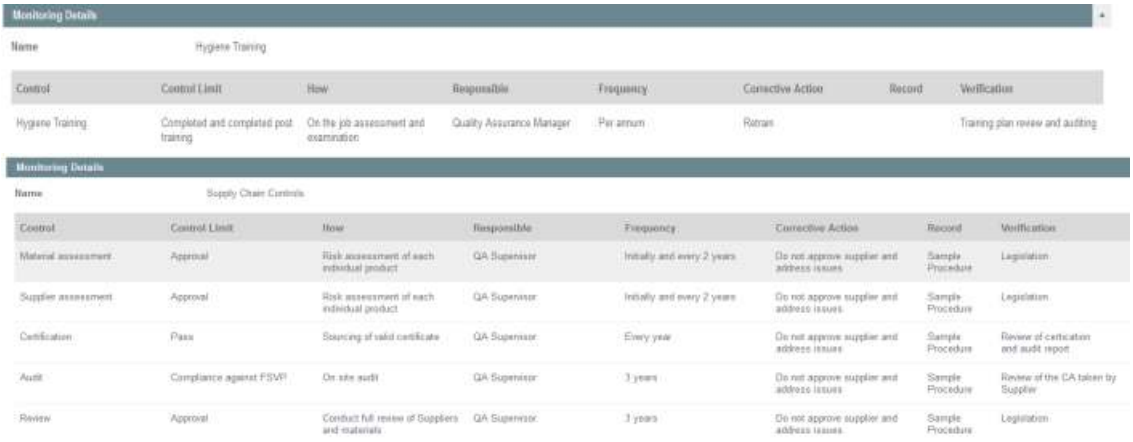
Figure: Process control examples for Labelling

- **Sanitation preventative controls** - procedures and practices for cleanliness of food contact surfaces and prevention of allergen cross-contamination.

Figure: Sanitation controls example

- **Supply chain Preventive controls** - Controls are needed when there is dependence on the supplier of an ingredient to control a hazard as there is no step to control the hazard in the receiving facility.

Figure: Supply chain controls examples



Monitoring Details

Name: Hygiene Training

Control	Control Limit	How	Responsible	Frequency	Corrective Action	Record	Verification
Hygiene Training	Completed and completed post training	On the job assessment and examination	Quality Assurance Manager	Per annum	Retrain		Training plan review and auditing

Monitoring Details

Name: Supply Chain Controls

Control	Control Limit	How	Responsible	Frequency	Corrective Action	Record	Verification
Material assessment	Approval	Risk assessment of each individual product	QA Supervisor	Initially and every 2 years	Do not approve supplier and address issues	Sample Procedure	Legislation
Supplier assessment	Approval	Risk assessment of each individual product	QA Supervisor	Initially and every 2 years	Do not approve supplier and address issues	Sample Procedure	Legislation
Certification	Pass	Sourcing of valid certificate	QA Supervisor	Every year	Do not approve supplier and address issues	Sample Procedure	Review of certication and audit report
Audit	Compliance against FSVP	On site audit	QA Supervisor	3 years	Do not approve supplier and address issues	Sample Procedure	Review of the CA taken by Supplier
Review	Approval	Conduct full review of Suppliers and materials	QA Supervisor	3 years	Do not approve supplier and address issues	Sample Procedure	Legislation

- **Recall Plan** - A recall plan is not directly needed to manage hazards requiring a preventive control, but it can help in reducing the number of illnesses if a product is contaminated.

Depending on the hazard identified one or more of the preventive controls may be required.

Preventive control examples for biological hazards:
- Process control, e.g., cooking, temperature control
- Supply chain program for ingredients with not kill step
- Sanitation control

Preventive controls examples for chemical hazards:
- Supply chain program
- Sanitation control to prevent cross-contamination of allergens
- Allergen labeling

Preventive controls examples for physical hazards:
- Process controls such as metal detection or sieving

5 VERIFICATION & VAILDATION

5.1 Overview

According to regulation 21 CFR 117.3, verification is "The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan." Validation has been defined as "obtaining and evaluation scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented is capable of effectively controlling the identified hazards."

Verification is important to confirm that the PCP Plan is working as intended and specifically for the preventive controls. Validation ensures the PCP plan is effective in controlling hazards. The PCQI must manage the verification and validation activates.

5.2 Verification

Some examples of verification procedures for preventive controls include record review, visual inspection, and testing. Other verification procedures include internal audits and 3rd-party audits.

Figure: Examples of verification procedures for Preventive controls

Sanitation	Process	Supply Chain	Allergen
Monitoring of the environment Visual inspection	Calibration of equipment Review of records Sampling & testing	Audits Sampling & testing	Label checks Visual inspection


Monitoring Details

Name Cooking

Control	Control Limit	How	Responsible	Frequency	Corrective Action	Record	Verification
Temperature/Time	Ham should have a minimum internal temperature of 145F. Recommended using 154.4F or higher	Continuous chart recorder per each batch. Temperature probe measurements at the core of ham located in the cold part of the oven	Cooking Operator	Continuous	Divert to rework, completely reprocess through the entire cooking cycle, or reject and condemn product.	Sample Procedure	Daily review of records before shipping product by an individual who did not complete the records and who is responsible establishment official. Periodic calibration of temperature recording devices (recommend at least weekly calibration.) Periodic internal temperature checks to verify time/temperature parameters are reaching desired internal temperature (recommend at least weekly checks).

5.3 Validation

Validation is managed by the PCQI and should include:

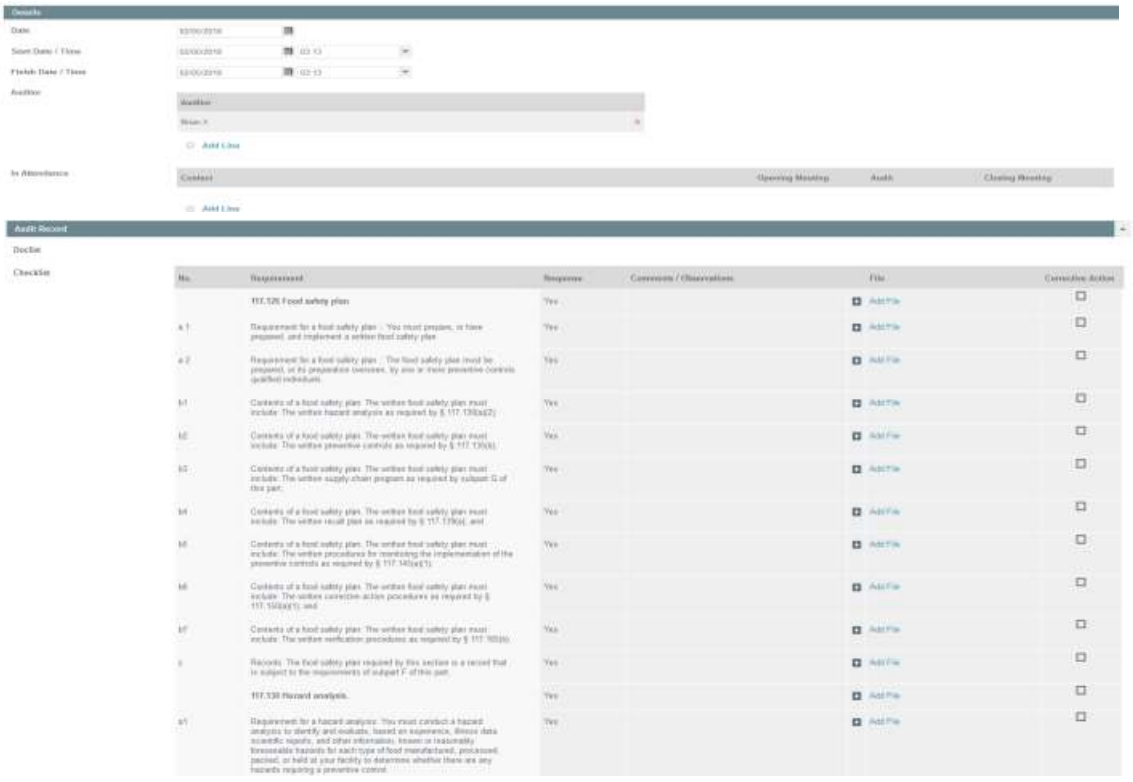
- Review of hazard analysis
- CCP determination
- Justification for critical limits, based on current good science and regulatory requirements
- Determination of whether monitoring activities are appropriate and accurate

Figure: Validation of a PCP Plan

5.4 Audits & Calibration

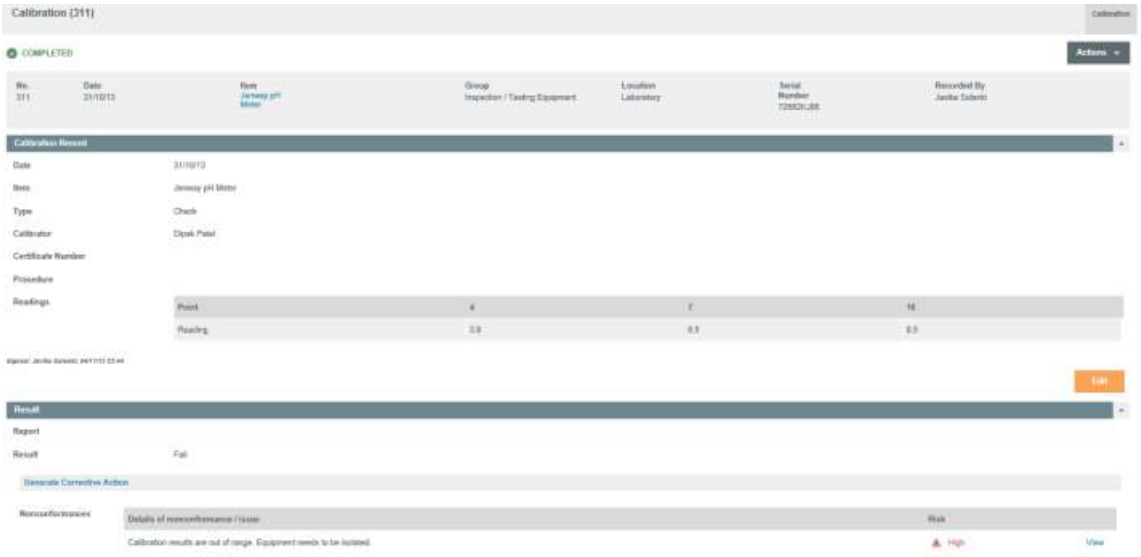
As part of verifying the PCP plan, audits are performed to compare the actual practices and procedures of the system with those written in the PCP plan. Audits are systematic and independent examinations involving on-site observations, interviews and review of records to determine whether the procedures and activities stated in the PCP plan are implemented in the PCP system. These examinations are usually performed by one or more independent persons who are not involved in implementation of the PCP system. Audits may be performed for individual preventive controls and/or for the overall plan.

Figure: PCP Plan Audit

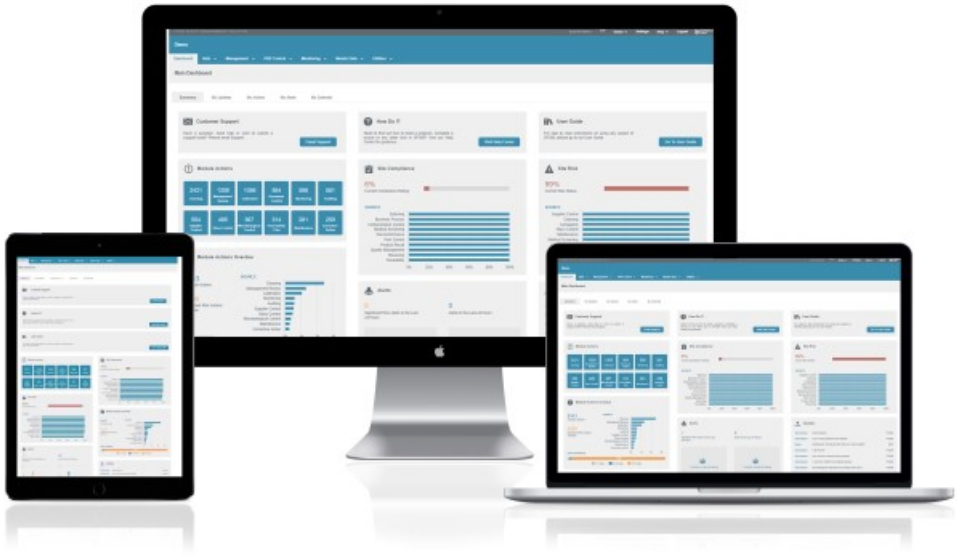


Calibration involves checking instruments or equipment against a standard to ensure accuracy. Calibration should be documented and the records should be available for review during verification. Calibration of appropriate equipment and instruments used in the development and implementation of the PCP plan should be carried out during monitoring and/or verification.

Figure: Calibration Record for pH Meter



Safefood 360° Food Safety Management Software



Product Benefits

- Easily record and manage all elements of your food safety system including HACCP and CCP monitoring, PRP's, management systems and documents
- Eliminate paper using the 30 integrated modules that come as standard
- Access and work with your system from any location at anytime
- Stay up to date and fully compliant with software that updates automatically in line with changes to global food standards
- Improve compliance and audit outcomes through the action driven features of the software
- Accelerate compliance with all of the international food safety standards including the BRC, SQF, IFS & FSSC 22000.
- Spend less time managing your food safety system and more on value adding activities

Product Features

- Dashboards & KPI's
- 100's of reports as standard
- Notifications
- Multi-site management & oversight
- Real-time legal and alert updates to dashboard
- Roles & security
- Actions management
- Safe and secure web based solution
- No internal IT support or data back-up required
- Unlimited Users
- 24/7 world class customer support
- Covers in complete detail the requirements of the SQF, BRC, IFS, FSSC 22000, retailer standards and legislation
- FDA 21 CFR Part 11 –Technical Compliance
- Automatic audit log
- One click data export

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