

# Verification Programs



**Kevin Keener, Ph.D., P.E.**

Food process engineer, Extension specialist, and associate professor of food science



## Outline

1. What is verification?
  - 1.1 What programs are verified?
2. Establishing verification procedures
3. Three aspects of verification
  - 3.1 Validation
  - 3.2 Ongoing verification
  - 3.3 Reassessment
4. Action steps for the processor

*Verification at a large food processing plant requires at least one additional full-time employee per shift. This translates into approximately \$50,000 per shift per year in wages and employee benefits. At smaller plants, a minimum two hours per day are required for verification activities. Over a year, verification costs at a small food processing plant can range from \$10,000 to \$25,000.*

*(Cost estimates from plant survey – North Carolina State University).*

## Introduction

For the very small meat and/or poultry processor, verification procedures are one of the most difficult aspects of a HACCP (Hazard Analysis Critical Control Point) plan, a sanitation program, or other required programs. This fact sheet explains the parts of verification and provides examples of verification activities and documentation required to meet HACCP regulations (9 CFR 417, [www.access.gpo.gov/nara/cfr/waisidx\\_02/9cfr417\\_02.html](http://www.access.gpo.gov/nara/cfr/waisidx_02/9cfr417_02.html)).

### 1. What is verification?

All food safety programs required by the U.S. Department of Agriculture's Food Safety Inspection Service ([www.fsis.usda.gov](http://www.fsis.usda.gov)), from the largest corporations to the very small processor, must include verification procedures. Verification procedures are the steps and documentation necessary to ensure the program is working correctly. Applicable programs would include employee training, sanitation program, recall program, HACCP program, pest control program, and others. Each process used in these programs must be proven effective by the verification procedures.

## 1.1 What programs are verified?

It is critical for the processor to realize that verification is not limited to the HACCP program. Verification must occur for all food safety programs. Let's look at a simple example of verification of the employee-training program before moving on to more complex examples of verification in HACCP.

### Example 1:

**Background:** very small meat plant specializing in smoked hams, six employees

**Regulations involved:** 9 CFR 416.5, ensuring employee hygiene ([http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr\\_2002/janqtr/9cfr416.5.htm](http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2002/janqtr/9cfr416.5.htm))

**Situation:** All employees at Sam's Meats are required to wash their hands every time they enter the processing area. The actual handwashing procedure, however, has never been validated nor verification procedures established. Brad, as the new supervisor, was responsible for validating the handwashing procedure.



He first called the soap manufacturer. A technician there provided evidence that handwashing using their soap and following recommended procedures is effective in removing 99.5 percent of all bacteria on a person's hands. Next, Brad drafted a handwashing procedure based on the information received from the soap manufacturer. Brad's written procedure included scrubbing time, amount of cleaner/sanitizer, and water temperature.

All employees were then provided handwashing training. Periodically, a supervisor reviews employees' handwashing practices to ensure compliance. Handwashing directions were posted in the restrooms and above all sinks. Documentation from the soap manufacturer was used as initial validation documentation in the plant's sanitation program. Documentation of periodic visual inspection of proper handwashing by employees is ongoing verification. Brad has documented all training sessions and all visual inspections for verification of compliance.

## 2. Establishment of verification procedures

All meat and poultry processing plants are required to establish and maintain a HACCP (Hazard Analysis Critical Control Point) food safety plan (9 CFR 417). A processing plant must have an effective HACCP program to comply with regulatory requirements and prevent adulteration of product.

HACCP is a systematic approach to the identification, evaluation, and control of food safety hazards. It is a proactive, prevention-oriented approach to eliminate hazards by determining how and where food safety hazards exist and how to prevent their occurrence.

There are seven fundamental HACCP principles:

- Principle 1** — Conduct a hazard analysis.
- Principle 2** — Determine the critical control points.
- Principle 3** — Establish critical limits.
- Principle 4** — Establish monitoring procedures.
- Principle 5** — Establish corrective actions.
- Principle 6** — Establish record-keeping and documentation procedures.
- Principle 7** — Establish verification procedures.

The most misunderstood and most difficult HACCP principle is **Principle 7: The Establishment of Verification Procedures**. All required programs — HACCP, Sanitation program, prerequisite programs (recall program, pest control program, training program, and others) — must be verified and shown to be effective.

Many very small processors establish a HACCP plan that simply does not effectively prevent contamination of the product. Why is the plan not effective? Their plan usually does not contain proper verification steps, thus they have no idea if it is working. Verification uses methods, tests, documentation, or procedures to

determine if the food safety plans (HACCP, sanitation, recall, employee hygiene etc.) are operating as they were intended. Verification procedures are required in the Code of Federal Regulations, 9 CFR Part 417.4a ([http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr\\_2002/janqtr/9cfr417.4.htm](http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2002/janqtr/9cfr417.4.htm)).

### 3. Three aspects of verification procedures

Verification procedures have been categorized into three parts:

1. Validation
2. Ongoing verification
3. Reassessment

#### 3.1 Validation

This is the collection of scientific, authoritative documentation that proves the stated procedures are effective. It is material that supports or corroborates “the proposed action” on an authoritative basis. This material may include government regulations, scientific literature, or in-plant data. These data show that the techniques and methods used by the plant are effective. Scientific literature may include citations from a textbook, refereed publication, Extension bulletin, or expert opinion from a process authority. An extensive list of validation material exists in the FSIS directives and guidance documents specifically for meat and poultry.

#### Example 2:

**Background:** very small plant producing custom sausages, three employees

**Regulations involved:** 9 CFR 417. 4, verification procedures for a HACCP plan

**Situation:** Blue Ridge Mountains Sausage Co. makes a fermented semi-dry summer sausage product. The product is a mixture of raw chopped pork, salt, sugar, spices, nitrite (150 parts per million minimum), sodium sorbate (0.5%), and starter lactic acid bacteria culture. The mixture is stuffed into casings reaching a diameter of 2 inches, then fermented for 26 days at a room temperature of 90°F with a final acid pH of 5.0. The HACCP plan has set three critical control points: 1) a minimum 150 ppm nitrite to prevent *Clostridium botulinum* growth, 2) the sausage shall be held in the drying room for 25 days to kill any trichinae, and 3) a final heating step of 155°F for two minutes to kill any *Salmonella*. Are these critical limits effective at controlling *C. botulinum*, trichina, and *Salmonella*?



Obviously, this processor did his homework and identified all of the potential disease-causing organisms in his sausage product. However, he must show documentation that his processing steps and critical limits are adequate to eliminate these organisms.

First, he found documentation that *C. botulinum* was inactivated by the sorbate and nitrate. The amounts of both additives exceeded the levels required to prevent *C. botulinum* toxicity as presented in CFR Title 9 Part 424.22 ([http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr\\_2002/janqtr/9cfr424.22.htm](http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2002/janqtr/9cfr424.22.htm)).

Next, he researched the Code of Federal Regulations and found Title 9, Part 318.10 ([http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr\\_2002/janqtr/9cfr318.10.htm](http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2002/janqtr/9cfr318.10.htm)), which prescribes treatment of pork and products containing pork to destroy trichinae. The 90°F for 25 days far exceeded the recommended time and temperature to destroy trichina.

Finally, the final product must be *Salmonella* free. There is no regulatory requirement for heating summer sausage to eliminate *Salmonella*; however, CFR Title 9 Part 318.17 ([http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr\\_2002/janqtr/9cfr318.17.htm](http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2002/janqtr/9cfr318.17.htm)) states that a 99.99997 percent reduction in the number of *Salmonella* bacteria must be achieved for beef products. Therefore, this processor chose to design a heat treatment for his summer sausage that would equal the beef product requirements. From a scientific publication (Orta-Ramirez et al., 1997: Journal of Food Protection 60: 471 - 475) he documented that reaching an internal temperature of

155°F instantaneously eliminates *Salmonella* or *Listeria*. A copy of these regulations and the journal article would be assembled in the verification section of the HACCP plan, along with a description of the current process being used.

If the product or process is very unique or deviates from known scientific documentation, the processor may initiate a “challenge study” of the product in question for validation. Microbiological and/or residue testing of critical control limits and processing conditions for all hazards would reveal the efficacy of the processes. This validation testing may be done at the plant in consultation with FSIS or other process authorities to ensure that the experiment will produce valid results. The USDA Eastern Regional Research Center has also created the Pathogen Modeling Program (<http://ars.usda.gov/services/docs.htm?docid=6786>) that can determine the lethality of pathogenic bacteria at certain temperature conditions in certain foods. A processor can input temperature and time, and the computer model will determine lethality of the process.

**Example 3:**

**Background:** very small processor producing wild game, three employees

**Regulations involved:** 9 CFR 417. 4, verification procedures for a HACCP plan

**Situation:** Harold’s Smoked Game Meats Co. produces a smoked jerky made from buffalo brisket meat. During the smoking step, a raw buffalo brisket is heated in a smoker set at 170°F for four hours. Harold has used this same procedure for 15 years, but now he needs to validate that his HACCP plan is adequate and working properly.

Harold’s HACCP plan has identified biological hazards of *E. coli* 0157:H7 and *Salmonella* in raw beef brisket. Harold begins by locating the scientific data for a comparable beef product, which state that a raw beef product must be heated to a center temperature of 150°F for 67 seconds to kill *E. coli* 0157:H7 and *Salmonella*. For his buffalo brisket, he identifies a minimum critical oven temperature limit of 150°F, because if his oven goes below that temperature, the product may still contain the hazard. He identifies the minimum critical cooking time to be two hours, to ensure that the center temperature of his briskets reach that temperature.



How does Harold validate that his process is acceptable for an exotic meat? The easiest and most effective way is for Harold to cook several of the largest briskets at 150°F for two hours. The center temperature must be recorded throughout the cooking to ensure that the coolest spot achieves a minimum time-temperature treatment of 150°F for 67 seconds. His process easily meets this requirement with the set critical limits. The FSIS standards for lethality and Harold’s experimental temperature data at the critical conditions easily validate the process. A copy of these results would be included in his HACCP notebook.

It is important to note that if the product or processes change, then the selected critical limits must be re-evaluated to determine if these changes might impact food safety. For the example above, the critical limits would need to be re-evaluated if the starting material was frozen buffalo brisket instead of fresh brisket, because the heating time to reach the critical temperature would increase dramatically.

Many times products that contain similar ingredients and that are produced by the same process may use the same HACCP plan and validation, because the associated hazards are the same. An example would be a product with different flavorings, such as spicy vs. mild. However, before clustering like products under a single HACCP plan, a processor must complete and document a hazard analysis of each product.

Often very small processors make unique and specific products. Each category or product type must be validated to ensure the hazards are controlled by the chosen critical limits. A common mistake made by

processors is to underestimate the time required to cool a meat product to a certain temperature. Different sizes of the same product will cool at different rates, so an adequate cooling process should be validated using the largest product size or product container.

**Example 4:**

Harold’s Smoked Game Meats Co. sells chopped venison BBQ in foam cups. Harold sells an individual 5-ounce serving and a family-size serving of 30 ounces. The cups are filled with hot meat and sauce, with an initial temperature of approximately 155°F. The filled cups are then cooled on racks in a cooling room at 10°F prior to packing and shipping. Harold’s HACCP plan has identified that a biological hazard of *Clostridium perfringens* exists if the cups are not cooled quickly enough. Based on scientific data for a similar beef product, Harold has established a critical limit for the cups reaching less than 40°F in four hours. How would Harold evaluate that this critical limit is adequate for his buffalo BBQ? He has three options: 1) Have a laboratory test his processed product for the presence of *Clostridium perfringens*. 2) Have a process authority certify that his critical limit is satisfactory. 3) Use the USDA Pathogen Modeling Program. Harold should be sure that he tests the largest size of foam cups, if the same cooling room is to be used for both sizes of cups.

Again, the easiest and most effective way to validate this critical limit is for Harold to place several large containers filled with BBQ at 155°F in his cooler normally loaded with product. His test should validate if the target temperature is being reached within four hours. This could be done using a calibrated thermometer placed in the center of the largest cup. The experiment should be repeated and documented. If successful, he would then compile this data as verification of the existing process and periodically would collect additional cooling data as ongoing verification. Harold should consult with FSIS to ensure that the experiment is properly designed.

**3.2 Ongoing verification**

This day-to-day type of verification includes such things as assuring proper calibration of monitoring devices such as thermostats, observing monitoring activities, and reviewing corrective actions. Periodic testing of incoming ingredients and outgoing products by an outside laboratory would also constitute ongoing verification.

Ongoing verification tasks must have specific, written procedures that provide what will be verified, how often verification will occur, who is responsible for the verification activities, and who will review the completed verification.

**Example 5:**

**Regulations Involved: 9 CFR 417.4**, establishing verification procedures

From the previous example, Harold’s HACCP plan must ensure that the smoker temperature is accurate. Thus, as part of ongoing verification, the two thermometers Harold uses to measure the smoker temperature will be checked for calibration weekly by the floor supervisor, Tom. Harold will then review the records to ensure that Tom calibrated the thermometers correctly.

Activity	Frequency	Responsibility	Reviewer
Calibrate smoker thermometers	Weekly	floor supv. (Tom)	Manager (Harold)

Another example would be verification that the spices used in the buffalo brisket jerky samples are free of *Salmonella*. The spice company sends a certificate of analysis (COA) ensuring the batch is *Salmonella* free. The COA is verification that the spices are safe. As ongoing verification, the purchaser may send a sample to an outside laboratory for *Salmonella* testing.

Activity	Frequency	Responsibility	Reviewer
Check COA and enter COA into records	per shipment	floor supv. (Tom)	Manager (Harold)



### 3.3 Reassessment

The HACCP plan and other monitoring programs must be reviewed and assessed for accuracy at least annually. Reassessment does not focus on the plant's daily operations, and it must be done by someone trained in that particular program. Often outside independent experts are hired to review the plan to ensure it is adequate and complete and up to date.

Any product or production changes that could affect the hazard analysis or alter the HACCP plan or other food safety programs call for a review and update of that program. Reassessment also should be done if a foodborne illness outbreak occurs.

#### Example 6:

**Background:** small meat processor with 15 employees

**Regulations involved:** 9 CFR 416.14, which says: "Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOP's and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as



necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel."

**Situation:** Johnson Foods recently hired several Spanish-speaking workers to help with cleaning and sanitation of facilities and equipment. The workers speak and read only Spanish. What programs must be reassessed?

The plant manager realizes that he must re-evaluate the employee training program to ensure that the new employees understand their job duties and receive training that they can understand. The quality control supervisor, Jon, updates the training program by purchasing Spanish sanitation training materials, and Jon hires an interpreter for a few hours during employee training to help him explain the critical aspects of cleaning and sanitation instructions. Jon has Spanish instructions printed up for each piece of equipment and all facilities requiring sanitation. Thus, the sanitation and employee training programs have both been reassessed and updated with the new material and supporting documentation.

### 4. Action steps for the small processor

- ✓ All food safety programs must have established verification procedures; survey each program and decide what material must be located.
- ✓ Contact chemical, equipment, pest control, or other companies to obtain useful validation materials for your procedures.
- ✓ Determine the HACCP critical control points, limits, and monitoring activities that require verification activities.
- ✓ Obtain validation materials and develop verification procedures for HACCP through regulations and university Extension personnel.
- ✓ Contact FSIS or process authorities for consultation on challenge studies for unique processes.

### Other publications in this series

FS-20-W, Small Meat Processing Plants: Overview of HACCP (Hazard Analysis Critical Control Point)

▶ [www.ces.purdue.edu/extmedia/FS/FS-20-W.pdf](http://www.ces.purdue.edu/extmedia/FS/FS-20-W.pdf)

FS-21-W, Small Meat Processing Plants: SSOP and GMP Practices and Programs (Sanitation Standard Operating Procedures and Good Manufacturing Practices)

▶ [www.ces.purdue.edu/extmedia/FS/FS-21-W.pdf](http://www.ces.purdue.edu/extmedia/FS/FS-21-W.pdf)

FS-22-W, Small Meat Processing Plants: A Pest Control Program

▶ [www.ces.purdue.edu/extmedia/FS/FS-22-W.pdf](http://www.ces.purdue.edu/extmedia/FS/FS-22-W.pdf)

FS-23-W, Small Meat Processing Plants: A Recall and Traceability Program

▶ [www.ces.purdue.edu/extmedia/FS/FS-23-W.pdf](http://www.ces.purdue.edu/extmedia/FS/FS-23-W.pdf)

FS-25-W, Small Meat Processing Plants: Selection and Maintenance of Temperature Measurement Devices

▶ [www.ces.purdue.edu/extmedia/FS/FS-25-W.pdf](http://www.ces.purdue.edu/extmedia/FS/FS-25-W.pdf)

### Additional resources

Purdue Department of Food Science,

▶ [www.foodsci.purdue.edu/outreach](http://www.foodsci.purdue.edu/outreach)

Food Safety and Inspection Service of the USDA,

▶ [www.fsis.usda.gov](http://www.fsis.usda.gov)

USDA Pathogen Modeling Program,

▶ <http://ars.usda.gov/services/docs.htm?docid=6786>

### Acknowledgement

The author would like to acknowledge the financial support of the United States Department of Agriculture/Food Safety Inspection Service/Strategic Initiatives, Partnerships, and Outreach Office in developing this fact sheet. This fact sheet was developed with a portion of the funds provided from cooperative agreement FSIS-C-30-2003.

### For additional information

Kevin Keener

Associate professor, food process engineer, and

Extension specialist

Director, Food Technology Development Laboratory

Purdue Department of Food Science

West Lafayette, IN 47907-2009

Phone: (765) 494-6648

[kkeener@purdue.edu](mailto:kkeener@purdue.edu)