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# Verification: Can Your Food Safety Plan Meet the Rigors of FSMA's Proposed Preventive Controls?


## Key Words

FSMA, foreign material detection, verification, validation, preventive controls


## Overview

Foreign material detection is very important to the food industry whether you are using in-line detection, packaged product detection, metal or X-ray detection. This paper will help you understand regulatory compliance as it relates to all verification activities. Verification is a topic that can be confusing to food safety professionals. The questions heard most often about verification are, "What are verification activities?" or "Is validation the same things as verification?" Verification and validation are two terms that are often confused.

As this paper will elucidate, verification, including validation, is critical to the maintenance of a strong food safety program and to the successful implementation of the Food and Drug Administration's (FDA) Preventive Control (PC) rule, as proposed, and to hazard analysis critical control point (HACCP) as it is required by the FDA for juice and seafood and by the United States Department of Agriculture, Food Safety Inspection Service for meat and poultry products. After providing a synopsis of the proposed requirements to implement preventive controls, this paper will dive into the details of verification, using several examples related to the detection of foreign materials.

## Background on FSMA and the Preventive Controls Rule

When the U.S. Congress passed and the President signed into law the Food Safety Modernization Act (FSMA), the intent was to give FDA the authority to require that companies build food safety into their processes so that issues could be prevented from occurring. The primary section of the act that will drive companies in this direction is commonly referred to as "preventive controls." When FDA proposed a rule that would implement this section, the basic elements were familiar to many food safety professionals. In a nutshell, FDA would require that firms:

- Conduct a hazard identification and evaluation to determine what hazards need to be controlled
    - This includes biological, chemical (including radiological) and physical hazards
- Identify "preventive controls" that will eliminate or significantly reduce the hazard
    - Process controls
    - Sanitation controls
    - Supplier controls
    - Allergen controls
    - Other appropriate controls
- Determine the parameters for process controls
- Monitor the parameters
- Develop written corrective actions
- Verify that the controls are working

Each of the bullets on the previous page could be exhaustively described. But collectively, they make up what FDA calls the "food safety plan". The food safety plan essentially provides an analysis of:

- hazards that exist,
- preventive controls that will be used to manage those hazards,
- "instructions" describing how the preventive controls are implemented,
- the determination that things are working properly through monitoring, verification, and record keeping, and
- corrective actions steps taken if something goes wrong.

All of these areas need to be addressed in the food safety plan. In many ways, this is similar to a HACCP plan in that there are parallels between some aspects of preventive controls and HACCP. It is likely that in the food safety plan, the critical control points (CCP) of HACCP as well as operational pre-requisite programs may be the "preventive controls" that are used to significantly minimize the levels of food safety hazards.

The proposed PC rule requires that validation and verification, among other things, are performed by a "Qualified Individual." These individuals must have the right training, or documented on-the-job experience that is comparable to the training. Examples of the verification activities performed by the qualified individual are as follows:

- validation of preventive controls,
- review of records for implementation and effectiveness of preventive controls,
- review the appropriateness of corrective actions, and
- performing the reanalysis of a food safety plan.

## Verification

There are two overarching aspects of verification: one is the initial validation and the other is the evaluation that the system is performing as expected. Both of these of aspects are directed at the effectiveness of the control for each significant hazard. They establish that the control is scientifically valid for controlling the hazard and verify that the control process or procedures are accomplishing the intended purpose to prevent, eliminate, or significantly reduce the likelihood of the hazard.

There has been quite a bit of confusion in the past about verification and validations, especially since the U.S. National Advisory Commission on Microbiological Criteria for Foods (NACMCF) definition for verification includes validation and excludes monitoring, and the Codex definition includes monitoring and does not specifically mention validation. Food safety employees may ask " Why are these different?" and " What is a verification activity and what is a validation activity?"

### Validation

Validation is the initial determination that the controls are scientifically and technically sound to prevent the hazard. This initial validation will answer the question, "How do I know that what I'm doing is working so that I have achieved the reduction in the hazard that I've specified achieve (e.g., 100% inspection for metal greater than 4mm in size)?" The information to support the initial validation can be peer-reviewed public literature, regulatory guidance, trade association publications, manufacturer's technical information, company knowledge, and initial in-plant data collection. Validation happens prior to putting the control or the plan into place.

### Verification

Verification involves evaluating that all hazards, as determined by a hazard analysis to be significant, have been identified and determining that if the food safety plan is properly implemented these hazards will be effectively controlled. Another aspect of verification is evaluating whether the facility's HACCP system is functioning according to the HACCP plan (HACCP Principle 6: "Establishing Verification Procedures" NACMCF). In other words, "Am I doing what I say I've said I am going to do in the plan?"

## Regulatory Requirements for Verification

Verification, as it is known today in Principle 6, was originally published in NACMCF HACCP in 1989 and adopted by the Federal regulatory agencies as a required part of HACCP (D.A. Corlett, 1998). Currently, there are three regulated HACCP programs:

- FDA Juice HACCP (21 CFR 120)
- FDA Seafood HACCP (21 CFR 123)
- USDA - FSIS meat and poultry HACCP regulations (9 CFR 417)

There is one difference to note as it relates to verification. In NACMCF, verification is Principle 6 and records is Principle 7, and these are used for the basis of the FDA Juice and Seafood HACCP regulations. In Codex, these two principles are transposed and this is the basis for the USDA-FSIS Meat and Poultry HACCP. For the purposes of this document, verification is noted as HACCP Principle 6.

## Required Verification Activities

As noted previously, verification will be a critical component of your food safety plan, because it demonstrates that you're keeping tabs on your food safety system. Table 1 is a brief description of the verification activities required by the specific HACCP regulations.

### TABLE 1: Brief Summary of Required HACCP Verification Activities

| Verification Activity | FSIS - USDA Meat and Poultry HACCP | FDA Juice | FDA Seafood |
|---|---|---|---|
| Validation | Initial validation and reassessments | Each processor shall validate the HACCP plan | Every processor shall verify the HACCP plan is adequate to control food safety hazards |
| On-going Verification (monitoring) | Including but not limited to<br>• Calibration<br>• Monitoring<br>• Corrective actions<br>• Records review | Includes<br>• Consumer complaints<br>• Calibration<br>• End-product testing, where appropriate | Including but not limited to<br>• Consumer complaints<br>• Calibration<br>• End-product or in-process testing |
| Complaint Review | 1 | Review to determine if they relate to the performance of a CCP | Review to determine if they relate to the performance of a CCP |
| Calibration | Calibration verification | Calibration of process and monitoring equipment | Calibration of process and monitoring equipment |
| Product Testing | 2, 3 | Optional, except that processors of citrus juice that rely in whole or in part of surface treatment of fruit shall perform end-product testing in accordance with 21 CFR 120.25 | Optional |
| Records | Maintain records supporting HACCP | Maintain records supporting HACCP; written hazard analysis and sanitation standard operating procedures; calibration; and product testing | All HACCP records subject to recordkeeping requirements; including calibration and product testing |
| Records Review | HACCP records[4] | Review including a signature and date of a trained individual of HACCP records within a reasonable timeframe; CCP within 1 week. | Review including a signature and date of a trained individual of HACCP records within a reasonable timeframe; CCP within 1 week. |
| Corrective Actions | 5 | Ensure complete records and appropriate corrective actions were taken; these activities shall occur within 1 week. | Ensure records are complete and appropriate corrective actions were taken; these activities shall occur within 1 week. |

(9 CFR 416, 21 CFR 120, 21 CFR 123, FPA 2006)

[1] In the HACCP regulations for USDA/ FSIS meat and poultry there is no direct requirement to evaluate consumer complaints. The FSIS has published Directive 5610.1, 2005 instructing how the FSIS will handle consumer complaints. The Directive instructs the FSIS to contact the manufacturing facility, where appropriate. Although it is not specifically stated in the HACCP regulations, it is important that FSIS official establishments will have a way to review consumer complaints and react appropriately.

[2] FSIS control Listeriamonocytogenes (9 CFR 430.4, FSIS 2014). In this regulation and directive the FSIS identify certain times that finished product should be tested as a result of potential environmental contamination. (FDA 2014 (2)).

[3] E. coli O157:H7 and the other non-Shiga producing pathogenic E. coli strains considered to be adulterants in ground beef are regularly tested for by industry and regulators (USDA – FSIS, 2012 & 2014 (3)).

[4] This FSIS Directive 5000.1 Rev. 4 identifies all the HACCP records that will be reviewed during a food safety assessment by an EIAO officer (FDA 2014).

[5] ASK FSIS stated the following about Documentation of SSOP and HACCP corrective actions "The requirement in 9 CFR 416.16 and 417.3(c) is that you document Sanitation SOP and HACCP corrective actions. The establishment can document these corrective actions on its records or on the NR. If the documentation is on the NR, the NR can become part of the HACCP or Sanitation SOP records and is then required to meet the recordkeeping requirements of those regulations" (FSIS 2013).

### Proposed Verification Activities

This section will go into brief details on the new proposed FDA regulation that will expand upon the HACCP regulations currently in effect for juice and seafood and apply the same preventive philosophy to the rest of the FDA regulated industry. There are five aspects of verification that are proposed by FDA (§117.150). All five should be noted in the food safety plan, along with appropriate details on how each is accomplished. As proposed by FDA, the five components of verification are:

### 1. Validation

Validation is the scientific determination that a process works. This is described above, and is considered one element of verification (§117.150(a)).

### 2. Verifying that Monitoring is Occurring

This is either observing the generation of monitoring records or having a supervisor or other individual repeat a measurement. This requirement is separate from reviewing the records related to monitoring. Exactly how a facility will verify that monitoring is occurring does not need to be included in a food safety plan but we recommend that the food safety plan identify this (§117.150(b)).

### 3. Verifying that Corrective Actions are Occurring (§117.150(c)).

The FDA understands that not everything goes right all the time. That is why the proposed PC rule requires companies to think about what they are going to do when something goes wrong before something goes wrong. Every single preventive control needs an associated set of corrective actions written in the food safety plan (§117.145).

### Short Term Corrective Action

In the short term action needs to be specified in the food safety plan. This could mean holding all product that was not run through a functioning foreign material detection device. Document exactly what happened, what product was affected, who performed the corrective action, the action taken, etc.

### Root Cause Analysis

A "root cause analysis" is also needed to determine why the foreign material detection device was not functioning. The food safety plan needs to state that this will be investigated, and records showing that the investigation did occur, what the results of the investigation were, and what actions were taken as a result of the investigation.

### Unanticipated Hazard and Ad Hoc Corrective Action

Sometimes something unanticipated might occur, and a facility might need to implement a corrective action outside of those that are written in the food safety plan. The food safety plan should specify how the facility will react to unanticipated problems (§117.145(b)). In general, this should follow the same steps of evaluating safety, preventing an unsafe product from entering commerce, and performing a root cause analysis. In addition to these steps the food safety plan must be re-analyzed to address/include this new hazard (§117.145(b)(2)) and the plan should specify how quickly (e.g., within one week) the food safety plan will be updated after an unanticipated event requires an unplanned corrective action. Failure to reassess the food safety plan will be viewed unfavorably by the FDA. Reassessment must be performed even if the food safety plan does not change (but the fact that it was reassessed must still be documented).

### 4. Verification of Implementation and Effectiveness of Preventive Controls

There are two aspects to verify the implementation and effectiveness of a preventive control and they are overseen by the qualified individual, calibration and records review (§117.150(d)).

### Calibration

In many cases there will be equipment and measuring devices that are used to create monitoring records. These pieces of equipment and devices must be calibrated. The food safety plan does not need to spell out the process to calibrate (in many cases this might be done by a third party), but the food safety plan must specify how often calibration will be performed. In many cases the equipment manufacturer will recommend the calibration frequency. As a best practice the food safety plan should also note who will do the calibration (e.g., internal or by a third party) and if there is an SOP for the calibration, it is a good idea for the food safety plan to reference this.

### Records Review

This is a critical component of verification and is used to show that the food safety plan is being followed. There are a few key points.

- The qualified individual must perform the review of records.
- Records of monitoring activities and corrective actions must be reviewed within one week of the record being generated.
- A review of calibration must occur within a "reasonable time". Although FDA has not indicated a required timeframe for this review, your food safety plan must identify when calibration records will be reviewed.

- If the record review shows that records are missing or are incomplete (e.g., there are "blanks" where the value of parameters are not noted) then this means that you cannot show that your preventive controls are effective. It is as if the preventive control didn't happen at all and this will be viewed unfavorably by FDA.

**5. Recently, in the re-proposal of the rule the FDA described how testing can be used as verification.** Environmental testing can be used to verify sanitation efforts to assist in reduction of the potential environment cross-contamination. Also, similarly finished product testing can be used to verify process controls.

**6. Reanalysis (§117.150(f)).**

The food safety plan must be reanalyzed at least once every three years by the qualified indiviudal. Even if the reanalysis shows that nothing has changed, a facility must document that the reanalysis was conducted. There are several other things that can trigger a reanalysis sooner than the three years:

- Unanticipated hazard and subsequentad hoc corrective actions
- Significant change (e.g., a change in formulation, process, etc.)
- Identification or awareness of a new significant hazard
- If a preventive control is found to be ineffective
- FDA can also require reanalysis of a food safety plan

There is another component of verification which was recently published in the re-proposal of the Preventive Controls Rule; microbial food safety testing. It is up to each facility to determine if they want to test incoming materials (as part of verifying their suppliers), finished products (as a way to verify that the preventive controls in their food safety plan are working), and/or conduct environmental sampling to verify sanitation, mainly for those facilities producing ready-to eat products. The proposed rule is not final yet, and these re-proposed items are open for comment.

## Verification Examples

Let's walk through the proposed PC rule verification requirements using a few examples. It is important to think about these in the context of the food safety plan. Do you know all the reasonably foreseeable physical hazards? Have you identified and controlled the significant hazards? The proposed PC rule is a holistic approach to food safety. In the case of foreign materials there are many steps in the process that a manufacturer can understand and potentially control or reduce food safety risks by applying prerequisite programs and preventive controls. This section will introduce some possible inputs to the process that could introduce foreign materials into product. These inputs are not an exhaustive list. They are to provide context for the examples on foreign material control and demonstrate the types of questions and situations that a facility should consider when performing a hazard analysis around foreign materials.

### Supplier Risk

It is helpful to ask, "What are the foreign material risks from the supply chain?" The risks can either be an inherent risk of the ingredient such as bone in chicken, or poor supplier history, such as plastic glove pieces in a product. Understanding this risk can help the manufacturer require the right controls at the supplier to prevent occurrence for example, X-ray detectors for bones, and potentially supplier disqualification with a repeated poor performer.

### In-Process Risk

Another step in the process of foreign material control is to understand the risk in the manufacturing facility. One good way to do this is to develop a robust process flow chart. The proposed PC rule does not require a flow chart, but we recommend the development of a flow chart. A robust flow chart will identify all the inputs, steps and outputs of the process. (HACCP regulations for meat and poultry, seafood and juice require the development of a flow chart.) The qualified individual and the food safety or HACCP team can review the flow chart and identify all points where there may be a risk of physical hazards. Risks for physical foreign materials can come from equipment and personnel, for example:

- **Metal:** grinding metal such as blenders, agitators, gear boxes, etc. Metal can be accidentally introduced from loose equipment pieces, like nuts and bolts.
- **Plastic:** pieces from worn equipment, gloves and, other personal protective equipment, plastic bags, plastic pallets, etc.
- **Wood:** worn broken pallets, etc.
- **Glass:** broken glass jars, light bulbs, etc.

The examples below are designed to provide information to the reader on the application of the new proposed PC rule in regard to verification that foreign materials are being controlled. The examples will walk through different scenarios highlighting the verification steps outlined in the proposed PC rule.

## Inherent Risks

In this scenario the product is a blackberry cobbler packaged in an aluminum tin. The qualified individual determined during the hazard analysis that rocks are an inherent risk in blackberries as a physical hazard that is significant. Because the cobbler is packaged in an aluminum tin, the preventive control is X-ray detection.

During a production day, there were multiple X-ray kick-offs of the blackberry cobbler. Would this require corrective action? At this point based on the preventive control, it seems that the product may have contained foreign material that was larger than the X-ray preventive control parameter. Therefore, it is not known if a corrective action is required.

### Monitoring Records Verification

**X-ray:** As required by the preventive control the X-ray monitoring records were reviewed by the qualified individual. This verification revealed the daily checks were acceptable.

**Supplier Control:** The blackberries are purchased from two suppliers, supplier A and supplier B. Supplier B has a history of supplying blackberries that contain more rocks than supplier A. The food safety quality team confirmed the blackberries used during this production day were from supplier B.

### Corrective Action

From what we know so far in this scenario can we determine if a corrective action is required?

**X-ray:** This information led the team to believe that the higher level of X-ray kick-offs were due to an unacceptable blackberry ingredient and not due to a failure of the X-ray system, which means the X-ray preventive control was adequately controlling the risk. As precaution, the food safety and quality team want additional assurance that the blackberry cobbler finished product was acceptable, just in case the problem was with the X-ray equipment. The product was held and run through the separate calibrated X-ray. No additional kick-offs occurred. This confirmed that the X-ray process worked, and there is no need for a corrective action as related to the X-ray system.

**Supplier:** The blackberries were supplied by supplier B with a history of product that contained a higher level of rocks. We suggest that in this instance, a review of supplier B is definitely in order due to the higher amount of finished product found to contain foreign material, which is most likely blackberry briars.

## Metal Detector Failure

In this scenario the product is a 40 pound bag of dry powdered milk. The qualified individual determined during the hazard analysis that metal is a significant physical hazard. The preventive control is the finished product metal detector, but there are other programs that help prevent metal from entering the product stream, such as the facility and premise preventive maintenance program.

### Corrective Action – Product Control

During production, a quality technician was performing a metal detector check as designated by the preventive control (or HACCP CCP). The quality technician reported a failure of a prescribed test wand, or a failure to meet a preventive control parameter. All the product was placed on hold from the last good metal detector check, which is required to be performed every 2 hours, per the requirements for a corrective action for that control step. (Generally, industry best practice is to hold all the product for that day/lot of production until there is an investigation performed, even if the preventive control states “from the last good metal detector check” - just as precaution.) This failure of a routine monitoring step would initiate the prescribed corrective action. Another step in the prescribed corrective action is to ensure that all product from the last good metal detector check is evaluated for safety by being required to be re-run through a functioning metal detector.

### Corrective Actions – Metal Detector

Based on the new proposed PC rule, what would be an example of a functioning metal detector? Since documentation is foundational to FSMA compliance, how would you prove that a metal detector is truly effective?

- It is a metal detector that has been validated to ensure the hazard is detected, or the food safety risk associated with the size of the metal detected in the specific product matrixes is adequately controlled by eliminating failing product from reaching the consumer.The equipment manufacturer is generally the best resource to assist in validation of their detection device and the specific product matrices.
- The metal detector has been calibrated. Generally metal detection calibration is performed annually by the equipment manufacturer. Keep in mind, this calibration record will require a verification by the qualified individual.
- The metal detector is subject to ongoing verification of monitoring activities.

Once tested and found functional, the product can be re-run through the metal detector. It is important to remember to document, document, document, because if it is not documented the corrective action to ensure product safety did not happen.

## Foreign Material in Finished Product

In this scenario the product is a cheese-filled sandwich cracker. The qualified individual determined during the hazard analysis that there is a significant physical hazard for metal due to a previous issue with the cheese filling supplier. The preventive controls are supplier control and metal detection.

### Corrective Action – Product Control

The crackers were being kicked-off throughout the day at high rate. The quality team investigated and found multiple small metal balls. Immediately, all of the product was put on hold for that production lot, which started after sanitation that morning. Placing product on hold is the first step in the prescribed corrective action.

### Corrective Action – X-ray Machine or Metal Detector

The qualified individual was overseeing the corrective action process as required. It was discovered that the metal detector minimum sensitivity setting was very close to the size of the small metal balls found in the product.

In this case, to ensure product safety the facility qualified individual required that product is to re-run through a detection device that has a lower sensitivity than the current in-line metal detector. So they called on the experts: the detection device providers.

### Metal Detector Provider

In this case the metal balls were very close to the detection limit of the metal detector. What can a facility do in this instance? If they re-run the product and it all passes, does that make the product less of a food safety risk – no. Therefore, it may be appropriate to call in the experts. The X-ray machine and metal detector manufacturer can assist. The experts may be able to bring an X-ray machine to your site, to re-run the product at an increased sensitivity. We previously defined "functional metal detector" in the "Metal Detector Failure" so ensure the new special circumstance X-ray machine meets the food safety plan expectations. This process needs to be documented and all of this is overseen by a qualified individual.

### Corrective Action - Prevent Reoccurrence

What are the steps to ensure this does not happen again? The root cause investigation revealed an older gear box was in poor condition and ball bearings had gotten into the product stream. The gear box was replaced prior to start up and the preventive maintenance schedule was updated with the manufacturer's recommended settings. (We believe it a good practice to apply this corrective action elsewhere as a preventive action; on another line in the same facility or on a similar line in a sister facility.)

### Reanalysis

The next question that can be asked is "Would this corrective action require a reanalysis of the food safety plan?" These bullets will walk through the thought process so far to help answer this question.

- The daily monitoring of the preventive control identified multiple product kick-offs and subsequent investigation revealed small ball bearings present in the finished product.
- Corrective action was initiated
    - product was placed on hold;
    - bring in a x-ray machine, verify the functionality per the food safety plan;
    - re-run the product;
    - root cause investigation revealed the issue and it was resolved.

This scenario would not require a reanalysis. The current hazard analysis identified metal as significant hazard.

## Conclusion

Verification is one step to help ensure the food safety system is working to prevent, control or significantly reduce public health hazards. Verification includes validating the steps to ensure the process will work, and secondly includes the evaluation activities that verify the system continue to work. Verification activities are clearly defined in the FDA's proposed Preventive Controls rule, as well as in current regulated HACCP requirements. The scenarios provided examples of how to apply the required verification steps as outlined in the FDA's proposed Preventive Control rule.

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