MICHIGAN STATE UNIVERSITY | Product Center Food • Ag • Bio

Food Safety Systems

Prerequisite Programs and Validation

Prepared by
Robert Culler, Culler Consulting, LLC
Tina Conklin, Food Processing Specialist
Product Center Food Ag Bio
Michigan State University

Date
March 2015

Acknowledgement

Funding for the project was provide by the Michigan Department of Agriculture and Rural Development

Table of Contents

Introduction

During the preparation and processing of food products there are many aspects to assure that the item is wholesome, safe and not adulterated. "Adulteration" is a legal term meaning that a food product fails to meet federal or state standards. Adulteration usually refers to noncompliance with health or safety standards as determined, in the United States, by the Food and Drug Administration (FDA) and the Unites States Department of Agriculture (USDA).

The backbone of any Food Safety System is Hazard Analysis and Critical Control Points (HACCP). HACCP is a systematic preventive approach to food safety from biological, chemical, and physical hazards in production processes that can cause the finished product to be unsafe, and designs measurements to reduce these risks to a safe level. In this manner, HACCP is referred as the prevention of hazards rather than finished product inspection.

Meat and poultry HACCP systems are regulated by the USDA, while seafood and juice are regulated by the FDA. The use of HACCP is becoming mandatory under the Food Safety Modernization Act (FSMA) for other food industries.

HACCP itself was conceived in the late 1960s when the US National Aeronautics and Space Administration (NASA), US Army Natick Laboratories and Pillsbury collaborated to design a food safety tool to manufacture the first foods for space flights. It was, however, recognized that HAACP by itself does not provide the complete food safety system. For a complete food safety system, HACCP is supported by numerous programs that are generally referred to as “prerequisite programs”. Depending on the industry other names for prerequisite programs are Good Manufacturing Practices (GMP’s), Standard Operating Procedures (SOPs), Preventative Maintenance Program, etc.

The goal of this document is to identify the various prerequisite programs and explain their purpose.

I. Sanitation Standard Operating Procedures

A. Sanitation

The Sanitation program identifies the routine and special / deep cleaning of the entire facility.

The basis for sanitation is the removal of soils from the manufacturing environment. There are many benefits to this process. From a food safety standpoint, there is the removal of pathogenic organisms, prevention of the formation of biofilms and removal of potentially harmful chemicals from food contact surfaces. From a quality standpoint, there is removal of spoilage organisms to improve the shelf life of refrigerated or ambient product and decrease the opportunities for spoilage. Sanitation is also used to prevent cross-over of residue from different animal species as well as preventing flavor impact by cross-over of spices and flavorings. Improved sanitation performance can also increase productivity by facilitating efficient processing start-up.

Microbiological contaminants of concern can depend on the type of product and the process through which the product passes. Pathogenic bacteria have been associated with human foodborne illness. They can result in consumer sickness, hospitalization, fatality, recall, liability and loss of business. For this reason, they are of great concern to the consuming public, the food industry and the regulatory agencies. Specific pathogenic organisms that have been most often associated with illness are *Listeria monocytogenes*, *Salmonella* and *E. coli* O157:H7. The primary pathogen of concern for sanitation, particularly in ready-to-eat meat and poultry operations, is *L. monocytogenes* as it is a ubiquitous organism, meaning it can be found frequently throughout the environment and can grow under a wide range of conditions in food plants. *Salmonella* and *E. coli* O157:H7 are not generally considered environmental contaminants; however, they are organisms that need to be removed from the environment.

Contamination of food products with spoilage microorganisms that do not result in foodborne illness, however, may be the underlying cause for reduction in shelf life of food products. While these organisms is easily eliminated through cooking, they are responsible for spoilage of product in the ambient shelf or refrigerated state. Spoilage organisms include yeast, mold, *Lactobacillus, Pseudomonas* and rope spores. These are all removed by effective cleaning and sanitation.

One of the great challenges that face the sanitation team is the formation of biofilms on food equipment surfaces. Food manufacturing plants have recognized that biofilms can have a profound impact on the safety and quality of their products. Their formation has the potential to contaminate product through the introduction of pathogenic microorganisms or spoilage bacteria. They are difficult to remove once they mature as they are resistant to normal sanitation procedures and can result in other detrimental process effects. Even when a food surface appears to be clean, the presence of biofilms is a potential hazard that must be eliminated and prevented from reoccurring. Biofilms begin with a conditioning layer of organic (protein) or inorganic matter forming on an otherwise visually clean food contact surface. The accumulation of organic and inorganic material on processing surfaces creates an environment to which bacteria can adhere. As the layers of bacteria attach to the surface and each other, they trap debris and nutrients and the biofilm begins to take shape. Development and growth, without removal, results in the film becoming irreversibly attached to a substratum or interface

or to each other. Biofilms form at a slow but steady rate and become harder to remove over time. They are most likely to form on rough, penetrable surfaces but can also form on just about any surface. Fortunately, the original biofilm attachment is weak and easy to remove through proper sanitation procedures. Therefore, the film soil must be removed and the most effective method process includes a potable water rinse, soap/cleaner application, mild mechanical action to further loosen soil, final potable water rinse and sanitizing.

Chemical contaminants of primary concern are allergen proteins. The "Big 8" allergens that are recognized as significant concern for food manufacturers include eggs, soy, wheat, milk, fish, Crustacean, peanuts and tree nuts. Human allergic reactions to foods are the results of sensitivity to the major protein of the food. For example, the primary protein in egg is albumen. These proteins are often left behind as residue on production surfaces during processing. It is important that the sanitation process be rigorous enough to remove the protein from food contact surfaces.

Other chemicals that can be removed through the sanitation process include hydraulic oil and lubricants. While plants should use lubricants that are H1 rated (food grade) for incidental contact, it is still important to remove surplus grease that may make its way onto contact surfaces from over-lubrication.

Physical contaminants may present a lesser challenge for the sanitation crew but should still be recognized. In grinding, chopping and mixing operations, there is always the possibility that metal shavings or fragments may be left on surfaces due to metal-to-metal contact. The sanitation process may be able to remove these fragments before they enter the product or the product stream. In addition, particles of meat, dough or starch that may form during manufacturing may also be removed during the sanitation process, preventing hardened material that can pose a dental hazard.

The Sanitation program needs to include facility area / room and items that will be cleaned after production processes:

- Facility areas include: Exterior and grounds, Receiving, Production (raw, spice, ready-to-eat), storage (raw, work-in-process, finished), employee welfare, break / lunch, offices, etc.
- Listing of food contact equipment, utensils, and containers; facility equipment, such as, hand wash sinks, trash and inedible containers, etc.; facility structures including walls, floors, ceilings, cooling units, piping and drains.
- Chemical (cleaners and sanitizers) utilized and mixing instructions.
- Frequency of cleaning (each production day, weekly, monthly or quarterly).

A Master Sanitation Schedule containing the above information is typically used to as a record of the cleaning activities and is initialed by the sanitation lead employee.

B. Pre-operational Inspection

Verification of the sanitation program is by pre-operational inspection. Pre-operational inspection is a visual / organoleptic examination of the post-sanitation and pre-operation environments. Documented organoleptic pre-op inspection is required as part of the plant SSOPs, and there is no regulatory requirement to incorporate other investigative tools. Organoleptic evaluation uses the physical senses of sight, smell and touch. The objective is the verification of sanitation by looking and smelling for indication that food residues have not been removed. It is important to have proper tools to assist in the inspection, including a flashlight, ladder for accessing high areas of the equipment or plant and reflective mirror (polished stainless, not glass) to access undersides of equipment. Other tools and documentation provide extra insight into the thoroughness of the sanitation process. Bioluminescence ATP measurement is an extremely effective, relatively inexpensive tool that many food manufacturers employ for rapid verification feedback about sanitation.

Validation of the sanitation program is by microbial and chemical residue testing, if necessary.

Before beginning a microbiological or chemical residue testing program, a company should ask itself four questions:

1. Why do we want to conduct microbiological or chemical residue testing?
2. What tests or test methods will be used?
3. What locations will be sampled and at what frequency?
4. How will the data be collected, analyzed and what actions will be taken based on the data?

All findings will require documented follow-up actions to eliminate any positive or high microbiological counts or positive chemical residues.

C. Operational Inspection

Verification of the other prerequisite programs is by inspection during the production operation. Operational inspection is a visual examination of the facility environment and criteria listed in the prerequisite programs to prevent adulteration of the product. The preventative prerequisite programs may include: Allergen Control Program, Employee Hygiene, Facility Condition and Temperature, Food Defense / Security, Ingredient Traceability and Lot Coding, Maintenance Programs, Pest Prevention Program, and any other activity utilized by the facility. Documented operational inspection is required as part of the plant SSOPs, and there is no regulatory requirement to incorporate other investigative tools.

II. Allergen Control Program

Food Allergen Labeling and Consumer Protection Act of 2004 established the "big eight" food allergens. The eight are: wheat (i.e. modified food starches, flour), Crustacean shellfish (e.g. shrimp, crab, lobster), eggs, fish (e.g. bass, flounder, or cod), peanuts, milk (i.e. cheese, non-fat dry milk, sodium caseinate, whey protein), tree nuts (e.g. almonds, pecans, walnuts), and soybeans (i.e. soy protein concentrate). These allergens cause approximately 90% of all food allergy reactions.

Allergens are defined as a protein that triggers a human immune response and physical health response. Other substances, such as monosodium glutamate (MSG) and sulfites may also trigger an allergenic responses, but are not proteins.

If exporting to other countries, it is important to know what that countries allergen list includes. For example, Canada's allergen list includes the "big eight" along with mustard, sesame and sulfites.

Any highly refined oil or ingredient that is derived from an allergenic protein source is not classified as an allergen. Thus, highly refined soybean oil used in spice blend to improve flow is not allergenic. Additionally, lethicin, which is an emulsifying and release agent comprised of a mixture of phospholipids in soy oil, must be made from highly refined oil.

Allergen control responsibilities can be broken down into three steps:

- **Identify:** All ingredients going into your product must be identified before the assembly process. Inspect incoming ingredients by matching the label with the product formulation to ensure label accuracy. If there is a discrepancy, the ingredients must be held from use until they are correctly identified and properly labeled.
- **Prevent:** Storage containers and utensils should be designated if used for only allergenic ingredients, and sanitation and processing procedures must be in place to prevent cross-contamination. One simple step you can take to prevent cross-contamination is to handle and process non-allergenic ingredients before handling and processing allergenic ingredients. Cleaning procedures in Sanitation Standard Operating Procedures, allergen control plan, or other prerequisite program should sufficiently and effectively prevents the potential for undeclared allergens.
- **Declare:** Packaging and storing of allergenic and non-allergenic final products should also be separated and labeled immediately according to their correct contents. Labeling procedures must be in place to ensure that the final product accurately reflects the packaged product. Labels may also include consumer notifications statements relating to other products with allergens. Such as "Made in a facility that manufactures other products with (allergen)".

  There are three ways that food allergens may be listed on the label:
  1. List the names of the allergens in the ingredient list (e.g., non-fat dry milk);
  2. List the names of the allergens next to the ingredient that does not disclose what is in it (e.g., flour (wheat), whey (from milk)); or
  3. List the allergens after the word "contains" (e.g., "contains wheat, soy, peanuts").

Verification of the Allergen Control program is by documentation that the procedures are being followed and product labeling is correct. Validation of the Allergen Control Program is by specific allergen testing swabs on equipment prior to start of the operation.

Allergenic Ingredients and Foods

1. Wheat

Consumers allergic to wheat products are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain wheat.

bread crumbs	Farina	sprouted wheat	wheat gluten
Bulgur	flour*	triticale	wheat grass
cereal extract	hydrolyzed wheat protein	vital wheat gluten	wheat malt
club wheat	Kamut	wheat	wheat protein isolate
Couscous	matzoh/matzo, matzah/matza	wheat bran	wheat sprouts
cracker meal	Pasta	wheat bran hydrolysate	wheat starch
Durum	Seitan	wheat durum	whole wheat berries
Einkorn	semolina	wheat germ	
Emmer	Spelt	wheat germ oil	

* all purpose, bread, cake, durum, enriched, graham, high gluten, high protein, instant, pastry, self-rising, soft wheat, steel ground, stone ground, whole wheat flour

Additionally, wheat is sometimes found in the following foods:

baking powders (particularly imported)	glucose syrup	starch	Worcestershire sauce
Bouillon	soy sauce	surimi	

2. Crustacean Shellfish

Consumers allergic to crustacean shellfish are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products have these ingredients, they contain a “Big 8” allergen

Barnacle	crawfish	lobster	shrimp
Crab	Krill	prawns	

Additionally, crustacean shellfish are sometimes found in the following foods:

bouillabaisse	fish stock	imitation fish/shellfish	surimi
cuttlefish ink	glucosamine	seafood flavoring	

3. Eggs

Consumers allergic to eggs are advised to avoid foods that may contain these ingredients. If meat or poultry products contain any of these, they likely contain eggs.

albumin/albumen	egg white	lysozyme	ovalbumin
dried egg	egg yolk	mayonnaise	powdered eggs
egg solids	eggnog	meringue	surimi

Additionally, eggs are sometimes found in the following foods:

baked goods	lecithin	marshmallows	nougat
egg substitutes	macaroni	marzipan	pasta

4. Fish

It is generally recommended that consumers allergic to fish should avoid all fish. The most common kinds of fish that individuals are allergic to are salmon, tuna, and halibut.

Additionally, fish is sometimes found in the following foods:

Asian foods	bouillabaisse	meatloaf	Worcestershire sauce
barbeque sauce	imitation fish/shellfish	salad dressing	

5. Peanuts

Consumers allergic to peanuts are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain peanuts.

artificial nuts	ground nuts	nut meat	peanut flour
beer nuts	mixed nuts	nut pieces	peanut protein hydrolysate
Goobers	monkey nuts	peanut butter	

Additionally, peanuts are sometimes found in the following foods:

African, Asian, Latin American foods	Chili	enchilada sauce	mole sauce
baked goods	egg rolls	marzipan	nougat
candy			

The FDA exempts highly refined peanut oil from being labeled as an allergen.

6. Milk

Consumers allergic to milk are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain milk.

butter	caseinates	half-and-half	recaldent
butter acid	cheese	lactalbumin	rennet casein
butter ester	cottage cheese	lactoferrin	sour cream
butter fat	cream	lactose	sour milk
butter oil	curds	lactulose	tagatose
buttermilk	custard	milk protein hydrosylate	whey
casein	diacetyl	milk*	whey protein hydrosylate
casein hydrolysate	ghee	pudding	yogurt

* milk in all forms (including condensed, derivative, dry, evaporated, goat's milk and milk from other animals, low fat, malted, milkfat, nonfat, powder, protein, skimmed, solids, whole)

Additionally, milk is sometimes found in the following foods:

artificial butter flavor	chocolate	luncheon meat	nondairy products
baked goods	hot dogs	margarine	nougat
bouillon	lactic acid starter culture and other bacterial cultures	nisin	sausages
caramel candies			

7. Tree Nuts

Consumers allergic to tree nuts are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain a "Big 8" allergen.

almond	coconut	Nangai nut	pili nut
artificial nuts	filbert/hazelnut	natural nut extract	pine nut
beechnut	gianduja	nut butters	pistachio
Brazil nut	ginkgo nut	nut meal	praline
butternut	hickory nut	nut paste	shea nut
cashew	litchi/lichee/lychee nut	nut pieces	walnut
chestnut	macadamia nut	pecan	
chinquapin	marzipan/almond paste	pesto	

Additionally, tree nuts are sometimes found in the following foods:

alcoholic extracts	black walnut hull extract	nut distillates	walnut hull extract
Asian foods	natural nut extract	nut oils	

8. Soybeans

Consumers allergic to soybeans are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain soybeans.

edamame	soy fiber	soy protein	tamari
miso	soy flour	soy sauce	tempeh
natto	soy grits	soy sprouts	textured vegetable protein
shoyu	soy ice cream	soy yogurt	tofu
soy albumin	soy milk	soya	
soy cheese	soy nuts	soybean	

* FDA exempts highly refined soybean oil from being labeled as an allergen. However cold-pressed soybean oil, which is less commonly used, is not exempt from allergen labeling as it likely contains more residual protein.

Additionally, soybeans are sometimes found in the following foods:

Asian foods	vegetable broth	vegetable starch	
soy lecithin*	vegetable gum	Worcestershire sauce	

* With the exception of a few specific products, FDA does not exempt soy lecithin from allergen labeling as it generally contains residual protein. The use of soy lecithin in non-stick sprays and coatings (i.e. releasing agents) has led to recalls of FSIS-regulated product when the soy was not properly declared.

III. Customer Complaint Program

Customers want their complaints to be easy to report, acknowledged, and dealt with quickly, fairly and sensitively.

A written complaint handling policy is a good way to ensure that complaints are taken seriously, and dealt with appropriately and consistently. It also helps to support your staff, so be sure they understand your policy and program.

Developing a Customer Complaint Program.

- Make it easy for all customers to complain (i.e. company phone number on the label, etc.)
- Decide which staff have the authority to resolve a complaint, and make sure they know what to do. The more a complaint is escalated to someone higher in the business, the more dissatisfied the customer may become.
- Set a time frame to respond to a complaint. Taking too long makes the problem worse.
- Give one person responsibility for managing the complaint from beginning to end, so the customer does not have to repeat their complaint to different staff. state who is responsible for taking, recording / logging, resolving, analyzing and reporting on complaints
- Ensure staff know the complaint policy and how to treat complaints fairly. Poor complaint handling, for example blaming the customer for the problem, or marginalizing them by saying “no one else has complained”, will only worsen the problem.
- If the complaint involves an injury or illness, direct the complaint to your liability insurance company. The liability insurance company will totally handle the complaint with the claimant. Company involvement with claimant will stop. Document all communications with the liability insurance company.
- Review your policy regularly, and make changes as necessary.

Example of Customer Complaint Form

Customer:			
Address:			
Phone Home: Work:	Email:		
Date Complaint received: ___ / ___ / 20___			
Person receiving the complaint:			
How was the complaint received?	Phone	In person	In writing
Describe the product:			
Describe the problem/complaint:			
What does the customer want done?			
What is the business policy for this complaint?			
What is the agreed solution?			
Action required:			
Date action completed:			
Record of action taken:			
Date complaint resolved: Signature:			

IV. Employee Hygiene and Practices

Employee hygiene and practices, also known as Good Manufacturing Practices (GMPs) or current Good Manufacturing Practices (cGMPs), are another key to producing safe, wholesome foods. The employee hygiene and practices need be written and presented to any new employee and re-presented to all employee on a regular basis. These criteria need to be followed each production day and if there is any issue of non-compliance a refresher presentation / training session would be done as part of any corrective action. A training / presentation record needs to be completed and maintained on file.

- Employee Hygiene
    1. Illness
       Work only when you are well. Do not work if:
       Feel sick; have a fever and sore throat; have diarrhea; are vomiting; have yellowing of the skin or dark tea colored urine; are sneezing and/or coughing; or have an infected cut, burn or boil. These must be covered with a bandage and the affected area must have a glove worn to cover the affected bandaged area.
    2. Hand washing – Scrub approximately 15-20 seconds with warm running water and soap, Scrub under the fingernails.
    3. All employees must wash their hands at the hand-washing sink using warm water and soap. Dry their hands using a paper towel, air dryer or roll of linen towel. Wash hands:
       Before entering the processing room; touching anything used to prepare food; or touching any food or utensils that will touch food that will not be cooked.
       After working with raw product and allergenic ingredients; retrieving anything from a non-food contact area (i.e. floor); handling the trash or taking out trash; using cleaning chemicals; or using the rest room and again when you return to the processing room; touching any bare skin area, blowing nose, coughing, sneezing, or take a smoke break.
       Before and after you eat

- Practices
    1. Do not smoke or chew tobacco while working near food.
    2. Jewelry including watches, necklaces (except medical), earrings, and other body piercing jewelry is not allowed. Plain wedding bands are allowed, but should be covered with a glove.
    3. Fake fingernails, polished finger nails and fake eye lashes are not permitted in the processing or packaging area.
    4. No objects are allowed in pockets above the waist.
    5. Ink pens must be of the single unit type (i.e., no removable cap).
    6. Gloves must be worn when handling any product. Wash and dry your hands before putting on the gloves, change the gloves if they become torn or soiled.
    7. Maintain a clean apron or coat, change as necessary, remove the apron or coat when leaving the processing room.
    8. No sleeveless shirts or shorts.

V. Employee Training / Education

Employee Training / Education may be time consuming, but will provide numerous regulatory and food safety benefits. It should be presented to any new employee(s) and re-presented to all employee(s) on a regular basis. A training / presentation record needs to be completed and maintained on file.

The following is an example of a training / education presentation outline and record.

Good Manufacturing Practices / Company Policies Training

I. Personal Hygiene
   a. Hand washing
      i. Hand washing is required after:
         1. Using restroom.
         2. Consuming food or drinks.
         3. Contacting non-food contact items.
      ii. Wash hand in designated sinks only.
      iii. Wash hands by:
         1. Pulling clothing sleeves up your arm as far as possible.
         2. Apply soap to hands and scrub for approximately 20 seconds.
         3. Rinse hands with warm water.
         4. Dry hands with disposable toweling.
         5. Place toweling in trash container.
   b. Personal Clothing:
      i. No sleeveless shirts
      ii. No shorts
      iii. Good repair (i.e. no holes, tears, etc.)
      iv. Clean
      v. Foot ware - Moisture proof, slip resistant, and toe protected
   c. Remove all of the following prior to entering the plant:
      i. Earrings
      ii. Watches
      iii. Necklaces
      iv. Bracelets
      v. Pins
      vi. Rings (plain wedding bands are acceptable)

II. Chewing gum, and tobacco products are prohibited in the plant. Food and drinks are prohibited in the production area. Food and drinks are permitted in office and lunch/ locker rooms.

III. Cuts and wounds must be covered by bandage. Bandages on hands must be covered by disposable gloves.

IV. Smocks and gloves must be removed and placed on hooks before:
   a. Entering restrooms.
   b. Consuming food or drinks.

V. No loose items (pens, thermometers, note books, etc.) that could fall out may be in pockets above your waist

VI. Glass containers are not permitted in the plant. Plant lighting is either protected or shatter-proof. Brittle plastic materials in production areas are identified and monitored.

VII. If you feel the need to cough or sneeze, please do so in the arm / shoulder of your smock.

VIII. Tools and processes
   a. Knives
      i. Raw processing – (color) handle
      ii. RTE – (color) handle
   b. Utensils, scoops (color)
   c. Pens and markers
   d. Floor sanitizing foam or mat – the floor sanitizing foam or mat is for microbiological control of our foot ware. Please step in the foam or on the mat.
   e. Equipment sanitizer.
   f. Tool sanitizer.

IX. Product safety
   a. Raw / Ready-to-Eat (RTE) separation
      i. RTE rooms are identified.
      ii. Only designated employees are allowing in the RTE rooms.
   b. Allergen control
      i. Allergenic foods as defined in the U.S. are **Milk products** (Non-Fat Dry Milk, cheeses, caseinate, and whey); **Eggs**; **Fish** (bass, flounder, cod, etc.); **Crustaceans / Shellfish** (crab, lobster, shrimp, etc.); **Peanuts** (ground nuts); **Tree nuts** (walnuts, almonds, pecans, etc.); **Wheat (glutens)**, also includes barley, rye, oats and spelt; and **Soybeans** (soy proteins, lecithin, residual proteins in soy oils).
      ii. Other food ingredients are classified as “sensitive ingredients”, which do not involve allergenic responses. Those ingredients include: sulfites, MSG, FDC Yellow #5 and #6 (food dyes).
      iii. All products produced by Kelly Corned Beef are allergen free.
      iv. Spices and seasoning ingredients are confirmed at receiving.
   c. Condensation control
      i. Condensation is water droplets on overhead surfaces (pipes, trays, cooling units and ceiling), which are <u>not</u> cleaned and sanitized each production day. These droplet may contain harmful bacteria.
      ii. If condensation is observed, immediately notify supervisor or lead person
      iii. Condensation will be wiped by use of special mop maintained in a sanitizer solution.
   d. Product container color code:
      i. (Color) and stainless steel – edible product
      ii. (Color) – Trash
      iii. (Color) – Inedible

X. Governmental or Company Hold Tag
   a. In the event of a hold tag on equipment or area, do not touch or use that equipment or enter the area.
   b. Plant management will provide directions for corrections of the issue.

XI. Food Defense / Security
   a. Your safety and our product safety is important to management.
   b. Visitors in the plant will be escorted by management or designee.
   c. If you see an unknown person not being escorted by management, report it immediately to supervisor.

XII. HACCP
   a. HACCP stands for “Hazard Analysis Critical Control Point”.
   b. HACCP is a food safety plan that evaluates and defines controls to prevent Biological (bacteria), Chemical (soaps and lubricants) and Physical (wood, plastic) contamination.
   c. Our Critical Control Points are product cook, chilling and storage temperature.
   d. If you are assigned to any of these process you will receive special training.

Training Record

Date: _____ Start Time: _____ End Time: _____

Trainer: _____

The following employees were trained on:

___ Good Manufacturing Practices / Company Policies, Food Defense / Security and HACCP

___ Lock-out / Tag-out

___ Other, as listed below:

Employee Names:

Verification:
The following categories were confirmed by verbal response from employee(s):

_____

_____

VI. Equipment Calibration

Equipment calibration is the adjustment of the equipment with a known standard. Equipment specifications will list the accuracy of the readings. In general, the more expensive the equipment the more accurate the readings.

Equipment accuracy needed depends on the intended use. If the equipment is measuring a Critical Control Point, then based on its accuracy, it will require different reading than that listed as the Critical Limit in the HACCP plan. For example, if the designated thermal processing thermometer accuracy or calibration is $\pm$ 2^0F and the Critical Limit is 160^0F, then the product needs to be cooked to 162^0F to assure that the product is cooked to 160^0F.

A. pH meter

Buffers. A pH meter calibration is performed by measuring a series of reference standards, also called pH buffers that have known and accurate pH values at different temperatures.

Before Calibration. Proper cleaning of the electrode prior to calibration is essential. If you have stored your electrode, make sure it is ready for use.

Calibration.

- Turn the pH meter on and allow adequate time to warm up (check the operating manual).
- Select two pH buffers that bracket the expected sample pH. The first buffer should be pH 7.00 (zero point adjustment) and the second buffer should be near the expected sample pH (pH 4 or pH 9.21). If you will measure both acidic and basic samples, and only perform one pH calibration, you should use a multi-point calibration.
- Before starting calibration, be sure the sensor and the buffer solution are at the same temperature. If not, allow time for temperature equilibration.
- Pour the necessary amount of buffer solutions into individual glass beakers. Buffer solutions will remain stable in a glass beaker for a maximum of 2 hours. Note: To minimize the risk of contamination, calibrations should never be carried out in the storage container.
  Close the buffer containers promptly to avoid carbon dioxide absorption. Do not pour used buffer back into the storage container. Discard it.
- Place the electrode into the first buffer. When the reading is stable, set the pH meter to the pH value of the first buffer at the measured temperature. Most modern pH meters have an "auto-read" function for early detection of a stabilized reading.
  It is not strictly necessary to stir samples for pH measurement. However, if the buffer solutions are stirred, then the sample should also be stirred in the same way.
- Between buffers, rinse the electrode with distilled water and then with the next buffer.
  If you do not want to rinse the pH electrode with the next buffer, rinse the electrode with distilled water and gently blot it dry with a lint-free tissue. Avoid rubbing or wiping the electrode bulb.
- Repeat step 3 for the next buffer.
- When the pH meter calibration is done, rinse the electrode and place into the sample and make your pH measurement.

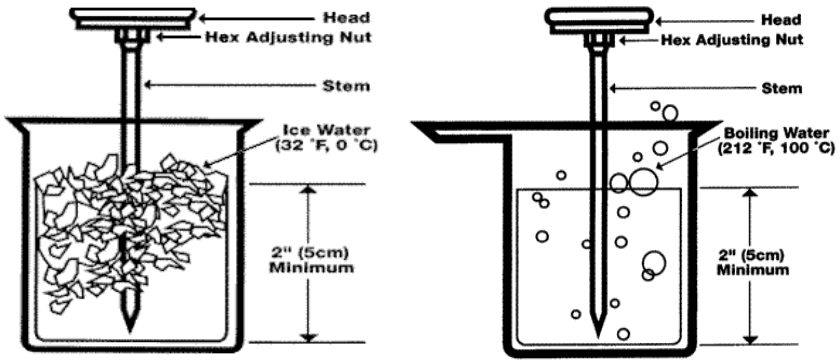
Note. Some pH meters also give recommendations regarding the used pH electrode. The electrode may need to be cleaned or replaced.

B. Thermometer

1. Bi-metal Coil Thermometer

Ice Point Method

- Fill an insulated container, such as a wide mouth "thermos" bottle with a mixture of potable crushed ice and water.
- The container must have crushed ice throughout to provide an environment of 32°F, so you may have to pack more ice into the container during the process.
- When the mixture of the water has stabilized after four or five minutes, insert the thermometer to be calibrated to the appropriate immersion depth (note: from tip of thermometer to the dimple on stem is the sensing portion).
- Be sure to hold the stem of the instrument away from the bottom and sides of the container (preferably one inch) to avoid error. Wait until the thermometer stabilizes before adjusting the thermometer.
- If your thermometer is not accurate within +/- 2°F of 32°F., adjust the thermometer accordingly. The ice point method permits calibration to within 0.1°F.



Boiling Point Method

- After the water in the container has reached a complete "rolling" boil, insert the instrument to the appropriate immersion depth. The boiling point in the Midwest U.S. is 212°F.
- Be sure there is at least a two-inch clearance between the stem or sensing element and the bottom and sides of the container.
- If your thermometer is not accurate within +/- 2°F of 212°F., adjust thermometer accordingly. The boiling point method permits calibration to within 1.0°F.

2. Thermocouple thermometer

- The calibration methods used for bi-metal coil thermometers can be used for thermocouple thermometers.
- Some electronic units include a calibration mode, which does an internal circuitry calibration. However, a thermocouple thermometer must be checked with external temperatures to ensure proper reading within a specified temperature range. As with any electronic equipment, check with the manufacturer for the proper method to calibrate the instrument.

3. **Thermistor thermometer**
   - Thermistors are fragile and can lose calibration at extremely high temperatures. Because of the nature of the component metals, thermistors are not easy to calibrate. These instruments may have an internal calibration setting similar to a thermocouple thermometer.
   - Using the method described for bi-metal coil thermometers will indicate if the instrument is operating within a specified temperature. Check with the manufacturer for proper calibration methodology for thermistors.
4. **Smokehouse Temperature Recording Device (Thermocouple or RTD)**
   - Batch or continuous ovens (smoke house) use either thermocouples or RTD to monitor oven temperature during thermal processing. Oven temperature must be continuously recorded by a chart recorder. Several electrical components involved in this process must be checked weekly and calibrated monthly by a certified technician or by the equipment manufacturer service technician. The accuracy of the probes can be checked by placing them into 140^0F to 180^0F hot water and comparing the temperature reading to a certified NIST reference thermometer. Note: if the thermocouple or RTD is used during chilling, they should be checked by placing them into 40^0F to 80^0F cool water and comparing the temperature reading to a certified NIST reference thermometer.
   - Record keeping is essential to track trends and any possible drift in temperature measurement.
5. **IR thermometer**
   - IR thermometers are calibrated using a "Blackbody," which emits a given amount of energy at a given temperature. A blackbody calibration instrument is expensive. Most manufacturers of NIST IR thermometers provide a calibration service for a nominal fee for yearly calibration and certification.
   - However, IR thermometers accuracy can be verified by using the following simple procedure. It is suggested that the accuracy of the instrument be verified on a regular basis. For food applications, the IR thermometer accuracy should be verified at the relevant critical food temperatures (40°F to 80^0F) or (140° to 165°F). A two-point verification is recommended.

Materials needed:

1. Aluminum container (beverage can).

2. Matte-black spray paint or matte-black self-adhering paper appliqué. Masking tape may also be used.

3. Temperature-standard thermometer.

Preparation: - Prepare container by painting or applying the matte material to the outer surface.

Verification Procedure:

1. Fill the aluminum container with water, insert the temperature standard thermometer and allow the can and temperature-standard thermometer to come to equilibrium.

2. Take a reading with the IR thermometer pointed at the outer surface. Do not exceed the spot size of the IR thermometer as indicated on the unit.

3. Compare the temperature reading of the IR unit with the temperature standard thermometer.

VII. Facility Condition and Temperature

The set point and controls of processing and storage areas in a facility are important for control of bacteria growth on equipment and product. The growth of bacteria with sources of food is a time and temperature relationship. The longer the time the product is held at optimum bacteria growth temperature the shorter the shelf life and greater potential for pathogenic (food poisoning) bacteria.

Processing areas, however, can be set at too low of a temperature. This is especially true when the process generates moisture or steam and after wet sanitation cleaning. When the warm moist air contacts a colder surface, condensation forms. The concern is that those surfaces than are not cleaned and sanitized may contain pathogenic bacteria and will contaminate the food or food contract surfaces.

The following are recommended facility temperature settings:

- Processing areas: 50^0F or less
- Storage Coolers for Raw materials: 45^0F or less for chilling, 40^0F or less for storage
- Storage Coolers for Ready-to-Eat products: 40^0F or less
- Freezer: 10^0F or less

Facility rooms or area temperature should be measured by a calibrated room or area thermometer or a hand held calibrated thermometer.

The location of thermometer in the room or area will be dependent on air flow and warmest location in relation to the product.

Facility rooms or area temperature shall be recorded at least prior to the start of operations. Temperatures shall not be recorded when refrigeration units are in defrost mode.

It is recommended that storage coolers / freezers be monitored each day or contain a 24/7 alarm system.

VIII. Food Defense / Product Tampering / Crisis Management

Food defense is *not* the same as food safety. Food defense focuses on protecting the food supply from intentional contamination, with a variety of chemicals, biological agents or other harmful substances by people who want to do us harm. These agents could include materials that are not naturally-occurring or are not routinely tested for. An attacker's goal might be to kill people or disrupt our economy. Intentional acts are generally not reasonable and are hard to predict.

A Food Defense Plan helps you identify steps you can take to minimize the risk that food products in your establishment will be intentionally contaminated or tampered with. A plan increases preparedness. Although the plan should be in place at all times, it may be particularly helpful during emergencies. During a crisis, when stress is high and response time is at a premium, a documented set of procedures improves your ability to respond quickly.

Steps in Developing a Food Defense Plan

Step 1 – Conduct a Food Defense Assessment. Begin by choosing a person or team to be responsible for the security of the facility. The team or responsible person will answer the questions an assessment to help understand which parts of the facility may be more vulnerable. When completing this assessment remember to consider both potential internal and external threats. The results of the assessment should be kept confidential so that they do not provide a roadmap for future attacks.

Areas to include in the assessment:

- Outside Security
- General Inside Security
- Processing Area Security
- Storage Security
- Shipping and Receiving Security
- Water and Ice Security
- Mail Handling Security
- Personnel Security

Step 2 – Develop a Food Defense Plan

Vulnerable areas outside or inside your plant, or procedures used in daily operations that are identified should be address with cost-effective preventive actions that can be taken to minimize those vulnerabilities.

Step 3 – Implement the Food Defense Plan

Implementing the food defense plan includes assigning responsibilities, training staff, conducting drills, developing contact lists, and checking your recall plan.

Product tampering is defined as any act that changes a product in a way that could lead to injury. It can be classified in different ways depending on the circumstances surrounding the offense. These classifications include:

- Threatening to tamper with a product is classified as a third-degree felony.
- Tampering with a product is classified as a second-degree felony.
- Tampering with a product, leading to injury, is classified as a first-degree felony

How to detect product tampering at receiving

- Carefully examine all food product packaging. Be aware of the normal appearance of food containers. That way you'll be more likely to notice if an outer seal or wrapper is missing. Compare a suspect container with others.
- Check any anti-tampering devices on packaging. Make sure that product container seal is intact.
- Don't accept products if the packaging is open, torn, or damaged.
- Don't accept products that are damaged or that look unusual.
- Check the code date or lot code dates as compared to bill of lading.

Crisis Management is an advance plan to address company “crisis” situations. Some of the most common crises confronted are: natural disasters, product tampering or threats of product tampering, food borne illness outbreaks, government investigations, unauthorized photography of plant operations, strikes, demonstrations and product boycotts, workplace accidents and food security issues. Events threatening the safety or quality of a company’s products seriously jeopardize the reputation of the company. In addition, company officials are subject to criminal and civil liability resulting from their failure to respond efficiently and effectively to incidents adversely affecting the safety or quality of products being manufactured.

A written crisis management plan enables a company to respond to particular crisis in a way that reduces most dramatically the exposure of the company, its executives and its products to the adverse consequences that crises can bring. Indeed, the mere existence of a plan helps prevent “knee jerk” reactions by the company and those government agencies that become aware of a crisis.

The key elements of crisis management planning include advance planning, fact gathering, fact sharing (communication) and corrective action. Advance planning needs to include a listing of emergency contact numbers, spokesperson and business continuation options. Some facilities will sign business continuation agreements with other facilities.

IX. Foreign Object Control

Foreign objects control includes metal, rubber, glass, wood, steel shot and lead shot. Other items associated with equipment or tools (such as hard / brittle plastic) may also be considered foreign objects. Items that are naturally a part of the raw material (i.e. seeds, stems, nut shells) are not considered foreign objects, but need to be controlled to prevent consumer injury.

Bones in meat products are not considered foreign material because they are a natural part of the carcass. Foreign materials are non-animal objects such as metal, rubber, glass, wood, steel and lead shot (Ask Karen, USDA, FSIS 03/26/2009).

Hard or sharp natural components of a food (e.g. bones in seafood, shell in nut products) are unlikely to cause injury because of awareness on the part of the consumer that the component is a natural and intrinsic component of a particular product. The exception occurs when the food's label represents that the hard or sharp component has been removed from the food, e.g., pitted olives. The presence of the naturally occurring hard or sharp object in those situations (e.g., pit fragments in pitted olives) is unexpected and may cause injury. Product is considered adulterated if the product contains a hard or sharp foreign object that measures 7 mm to 25 mm (1/4" to 1"), in length, and the product is ready-to-eat, or according to instructions or other guidance or requirements, it requires only minimal preparation steps, e.g., heating, that would not eliminate, invalidate, or neutralize the hazard prior to consumption (FDA Compliance Policy Guide, Updated: 2005-11-29, SECTION 555.425).

Foreign object verification is the examination of all potential sources. This includes examination of raw materials for plastic, cardboard, wood and steel or lead shot, etc. Examination of equipment with metal to metal contact, conveyor belting, gage and other protective shields should be performed at pre-operational inspection and at the end of the production day. In processing area, wood pallets should be maintained below product work areas.

If an incident occurs in which product may have become contaminated with a foreign material, the facility is to examine the suspect product and to sort out and properly decontaminate or dispose of any adulterated product. When examining suspect product to segregate contaminated product, regulatory agencies expects a facility to use the most effective (sifting, magnet, etc.) or sensitive detection technique (metal detection, X-ray, etc.) available and to have a supportable justification as to how the procedures it employs will detect the foreign materials present.

A. Glass, Brittle Plastic and Ceramic Materials

All glass must be shatter proof or be protected by a shatterproof barrier. Items that should have shatter proof lights or shatter proof barriers on the lights include: all overhead lights in Shipping/Receiving, Storage, Processing and Packaging areas, door windows, room windows, exit lights, hi-lo lights, emergency power lights, loading dock lights, maintenance lights. Shatter proof glass should be on equipment viewing guards, ports and gages.

Brittle plastic and ceramic utensils and containers need to be examined between each use.

A list of all items should be developed and examined on a defined basis.

B. Metal Materials

The hazard of metal inclusion may also be controlled by periodically examining the processing equipment for damage that can contribute metal fragments to the product. This measure will not necessarily prevent metal fragments from being incorporated into the product, but it will enable the facility to separate products that may have been exposed to metal fragments. Visually inspecting equipment for damaged or missing parts may only be feasible with relatively simple equipment, such as band saws, small orbital blenders, and wire mesh belts. More complex equipment that contains many parts, some of which may not be readily visible, may not be suitable for visual inspection and may require controls such as metal detection or separation.

Metal detectors have been utilized for various reasons in food processing. Metal detection can be used to test initial processing of incoming raw materials or in process steps to preventative damage to processing equipment. The use of metal detection or x-ray examination of finished product is associated with food safety. The use of detection should not be used as a method in place of equipment or facility maintenance and observations.

Once introduced into a product, metal fragments may be removed from the product by passing it through a screen, magnet, or flotation tank. The effectiveness of these measures depends on the nature of the product. These measures are more likely to be effective in liquids, powders, and similar products in which the metal fragment will not become imbedded.

The use of electronic metal detectors is complex, especially with regard to stainless steel, which is difficult to detect. The orientation of the metal object in the food affects the ability of the equipment to detect it. For example, if a detector is not properly calibrated and is set to detect a sphere 0.08 inch (2 mm) in diameter, it may fail to detect a stainless steel wire that is smaller in diameter but up to 0.9 inch

(24 mm) long, depending on the orientation of the wire as it travels through the detector.

Processing and product factors will affect the conductivity of the product and create an interference signal that may mask metal inclusion. These factors include: stability of detector (vibration), ambient humidity, product temperature (frozen product is more sensitive for detection), product acidity, salt and spice content.

At the start and end of each production run, test the functionality of the metal detector. This requires placing the detection wands on or under a piece of product. The metal detector must reject this detection wand under product 3 out of 3 times.

Test Standards	Example
Non-Ferrous	1.5 mm
Ferrous	1.5 mm
316 Stainless Steel	2.5 mm

X. Ingredient Control, Traceability and Lot Coding

A. Water

At any processing facility, water is the most widely utilized substance. Water uses may include raw material rinsing, thawing, cooking, chilling, ice making, initial and final rinsing of equipment. The quality of the water additionally affects the functionality of ingredients and effectiveness of sanitation cleaners and sanitizers.

Municipal Water. For municipal water, a water report or certificate from the State or municipal water authority is acceptable that the water complies with federal water quality standards of 40 CFR Part 141.

Ice. Ice may be purchased from a retail store or ice manufacturer that is intended to be used for human consumption to cool or formulate product. Generally, such ice would have been produced under applicable FDA, state, or local requirements for ice intended for use in contact with food. Ice manufacturing establishments and retail stores that sell ice are required to be licensed and regulated by the State and local (county, city) authorities.

Private Well Water. For private well water, an accredited laboratory certifying or attesting to the water's potability provides evidence that the water supply is in compliance with 40 CFR Part 141. Private well water testing is required every 6 months.

Either source of water certification does not guarantee that the water is microbiologically acceptable at point of use. Depending of the age and type of piping and pipe connections, water and ice microbial testing is recommended.

If steam is utilized for direct or indirect product contact, the use of approved boiler treatment compound is required.

B. Raw Materials and Ingredients

Incoming raw materials and ingredient control starts at purchasing. When ordering these materials, the use of product numbers versus product names avoids confusion.

Confirmation of ingredient. Incoming raw materials and ingredient purchase orders should be compared to the receiving bill of lading. The supplier's lot number needs to be recorded or confirmed if supplied.

Rotation of ingredients. If the supplier uses an open code date, this should to be compared to the material or ingredient on hand in inventory. Proper rotation to utilize that material or ingredient in order needs to be based on the age of the product. Another option for product rotation is based on received date also known as First-in / first out (FIFO). This method does not take in to account the suppliers code date.

Ingredient controls. Each item with multiple ingredient should also be compared to specifications or previous shipment to confirm that the ingredients are still the same. This verification of the item's ingredient will prevent production of product that would be misbranded and result in a product recall.

Restricted Ingredients. Restricted ingredients are items that can be used within specific limits in the product. Most restricted ingredient limits are based on the functional affects and "economic adulteration" without food safety affects or concerns. Other restricted ingredients have food safety affects when used at the appropriate levels. All restricted ingredients need to have documentation for each batch or production lot of product.

Certificate of Analysis (COA). Certificate of Analysis is a document from the supplier that confirms that the ingredient meets or exceeds specifications. COA should be reviewed prior to delivery and then confirmed that the ingredient lot number matches the received ingredient. COAs need to be maintained on file.

C. Traceability

Traceability starts with labeling or marking the ingredient with the receiving date. Additionally, a record with receiving date; product name; product code and lot number is a benefit.

The next step in traceability is recording of the product lot code used either for that production day or lot of product. This record needs to be maintained and tied to the finished product lot code.

D. Lot Coding

Lot coding is the facilities method of identification of the finished product. A lot code time frame is dependent upon the product isolation / recall risk that the facility wants to take.

There are various options for lot coding of finished product. The lot code may be:

- Open Code
  Date Code (packed on, use-by, sell-by or best before) Jan 01 2015
- Closed Code
  Julian date plus year (i.e. January 01, 2015 = 001 15)
  A numerical and alphabetic system that only the facility can translate.
- Additional code. This code provides the facility additional information on the product. It may include machine pocket number, packaging line, production hour, etc.

Lot codes on packages need to be confirmed each production day or production lot.

XI. Label Approval

Label development for accurate identification of the product is defined by federal laws. Proper labeling is a complex process due to the various criteria enforced.

Mandatory items on a label include:

- **Product Name -** based on "Standard of Identity" or "Truthful Name"
- **Ingredients** - Listed by order of predominance
- **Net Contents** – Net weight ___ lbs. (oz.)
- **Company Name and Address**
- **Handling Statement** (i.e. Keep Refrigerated)
- **Allergen Statement** (USDA voluntary)
- **Inspection Legend / Establishment Number** (USDA and State Inspected)
- **Safe Handling Instructions** (USDA raw products)
- **Nutritional Information Panel** (exemptions apply)

A record of label approval must be maintained on file with the following information:

- Product Name
- HACCP Category
- Product formulation
- Processing procedure
- Finished Label

XII. Laboratory Practices

A. Internal

Internal laboratories size and scope vary depending on the facilities product or processes. Basic laboratory capability may include general microbiological and chemical analysis.

General microbiological analysis would include purchased analytical kits and an incubator. This type of testing would be for pre-operational, operational and environmental air. The main disadvantage of historical testing methods is the length of time the testing takes. It can typically take 48 to 72 hours for the completion of a test. Recent advances in technology have provided rapid (less than 10 minute) ATP bioluminescence analysis of sanitation effectiveness. ATP bioluminescence is a rapid, simple, and reliable test to monitor surface contamination during processing and to detect contaminants in drinking water or beverages. In the case of surface contamination, a pen-like device containing reagents is simply swabbed over an area, then inserted into a handheld reader that displays results within seconds in relative light units (RLU), indicating clean/unclean and, in some cases, marginal results. The cost is only dollars per test. Since ATP methods only give a broad measure of the presence of organic substances—not the specific microorganism containing the molecule—they must still be used in conjunction with microbial culture or other tests.

General chemical analysis could include criteria that the raw material received met or exceeded specifications. Some examples of this type of testing are fat, moisture, pH, sifting screens, and water activity. Certain analysis can be as a non-certified test to provide a claim against the raw material. Typically, a supplier will require additional sampling and testing by an outside certified laboratory. Finished product testing can be used for shelf stability confirmation.

Most importantly, the analysis method need to follow appropriate recognized standards and record keeping. Additionally, the equipment accuracy must be verified and recorded on each production day.

B. Outside

Outside independent laboratories provide a variety of services depending on their capabilities. When selecting an outside laboratory, the USDA recommends the following criteria: Personnel qualifications; Procedures for sample receipt and handling, sample integrity maintenance, identity and chain of custody; Quality assurance management system; Method selection and implementation; and Reporting of results and establishment's interpretation of results. At a minimum the outside laboratory must be ISO 17025 accredited.

C. Documentation

The following documentation is needed by a facility during regulatory audits:

- Testing protocol for requested analyses, including modification necessary to meet the needs of the establishment program;
- Evidence of method validation;
- Establishment's sampling plan, including purpose, type, and frequency of sampling;
- Correspondence between the establishment and laboratory, including acknowledgement from the laboratory that it meets the criteria established in this guidance (for example, including a completed laboratory assessment checklist);
- Chain of Custody (COC) documentation when samples are needed to be transported from the establishment to an off-site laboratory (e.g. by a delivery service such as FedEx or courier) where they may not be under the direct control of the establishment or the laboratory for a period of time;
- Microbiological test results and reports;
- Interpretation of results (acceptable/unacceptable) for use by the establishment such as applying results to determine process control or following HACCP (Hazard Critical Control Points) plan, or integrating results in conjunction with SOP;
- Corrective actions related to test results, such as laboratory error, unacceptable sample temperature or failed proficiency testing;
- Data and supporting documentation associated with testing; and
- Testing associated with prerequisite programs and with good manufacturing procedures

.

XIII. Letters of Guarantee

Letters of guarantee are legal documents that protect facilities from penalties if a supplier provides adulterated or misbranded food additives. Letters of guarantee have expanded to include any ingredient, compound or substance provided from an FDA regulated facility.

A file of these letters from suppliers (manufactures or distributors) should be maintained.

Title 21 CFR 7.13 "Suggested forms of guaranty", provide example language for limited or general and continuing letters of guarantee.

A. Limited to a specific shipment or other delivery of an article, in which case it may be a part of or attached to the invoice or bill of sale covering such shipment or delivery.

   "(Name of person giving the guaranty or undertaking) hereby guarantees that no article listed herein is adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, or is an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce."

   (Signature and post-office address of person giving the guaranty or undertaking.)

B. General and continuing, in which case, in its application to any shipment or other delivery of an article, it shall be considered to have been given at the date such article was shipped or delivered by the person who gives the guaranty or undertaking.
   "The article comprising each shipment or other delivery hereafter made by (name of person giving the guaranty or undertaking) to, or in the order of (name and post-office address of person to whom the guaranty or undertaking is given) is hereby guaranteed, as of the date of such shipment or delivery, to be, on such date, not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, and not an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce."

   (Signature and post-office address of person giving the guaranty of undertaking.)

C. Packaging Material
   In addition to the above statements, packaging materials need the following information included in the letter:
   - Statement that the material complies with the FFDCA and all applicable food additive regulations;
   - Brand name or code designation of the material;
   - Name of the supplier;
   - Conditions of use for the material, including temperature and other pertinent limits; and
   - Signature of an official of the supplier.

   Facilities must maintain a file containing guaranties for all packaging materials on site. This file must be open to regulatory officials at all times. All packaging materials in the facility must be traceable to a guaranty in the file.

XIV. Lock-out / Tag-out Program

This procedure establishes the requirements for the lockout/tag out of energy isolating devices whenever pre-operational or operational sanitation process verification or verification of corrective actions tasks are done on machines or equipment that may expose inspection personnel to hazardous energy. It shall be used to ensure that the machines or equipment is stopped, isolated from all potentially hazardous energy sources and locked or tagged out before any inspection personnel perform pre-operational/sanitation inspection tasks where the unexpected energization or start-up of the machine or equipment or release of stored energy could cause injury. These procedures do not apply to pre-operational/operational sanitation inspection tasks that do not expose inspection personnel to unexpected release of hazardous energy. These procedures also do not apply to cord and plug connected electrical equipment under following conditions: (1) The hazard must be controlled by unplugging the equipment from the energy source and (2) the plug must be under the exclusive control of the person performing the pre-operational sanitation inspection.

COMPLIANCE WITH THIS PROGRAM

All FSIS and plant employees are required to comply with the restrictions and limitations imposed upon them during the use of lockout/tag out procedures. The authorized FSIS and plant employees are required to perform the lockout/tag out in accordance with this procedure. All employees, upon observing a machine or piece of equipment which is locked/tagged out to perform pre-operational sanitation inspection or other servicing tasks shall not attempt to start, energize, or use that equipment or machine.

SEQUENCE OF LOCKOUT

(1) The secondary authorized FSIS employee will inform the primary authorized plant employee of the machines or equipment that will be inspected.
(2) The primary authorized plant employee will notify all affected employees that sanitation inspection is required on a machine or equipment and that the machine or equipment must be shut down and locked/tagged out to perform the inspection.
(3) The authorized FSIS and plant employees shall refer to the plant lockout/tag out procedures for the following information:

A. Description and location of machinery or equipment subject to lock/tag out.
B. Type and magnitude of the energy that the machine or equipment utilizes.
C. Hazards of the energy.
D. Type and location of machine or equipment operating controls.
E. Type and location of energy isolating devices.
F. The lockout/tag out procedure used to lockout or tag out the machine or equipment.
G. Type of stored energy and method to dissipate or restrain.
H. Method of verifying the isolation of the machine or equipment.

(4) If a machine or equipment is operating, the primary authorized plant employee will shut down the machine or equipment by the normal stopping procedure.
(5) The primary authorized plant employee will de-activate the energy isolating device (s).
(6) Lockout or tag out the energy isolating devices with one of the following procedures.

A. The primary authorized plant employee will lock/tag out the energy-isolating device with an assigned individual lock or tag. The FSIS secondary authorized employee will place his/her lock or tag on the energy-isolating device.

AND/OR

B. The primary authorized plant employee will lock/tag out the energy-isolating device with an assigned individual lock or tag. The key to the lock or the tab to the tag will be placed in a lockbox. The primary authorized plant employee and the secondary authorized FSIS employee will affix his/her lock on the lockbox.

(7) The primary authorized plant employee will dissipate or restrain stored energy.
(8) The primary authorized plant employee will verify the isolation of the equipment or machine. The secondary authorized FSIS employee will observe verification tests and prior to inspection will be certain that all energy sources have been isolated and there is no stored energy.
(9) If the machine or equipment is satisfactorily locked or tagged out, then the secondary authorized FSIS employee will initiate pre-operational sanitation inspection tasks, following the procedures in the sanitation standard operating procedures (SSOP) guide.

RESTORING EQUIPMENT OR MACHINES TO SERVICE

(1) Upon completion of the SSOP tasks, the secondary authorized FSIS employee will remove his/her lockout devices and/or tags and inform the primary authorized plant employee that the machine or equipment is ready to return to operating condition. The secondary authorized FSIS employee will never leave a plant without removing locks/tags.
(2) The primary authorized plant employee will check the machine or equipment and the immediate area to ensure that nonessential items have been removed and the machine or equipment components are operationally intact.
(3) The primary authorized plant employee will check the work area to ensure that all affected employees have been safety positioned or removed from the area.
(4) The primary authorized plant employee will verify that the controls are neutral.
(5) The primary authorized plant employee will remove his/her lockout devises and/or tag and re-energize the machine or equipment.
(6) The primary authorized plant employee will notify affected employees that the pre-operational inspection is completed and the machine or equipment is ready for use.

GENERAL

The plant will immediately inform FSIS when there is a change in machines, equipment, or energy control procedure.

If lockout/tag out procedures have not been implemented, SSOP hands-on verification tasks will not be performed. If this occurs, the secondary authorized FSIS employee will take "Official Control Action" (i.e., U.S. Reject Tag procedure) in the area (s) of the plant where machines or equipment are located. The inspector will inform plant management of this action and withdraw him/herself and other inspectors to a safe location.

TRAINING

All authorized employees must be trained and familiar with the requirements of the OSHA standards, and the cooperative agreement, covering lockout/tag out, agreed to at this establishment.

This agreement shall be subject to review and modification at any time by either Company or FSIS if problems or concerns arise during its execution.

XV. Maintenance

A. Preventative

The primary goal of maintenance is to avoid or mitigate the consequences of failure of equipment. This may be by preventing the failure before it actually occurs by Planned Maintenance and Condition Based Maintenance programs. It is designed to preserve and restore equipment reliability by replacing worn components before they actually fail. Preventive maintenance activities include partial or complete overhauls at specified periods, oil changes, lubrication, etc. In addition, maintenance employees can record equipment deterioration so they know to replace or repair worn parts before they cause system failure. The ideal preventive maintenance program would prevent all equipment failure before it occurs.

A preventative maintenance program would include:

- Food handling equipment list.
- Precautions. Repairs are conducted by designated personnel or outside contractors that are trained in Good Manufacturing Practices procedures for personal hygiene, food defense / security and product contamination. Preventative maintenance is performed during non-production hours prior to sanitation of the equipment and facility.
- Preventative Maintenance Schedule performed on at least a monthly basis.
- Emergency Repair. Plant manager or designee must be notified prior to emergency repair. Emergency repair of removal equipment is done in non-production area. Repair of non-removal equipment during production hours will be separated by appropriate physical barrier to prevent product contamination.
- Post Repair Control / Sanitation. Any equipment that repaired during operations or post sanitation will be identified with “Clean Prior to Use” tag.
- Tool Accountability. Accountability for tools utilized during preventative maintenance will be documented on the Preventative Maintenance Schedule.

B. Temporary Repairs

Temporary repairs are also addressed in the maintenance program. These repairs should be limited to the time to accomplish a permanent repair. Materials identified as not acceptable for temporary repairs would include: Tape, porous / fibrous materials or other materials that are not cleanable.

C. Lubricants and Nonfood Compounds

Lubricants and non-food compounds must be clearly identified in all areas of the facility. Incidental food contact lubricants shall be from not allergenic ingredients. Any lubricant should not be stored in the production areas. Incidental food contact lubricants should be stored separately from non-food contact lubricants.

After USDA stopped approving and publishing a Nonfood Compound listing, NSF International adopted the program to evaluate the risk of contamination of chemical compounds used in and around food processing facilities. Nonfood compounds and proprietary substances found compliant to food safety regulations are listed in the NSF White Book™. The following is a partial category listing utilized:

G1 Water Treatment Products – General
G2 Water Treatment Products – Phosphate
G3 Water Treatment Products – Silicate
G4 Water Treatment Products – Chlorine
G5 Cooling and retort water products (all areas)
G6 Boiler, steam line products – food contacts (all areas)
G7 Boiler, steam line products – nonfood contact (all areas)
G8 Cooling and retort water treatment (non-meat and poultry areas)
G9 Boiler treatment - food contact (non-meat and poultry areas)
G10 Boiler treatment - nonfood contact (non-meat and poultry areas)
GX Ingredients for use in Water Treatment Products
H1 Lubricants – General incidental contact
H2 Lubricants – General no contact
H3 Soluble oils
HX-1 Ingredients for use in H1 lubricants (incidental contact)
HX-2 Ingredients for use in H2 lubricants (nonfood contact)
HX-3 Ingredients for use in H3 lubricants (soluble oils)
HT1 Heat transfer
HT2 Heat transfer fluids – no food contact r fluids – incidental food contact
HTX-1 Ingredients for use in HT1 heat transfer fluids (incidental contact)
HTX-2 Ingredients for use in HT2 heat transfer fluids (no food contact)
J1 Absorbents/Anti-slip agents – General
JX Ingredients for use in Absorbents/Anti-slip agents
K1 Solvent cleaners – Non-processing area products
K2 Solvent cleaners – Electronic instrument cleaners
K3 Solvent cleaners – Adhesives/glue removers
KX Ingredients for use in Solvent Cleaners
L1 Sewer and Drain Cleaners - General
L2 Sewer and Drain Cleaners - Enzymatic
LX Ingredients for use in Sewer and Drain Cleaners

XVI. Microbial & Chemical Control

A. Raw Material (Harvest anti-microbial, Pathogens, Chemical Residues)

Depending on the raw materials purchased and the finished product manufactured, microbial and chemical controls by the harvester is critical for food safety. Raw material controls need to be grown based on appropriate "good practices". The good practices for that raw material are available through governmental agencies / departments or commodity associations. Documentation relating to origin of the raw material (where animals were born, source and genetic properties of the seed, etc.); growing methods and location (organic, where the raw material was raised or grown, etc.); and harvested location are becoming more prevalent. These practices are in place for marketing and labeling compliance and certification.

Harvest anti-microbial. Harvest anti-microbial treatments application needs to be appropriate for the raw material and included in the facilities HACCP plan as a CCP or prerequisite program. The treatment compounds typically are classified as a process aid and do not need to be listed on the label, but they need to be effective at the concentration applied and meet any claim (organic, natural, etc.) restrictions. The anti-microbial treatments have be shown to increase the shelf life of the raw material by elimination of spoilage and pathogenic bacteria. However, if recontamination of the raw material with pathogenic bacteria occurs, there is not competitive bacteria to help control a potential issue.

Pathogens. Foodborne illness (sometimes called "foodborne disease," "foodborne infection," or "food poisoning") is a common, costly—yet preventable—public health problem. Each year, 1 in 6 Americans gets sick by consuming contaminated foods or beverages. Many different disease-causing microbes, or pathogens, can contaminate foods, so there are many different foodborne infections.

More than 250 different foodborne diseases have been described by Center for Disease Control (CDC). Most of these diseases are infections, caused by a variety of bacteria, viruses, and parasites that can be foodborne. These different diseases have many different symptoms, so there is no one "syndrome" that is foodborne illness. However, the microbe or toxin enters the body through the gastrointestinal tract, and often causes the first symptoms there, so nausea, vomiting, abdominal cramps and diarrhea are common symptoms in many foodborne diseases.

Many microbes can spread in more than one way, so we cannot always know that a disease is foodborne. The distinction matters, because public health authorities need to know how a particular disease is spreading to take the appropriate steps to stop it.

For example, Escherichia coliO157:H7 infections can spread through contaminated food, contaminated drinking water, contaminated swimming water, and from toddler to toddler at a day care center. Depending on which means of spread caused a case, the measures to stop other cases from occurring could range from

removing contaminated food from stores, chlorinating a swimming pool, or closing a child day care center.

Campylobacter is a bacterial pathogen that causes fever, diarrhea, and abdominal cramps. It is the most commonly identified bacterial cause of diarrheal illness in the world. These bacteria live in the intestines of healthy birds, and most raw poultry meat has Campylobacter on it. Eating undercooked chicken, or other food that has been contaminated with juices dripping from raw chicken is the most frequent source of this infection.

Clostridium perfringens (C. perfringens) is a spore-forming gram-positive bacterium that is found in many environmental sources as well as in the intestines of humans and animals. C. perfringens is commonly found on raw meat and poultry. It can survive in conditions with very little or no oxygen. C. perfringens produces a toxin that causes illness.

Norovirus (previously called Norwalk-like virus) is an extremely common cause of foodborne illness, though it is rarely diagnosed, because the laboratory test is not widely available. It causes an acute gastrointestinal illness, usually with more vomiting than diarrhea that generally resolves within three days. Unlike many foodborne pathogens that have animal reservoirs, norovirus spreads primarily from one infected person to another, often through contaminated food, water, or environmental surfaces. Infected kitchen workers can contaminate a salad or sandwich as they prepare it, if they have the virus on their hands

Salmonella is a bacterium that is widespread in the intestines of birds, reptiles and mammals. It can spread to humans via a variety of different foods of animal origin. The illness it causes, salmonellosis, typically includes fever, diarrhea and abdominal cramps. In persons with poor underlying health or weakened immune systems, it can invade the bloodstream and cause life-threatening infections.

Some common diseases are occasionally foodborne, even though they are usually transmitted by other routes. These include infections caused by Shigella, hepatitis A, and the parasites Giardia lamblia and Cryptosporidia. Even strep throats have been transmitted occasionally through food. In addition to disease caused by direct infection, some foodborne diseases are caused by the presence of a toxin in the food that was produced by a microbe in the food.

For example, the bacterium Staphylococcus aureus can grow in some foods and produce a toxin that causes intense vomiting.

The rare but deadly disease botulism occurs when the bacterium Clostridium botulinum grows and produces a powerful paralytic toxin in foods. These toxins can produce illness even if the microbes that produced them are no longer there.

Chemical Residues. FSIS collects samples of meat, poultry, and egg products at federally inspected establishments and analyzes the samples at FSIS laboratories for chemical residues of veterinary drugs, pesticides, and environmental contaminants.

Laboratory findings that exceed established tolerances or action levels are shared respectively with FDA and EPA.

The National Residue Program (NRP) consists of two sampling plans: domestic and import. These plans are further divided to facilitate the management of chemical residues such as veterinary drugs, pesticides, and environmental contaminants in meat, poultry, and egg products. The domestic sampling plan includes scheduled sampling and inspector-generated sampling. The import re-inspection sampling plan is separated into normal sampling, increased sampling, and intensified sampling.

B. Pathogen Control

Finished product testing for pathogenic bacteria of concern is used as validation of the HACCP system. This testing shows that the facilities entire microbiological control program is effective. Some companies require finished product testing on each production lot or a pre-determined schedule.

A total microbiological control program, however, consists of finished product testing and environmental testing using a facility zone system. Zone 1 is the food contact sites, Zone 2 is the food incidental contact sites (i.e. machine buttons, door handles air units, etc.), Zone 3 are non-food contact sites in the processing rooms (drains, walls, ceiling, etc.), and Zone 4 are other areas of the facility (entries, docks, etc.).

C. Test and Hold Policy (Internal & Regulatory Sampling)

Regardless if finished product testing is done by the facility or a regulatory agency, the finished product must be held until receipt of all test results. Previously, USDA Food Safety Inspection Service (FSIS) had not required, facilities to maintain control of products tested for adulterants while waiting for receipt of all test results. FSIS found, however, inconsistencies with those controls. Consequently, recalls have occurred because product was already in commerce by the time unacceptable test results came back from the laboratory. Therefore, in 2013 FSIS announced that products subject to this policy will not be able to enter commerce until receipt of all test results that bear on the determination as to whether those products are adulterated are received.

The establishment is responsible for having a supportable basis to define the sampled lot. The sampled lot is the product represented by the sample tested for by FSIS. In order to limit the amount of product affected by a sample result, the establishment may be able to limit the size of the sampled lot on the day FSIS collects a sample. For sampling purposes, lots should be defined so that if a positive result is found on one lot, the product from the other lot would not be implicated. Two such lots are called (mutually) independent or microbiologically-independent lots.

XVII. Net Weight Program

The net weight of finished requirements, definitions, procedures and reasonable variations allowed, are presented in the National Institute of Standards and Technology (NIST) Handbook 133, ''Checking the Net Contents of Packaged Goods''. http://www.nist.gov/pml/wmd/pubs/hb133-14.cfm. A net weight program needs to comply with the following:

Package Requirements. The net quantity of content statement must be "accurate," but reasonable variations are permitted. Variations in package contents may be a result of deviations in filling. The limits for acceptable variations are based on current good manufacturing practices in the weighing, measuring, and packaging process. The first requirement is that accuracy is applied to the average net contents of the packages in the lot. The second requirement is applied to negative errors in individual packages. These requirements apply simultaneously to the inspection of all lots of packages.

Inspection Lot. An "inspection lot" or "lot" is defined as a collection of identically labeled (except for quantity or identity in the case of random packages) packages available for inspection at one time. The collection of packages will pass or fail as a whole based on the results of tests on a sample drawn from the lot.

Average Requirement. In general, the average net quantity of contents of packages in a lot must at least equal the net quantity of contents declared on the label. Plus or minus variations from the declared net weight, measure, or count are permitted when they are caused by unavoidable variations in weighing, measuring, or counting the contents of individual packages that occur in current good manufacturing practice. Such variations must not be permitted to the extent that the average of the quantities in the packages of a particular commodity or a lot of the commodity that is kept, offered, exposed for sale, or sold, is below the stated quantity

Individual Package Requirement. The variation of individual package contents from the labeled quantity must not be "unreasonably large." In this handbook, packages that are under filled by more than the Maximum Allowable Variation (MAV) specified for the package are considered unreasonable errors. Unreasonable shortages are not generally permitted, even when overages in other packages in the same lot, shipment, or delivery compensate for such shortage. This handbook does not specify limits of overfilling.

Maximum Allowable Variation. The limit of the "reasonable minus variation" for an under filled package is called a "Maximum Allowable Variation" (MAV). An MAV is a deviation from the labeled weight, measure, or count of an individual package beyond which the deficiency is considered an unreasonable minus error. Each sampling plan limits the number of negative package errors permitted to be greater than the MAV.

Definitions:

Tare weight. The weight of a container, wrapper, or other material that is deducted from the gross weight to obtain the net weight.

Used dry tare. Used tare material that has been air dried, or dried in some manner to simulate the unused tare weight. It includes all packaging materials that can be separated from the packaged product, either readily (e.g., by shaking) or by washing, scraping, ambient air drying, or other techniques involving more than "normal" household recovery procedures, but not including laboratory procedures like oven drying. Labels, wire closures, staples, prizes, decorations, and such are considered tare. It is not the same as "wet tare."

Wet tare. Used packaging materials when no effort is made to reconstruct unused tare weight by drying out the absorbent portion (if any) of the tare. **Wet tare is not allowed for meat and poultry products.**

Table 1-1. Agencies Responsible for Package Regulations and Applicable Requirements			
Commodity	**Responsible Agency**	**NIST Handbook 133 Sampling Plans**	**Table of Maximum Allowable Variations**
Meat and Poultry	U.S. Department of Agriculture/Food Safety and Inspection Service and state and local weights and measures.	**Use Table 2-1.** Sampling Plans for Category A to test packages at other than point of pack. **Use Table 2-2.** Sampling Plans for Category B to test packages in federally inspected meat and poultry plants.	**Table 2-9.** U.S. Department of Agriculture, Meat and Poultry, Groups and Lower Limits for Individual Packages
Foods, drugs, and cosmetics subject to the Food, Drug, and Cosmetic Act including those packaged at the retail store level that have been in interstate commerce (e.g., seafood) or those made with ingredients that have been in interstate commerce and beer made from substitutes for malted barley (e.g., sorghum, rice, or wheat) and wine beverages with an alcohol content of less than 7 % by volume	U.S. Food and Drug Administration and state and local weights and measures.	**Use Table 2-1**. Sampling Plans for Category A to test packages at all locations.	**Table 2-5. MAVs for Packages Labeled by Weight** **Table 2-6. MAVs for Packages Labeled by Liquid or Dry Volume**

Table 2-1. Sampling Plans for Category A (Not at Point of Pack)					
1	2	3	4	5	6
Inspection Lot Size	Sample Size	Sample Correction Factor	Number of Minus Package Errors Allowed to Exceed the MAV[1]	Initial Tare Sample Size[2]	
				Glass and Aerosol Packages	All Other Packages
1	1	Apply MAV	0[1]	2	2
2	2	8.985			
3	3	2.484			
4	4	1.591			
5	5	1.242			
6	6	1.049			
7	7	0.925			
8	8	0.836			
9	9	0.769			
10	10	0.715			
11	11	0.672			
12 to 250	12	0.635			
251 to 3,200	24	0.422		3	
More than 3,200	48	0.290	1[1]		

[1] Exceptions to the Maximum Allowable Variations – 1 package may exceed the MAV for every 12 packages in the sample.
[2] If sample size is 11 or fewer, the initial tare sample size and the total tare sample size is 2 samples.

Table 2-2. Sampling Plans for Category B (for Use in USDA-Inspected Meat and Poultry Plants Only)			
1	2	3	4
Inspection Lot Size	Sample Size	Initial Tare Sample Size	Number of Packages Allowed to Exceed the MAVs in Table 2-9
250 or Fewer	10	2	0
251 or More	30	5	

Table 2-5. Maximum Allowable Variations (MAVs) for Packages Labeled by Weight

Do Not Use this Table for Meat and Poultry Products Subject to USDA Regulations – Use Table 2-9.
For Polyethylene Sheeting and Film, see Table 2-10. Exceptions to the MAVs.

Labeled Quantity	Maximum Allowable Variations
Less than 36 g, 0.08 lb, or 1.28 oz	10 % of labeled quantity
36 g or more to 54 g **0.08 lb or more to 0.12 lb** 1.28 oz or more to 1.92 oz	3.6 g **0.008 lb** 1/8 oz
More than 54 g to 81 g **More than 0.12 lb to 0.18 lb** More than 1.92 oz to 2.88 oz	5.4 g **0.012 lb** 3/16 oz
More than 81 g to 117 g **More than 0.18 lb to 0.26 lb** More than 2.88 oz to 4.16 oz	7.2 g **0.016 lb** ¼ oz
More than 117 g to 154 g **More than 0.26 lb to 0.34 lb** More than 4.16 oz to 5.44 oz	9.0 g **0.020 lb** 5/16 oz
More than 154 g to 208 g **More than 0.34 lb to 0.46 lb** More than 5.44 oz to 7.36 oz	10.8 g **0.024 lb** 3/8 oz
More than 208 g to 263 g **More than 0.46 lb to 0.58 lb** More than 7.36 oz to 9.28 oz	12.7 g **0.028 lb** 7/16 oz
More than 263 g to 317 g **More than 0.58 lb to 0.70 lb** More than 9.28 oz to 11.20 oz	14.5 g **0.032 lb** ½ oz
More than 317 g to 381 g **More than 0.70 lb to 0.84 lb** More than 11.20 oz to 13.44 oz	16.3 g **0.036 lb** 9/16 oz
More than 381 g to 426 g **More than 0.84 lb to 0.94 lb** More than 13.44 oz to 15.04 oz	18.1 g **0.040 lb** 5/8 oz
More than 426 g to 489 g **More than 0.94 lb to 1.08 lb** More than 15.04 oz to 17.28 oz	19.9 g **0.044 lb** 11/16 oz
More than 489 g to 571 g More than 1.08 lb to 1.26 lb	21.7 g 0.048 lb
More than 571 g to 635 g More than 1.26 lb to 1.40 lb	23.5 g 0.052 lb
More than 635 g to 698 g More than 1.40 lb to 1.54 lb	25.4 g 0.056 lb

More than 698 g to 771 g More than 1.54 lb to 1.70 lb	27.2 g 0.060 lb
More than 771 g to 852 g More than 1.70 lb to 1.88 lb	29.0 g 0.064 lb
More than 852 g to 970 g More than 1.88 lb to 2.14 lb	31.7 g 0.070 lb
More than 970 g to 1.12 kg More than 2.14 lb to 2.48 lb	35.3 g 0.078 lb
More than 1.12 kg to 1.25 kg More than 2.48 lb to 2.76 lb	39.0 g 0.086 lb
More than 1.25 kg to 1.45 kg More than 2.76 lb to 3.20 lb	42.6 g 0.094 lb
More than 1.45 kg to 1.76 kg More than 3.20 lb to 3.90 lb	49 g 0.11 lb
More than 1.76 kg to 2.13 kg More than 3.90 lb to 4.70 lb	54 g 0.12 lb
More than 2.13 kg to 2.63 kg More than 4.70 lb to 5.80 lb	63 g 0.14 lb
More than 2.63 kg to 3.08 kg More than 5.80 lb to 6.80 lb	68 g 0.15 lb
More than 3.08 kg to 3.58 kg More than 6.80 lb to 7.90 lb	77 g 0.17 lb
More than 3.58 kg to 4.26 kg More than 7.90 lb to 9.40 lb	86 g 0.19 lb
More than 4.26 kg to 5.30 kg More than 9.40 lb to 11.70 lb	99 g 0.22 lb
More than 5.30 kg to 6.48 kg More than 11.70 lb to 14.30 lb	113 g 0.25 lb
More than 6.48 kg to 8.02 kg More than 14.30 lb to 17.70 lb	127 g 0.28 lb
More than 8.02 kg to 10.52 kg More than 17.70 lb to 23.20 lb	140 g 0.31 lb
More than 10.52 kg to 14.33 kg More than 23.20 lb to 31.60 lb	167 g 0.37 lb
More than 14.33 kg to 19.23 kg More than 31.60 lb to 42.40 lb	199 g 0.44 lb
More than 19.23 kg to 24.67 kg More than 42.40 lb to 54.40 lb	226 g 0.50 lb
More than 24.67 kg More than 54.40 lb	2 % of labeled quantity

Table 2-9. U.S. Department of Agriculture, Meat and Poultry Groups and Lower Limits for Individual Packages (Maximum Allowable Variations)		
Definition of Group and Labeled Quantity		Lower Limit for Individual Weights (MAVs)
Homogenous Fluid When Filled (e.g., baby food or containers of lard)	All Other Products	
Less than 85 g (3 oz)		10 % of labeled quantity
85 g to 453 g (3 oz to 16 oz)		7.1 g / 0.016 lb / 0.25 oz
More than 453 g (More than 16 oz)	85 g to 198 g (3 oz to 7 oz)	14.2 g / 0.031 lb /0.5 oz
	More than 198 g to 1.36 kg (7 oz to 48 oz)	28.3 g / 0.062 lb / 1 oz
	More than 1.36 kg to 4.53 kg (48 oz to 160 oz)	42.5 g / 0.094 lb / 1.5 oz
	More than 4.53 kg (160 oz)	1 % of labeled quantity

XVIII. Pest Prevention Program

There may be instances when product must be protected from pests to ensure food safety standards, when unsanitary conditions are present, when product could attract pests, or when seasonal hatching causes a prominence of pests. In such cases, areas of the establishment must be controlled by appropriate Pest Management practices.

A facility should utilize an Integrated Pest Management contract service to provide guidance for prevention and control of pests. The Integrated Pest Management contract service provides a plan for the control of flying pests and rodent control for the facility and the surrounding property. The establishment should also performs inspection of target areas.

Outer openings shall be protected against the entry of insects and rodents by:

- Filling or closing holes and other gaps along floors, walls, and ceilings;
- Closed, tight-fitting windows; and
- Solid, self-closing, tight-fitting doors.

Materials that may be utilized include:

- Interior, non-production areas:
  - Flying insect glue boards
  - Flying insect eliminator lights (shall be designed to retain the insect within the device)
  - Rodent live traps
  - Non-residual pesticides (Chemical or Organic)
- Exterior
  - Secured, tamper resistant rodent bait traps
  - Residual pesticides (Chemical or Organic) in approved areas that meet EPA guidelines and manufacturer's label instructions that state that use is allowed in a food facility

The Integrated Pest Management will provide written report of inspection findings, service and corrective actions of the facility and grounds. Corrective actions may include recommendations for improvement or repair to the facility.

Designated company personnel will record inspection findings and corrective actions on appropriate forms.

XIX. Product Withdrawal / Recall

A withdrawal can occur due to quality non-conformance of product. A recall can occur due to a product which is adulterated or misbranded, or that is otherwise hazardous to the consumer. The nature of the withdrawal or recall concern will dictate the urgency of the actions and the extent of the communication(s). Under a recall, numerous details will be needed. In all cases, it is the company's responsibility to have a quick, complete, positive response to minimize company and customer risk and expense.

DEFINITIONS:

Recall. A firm's voluntary removal of distributed products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of the Food, Drug and Cosmetic Act (FD&C Act), Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA). "Recall" does not include a market withdrawal or a stock recovery. If a recall extends to 13 or more States, it is considered a nationwide recall.

Market Withdrawal. A firm's removal or correction by its own volition of a distributed product that involves a minor infraction that would not warrant legal action by federal regulators or that involves no violation of the FD&C Act, FMIA or the PPIA, or no health hazard.

Stock Recovery. A firm's removal or correction of product that has not been marketed or that has not left the direct control of the firm. For example, product is located on premises owned by, or under the control of, the firm, and no portion of the lot has been released for sale or use.

Effectiveness Checks. Federal program personnel verify that adequate notice about the recall has been provided to all consignees; consignees have located and controlled products and removal instructions; and the recall is conducted in an effective manner (locating, retrieving, controlling and disposing).

Recall Classifications. Federal and state agencies will assesses the public health concern or hazard presented by the product being recalled, or considered for recall, whether firm-initiated or requested by the agencies and classifies the concern as one of the following:

Class I. This is a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death. For example, the presence of pathogens in ready-to-eat product or the presence of *E*. *coli* O157:H7 in ground beef. Note: Federal or state agencies will make available the names and locations of all products that are associated with a Class I recall.

Class II. This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product. An example of a Class II recall is the presence of undeclared allergens such as very small amounts of potential allergenic substance (soy) or small sized non-sharp edged foreign material (plastic).

Class III. This is a situation where the use of the product will not cause adverse health consequences. For example, the presence of undeclared generally recognized as safe non-allergen substances, such as excess water.

Depth of Recall. The level of product distribution to which the recall is to extend:

1. Consumer - This includes household consumers as well as all other levels of distribution.

2. Retail level - The level that includes all retail sales of the recalled product.

3. User level- This level includes hotels, restaurants, and other food service institutional consignees.

4. Wholesale level - The distribution level between the manufacturer and the retailer. This level may not be encountered in every recall situation; i.e., the recalling firm may sell directly to the retail or consumer level.

Scope. This defines the amount and kind of product in question. There are several factors used in determining the scope, such as the plant's processing and sanitation procedures, the definition of a lot, any finished product reincorporated into fresh product (rework). For example, in the absence of additional data, all products produced under a single HACCP plan between performance of complete cleaning and sanitation procedures (clean up to clean up), or all products including any reworked product added to subsequent days' production, may be included in a recall. The findings of epidemiological investigations that link certain lots of product with foodborne illnesses will also affect the scope of a recall.

Disposition. The firm's action to correct a situation leading to the recall such as relabeling, reworking, or destroying product.

XX. Returned Product Procedure

Returned product is defined as product that has not been maintained in company control or ownership. If product ownership is maintained by the company, placed in outside storage and brought back to the facility for shipment into commerce, then it is not considered returned product. However, product distributed on an independent carrier is considered returned product since the company has not maintained control.

A returned product procedure is needed in advance to avoid confusion of actions needed and responsibility of employees. The following provides basic criteria for the program.

Notification of intent to return product:

- Company owners or plant management approved return of product to the facility.
- Management provides direction / action and investigation activities based on circumstances.
- Facility designee investigates related product information, such as, production data, shipping records, etc.

Receipt of returned product:

- Facility designee coordinates product return, collects information and evaluation of product condition (product temperature, damaged / open product, etc.).
- Returned product will be place on “Hold” if corrective action cannot be completed at time of receipt.
- If required, facility designee notifies regulatory personnel to afford opportunity to inspect product and confirm action.

Corrective Actions:

- Facility designee develops preventative actions and modifications to process or procedure, as necessary. Employees are instructed in any process or procedure change.

XXI. Scale Verification

Scales utilized for weighing raw materials, ingredients and finished product need to be calibrated on an annual basis. The outside scale service company performs scale calibration, adjustment and, if necessary, repair. Scale tolerance are based on NIST Handbook 44. The outside scale service will provide documentation of the scale service and / or scale tag.

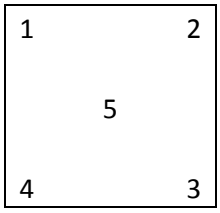
If scale preliminary load test reading exceeds test weight or cannot be adjusted or maintain final load test calibration, the facility needs to coordinate corrective actions, which may include, taking scale out of service, temporary scale replacement, etc.

Scale verification is a procedure is to confirm there has been no drift in between the outside scale service annual calibration.

During an outside scale service annual calibration, select an object for an in-house standard weight. Record the weight on the object and maintain for scale verification. Note: a certified weight is not required.

Verifying the scale by:

- Confirm that the scale is level.
- The weigh platform is positioned correctly.
- Place the standard in-house weight on one corner of the scale platform, allow the scale to stabilize, and record the value for that location.
- Move the standard in-house weight to the next corner of the scale platform allow the scale to stabilize, and record the value for that location.
- Repeat this process for the other two corners and the center of the scale platform.
- If the scale is reading +/- 1% from the standard weight, do not use and have the scale serviced.



XXII. Shelf life

The shelf life of products can be affected by many factors. Microorganisms and chemical changes limiting factors to shelf life. Odor, flavor, color and enzymatic textural changes may render the product unacceptable to the consumer.

The following is a recommendation for a standardized protocol for shelf-life determination of refrigerated RTE foods. It is applicable to many refrigerated RTE foods provided that a risk assessment is conducted to assure that this protocol sufficiently covers the hazards of concern.

The source of the product should be produced in the normal / standard process (production equipment and packaging material), stored at a defined temperature and tested for key microorganisms over a set time period. The shelf life test considers standard naturally contaminated food and organoleptic changes over time.

In perishable products, the product life will be linked to storage temperature. If a very low temperature is used in the study, then the apparent life of the product will be long, as the microbial flora will grow very slowly. However, if the real storage temperatures that the product encounters in the marketplace are higher than those used in the study, then microbial growth will be quicker and the product may spoil before the shelf life is reached. Conversely, if the study uses higher temperatures than those seen in the real marketplace, then the shelf life may be underestimated and product could be discarded when still acceptable, thus increasing waste.

The art of devising a good shelf life test is to understand the product and how it will be handled. Most studies will incorporate two phases of storage temperature, one quite low to represent distribution temperatures, one higher temperature to represent purchase and transport from the retailer to the home.

Sampling times are dependent on the intrinsic properties of the product. An initial test should be done soon after the manufacturing and packaging of the product to establish a base line. Subsequent testing should be suspended when organoleptic and microbial results are at unacceptable levels.

Organoleptic evaluation of the products appearance, smell or taste is a good indicator of shelf life. In conjunction with organoleptic evaluation, microbiological tests should be performed for general microbial flora and potential spoilage organisms. There is usually no point in looking for pathogens in this type of test as they are very unlikely to be found, and if they are it shows a failure of process or the HACCP plan controls.

Standardized protocol that meets basic requirements:

1. Shelf Life Analysis- Verification: complete testing to assure that consistent microbiological, chemical and sensory standards are measured, and parameters that dictate end of shelf life are identified. From a microbiological perspective, the standardized protocol will analyze potential for growth of indigenous organisms that may comprise both spoilage flora and bacterial pathogens. For shelf life verification, depending on the product, analysis may include the following:

a. Microbiological:
   1. Aerobic Plate Count (APC)
   2. coliforms / *E. coli*
   3. Coagulase positive *Staphylococcus*
   4. lactobacilli
   5. yeasts and molds

b. Chemical:
   1. Moisture
   2. Salt
   3. pH
   4. Titratable Acidity
   5. Aw (Water Activity)
   6. temperature

c. Sensory Analysis: Sensory specification that identifies important organoleptic attributes and acceptable tolerances around them.

2. Challenge Studies: performed in order to assess the fate of two specific pathogens (*Listeria monocytogenes* and in the case of reduced oxygen packaging, non-proteolytic *Clostridium botulinum* type E). Prior to challenge studies, mathematical modeling is recommended to determine the potential for growth and toxin production by non-proteolytic *C. botulinum* type E and growth of *Listeria monocytogenes*.

General Shelf Life Analysis Requirements:

1. Selection of Samples for Shelf Life Analysis:

For measurement of shelf life from a specific production run, sufficient samples should be set aside to complete 2 full schedules of tests at storage temperatures of 4^0C and 10^0C. For microbiological and chemical analysis, at each time point during the analysis, samples should be prepared from a minimum of two (duplicate) unopened containers for each storage temperature (N=4x 7 time points=28 total containers) to account for variations in test product composition, testing each package separately. Once samples have been aseptically removed for microbiological and chemical analysis, containers can be used for sensory analysis.

2. Sample Storage:

Samples will be stored at two specified temperatures: $4 + 1^0$C (optimal refrigeration) and $10 + 1^0$C (abuse temperature). Storage temperature will be monitored by use of an appropriate recording device. Samples will be properly labeled to clearly identify the shelf life protocol for which they are intended. Records will be kept as to the location and number of shelf life samples and when samples are removed for shelf life testing.

3. Sample Intervals:

All products will be tested at seven different ages regardless of length of expected shelf life. Sampling intervals should be determined at 20% of product shelf life, which comprise seven different ages from initial to full shelf life, plus a sampling to allow an interval 20% beyond shelf life for a total time to encompass 120% of shelf life.

Sample dates would be as follows:

Sample	30 day	45 day	60 day	90 day
1	0	0	0	0
2	6	9	12	18
3	12	18	24	36
4	18	27	36	54
5	24	36	48	72
6	30	45	60	90
7	36	54	72	108

4. Microbiological Analysis: All microbiological analysis should be performed by official methods by a certified laboratory. Microbiological results will be interpreted through use of pass/fail criteria.

Pass Criteria:

APC counts: Will not exceed 1x 10^4 CFU/gm upon initial sampling (except in cases where there are cultured ingredients or other ingredients were "high" APC is acceptable).

Total increase of <3 log APC over product shelf life.

Coliforms / Enterobactericeae: Will not exceed 1 x 10^2 CFU/gm upon initial sampling. Total increase of <2 log over product shelf life.

Yeasts and Molds: Not to exceed 10^2 within 24 h. Total increase should be limited to <3 log increase at end of shelf life.

Lactobacilli: <10^2 initially; Total increase should be limited to <3 log increase at end of shelf life.

CP Staphylococci: Will not exceed 1 x 10^2 CFU/gm upon initial sampling. No more than a 1 log CFU/gm increase for any two consecutive time points. Total increase of < 3 log throughout product shelf life.

5. Chemical Analysis:

All chemical analysis should be performed by official methods by a certified laboratory.

6. Sensory Evaluation:

a. All determinations should be made based upon comparison to a reference sample.

b. For each test temperature, 2 containers each of representative product should be removed from storage for analysis.

c. Each container or package should be inspected for gas formation by spoilage flora as evidenced by doming of lids or blowing in the package.

d. Containers/packages should be opened and held at room temperature for at least 10 minutes to allow samples to equilibrate (Mead, 1990).

e. For sensory properties associated with deterioration during refrigerated shelf life (odor, color, taste and texture) should be evaluated and results expressed as a mean score using a four point scale where:

Score	Odor	Color	Taste	Texture
1	Normal odor	Normal color	Normal fresh taste	Normal Appearance
2	Slight off-odor	Slight discoloration	Slight spoilage	Slightly soft/ watery/oily
3	Moderate off-odor	Moderate discoloration	Moderate spoilage	Moderately soft/ watery/oily
4	Strong off-odor	Pronounced Discoloration	Pronounce spoilage	Pronounce soft/ watery/oily

A mean score of 2.5 or below indicates an acceptable product. A mean score above 2.5 marks the potential end of product shelf life.

Challenge testing

Challenge testing is the deliberate inoculation of a food with known micro-organisms in order to determine if those organisms can grow in the product.
Challenge testing has many problems and difficulties and some are critical of this approach. However, for any company wishing to gain a real insight into whether a particular organism (this could be a spoilage organism or a pathogen) can grow in their product, this is an effective approach allowing them to clearly show that they have shown due diligence during the design and manufacture of a product. Challenge testing can be used to ascertain the growth potential of any specific organism in a particular food. So, for example, if a company is producing an acidic or high sugar product, they may be concerned about the potential for growth of yeasts or molds; this could be assessed by challenge testing. Conversely, a company may wish to consider the potential for the growth of Listeria in a chilled product. In this case, the company's HACCP plan should include all factors to prevent the presence of *Listeria* in the final product. It is in such circumstances that a manufacturer may need information on whether Listeria is able to grow during the shelf life of the product

Predictive microbiology

Predictive microbiology utilizes computer programs, which allow prediction of how various microorganisms respond to environmental conditions that could be found in a particular food.
With Combase and ARS's Pathogen Modeling Programs, it is possible to pick the organism of interest, and state what pH, water activity and storage temperature would be of interest, and the program will tell you how that organism would respond. Other models, such as Purac's predicts *Listeria* growth based on moisture, salt, pH for cured or non-cured product.
Predictions are easy and fast to do, but do take some expert interpretation of results. The output of models are usually 'fail safe', so an organism can just about grow, when in reality it cannot. This is, however, much better than a fail dangerous situation. Modeling is very useful in many stages of product design and development to get an indication of potential microbiological problems and to predicted shelf life. To get a more exact shelf life, however, shelf life testing or challenge testing may be better approaches.

XXIII. Specifications

Specifications are documents that relate to product. Specifications describe in detail process / equipment and product information, effective date, control number and approval signature.

Process / equipment specifications or Processing Standard Operating Procedures.

Examples include:

- Thermal processing / cooking schedules (i.e. dry and wet bulb settings and time at each step of the cook cycle, steam kettle set temperature, etc.)
- Equipment set-up and tear down procedures (I.e. grinder plate hole size, number of knife blades, packaging film loading, etc.)
- Processing information (i.e. order of ingredients, mixing time, RPM's of equipment, pumping or stuffing pressures, product separation, packaging configuration, packaging materials, etc.)

There are no specific format guidelines for Process / equipment specifications or Processing Standard Operating Procedures, but they should include:

- Facility Area
- Process description
- Materials / Equipment needed
- Employee safety instructions
- Food safety instructions
- Process steps

Product specifications

Product specification are typically more formal. The level of detail in the specification is based on the intended audience. A specification for customer's technical or purchasing department may go into specific technical detail. A specification for marketing provides less technical detail.

Product Specification format typically includes:

- Company Name, address and establishment, registration or license number
- Company contact information (Name, phone, email, etc.)
- Product Name
- Product Number
- Description
- Ingredients including Allergen statement
- Packaging description (materials, case dimensions, case cube, palletizing pattern)
- Storage conditions (ambient, refrigerated, frozen)
- Shelf life (days at specific storage temperature in sealed immediate container, days at specific storage temperature in opened immediate container)
- Product physical information (target or standard $\pm$ range)
- Product chemical information (target or standard $\pm$ range)
- Product microbiological information (maximum or standard $\pm$ range)
- Product nutritional information
- Product organoleptic information (appearance, aroma / flavor, texture)
- Product certifications (i.e. Country of Origin, religious, claims)

XXIV. Suppliers Programs

A. Specifications and Certificates

Suppliers need to provide specifications and various programs or certificates to meet audit and governmental requirements.

Supplier specifications for products or ingredients are needed prior to bring the item into the facility. The review of the specification would confirm that the item is

- what is wanted,
- will meet the intended use,
- perform the function needed and
- meet regulatory requirements

Once an item meets the intended requirements, then the facilities documents will need modification, assessment and validation. These documents would include product specifications, SOP's, SSOP's, GMP's and HACCP plan.

Certificates that are needed, include:

- Municipal water report
- Material Safety Data (MSD, previously known as MSDS) for Chemicals and if applicable ingredients
- Outside / Independent Laboratory Audit Certifications (ISO 17025, etc.)
- State Licenses
    - Weights and measures for scale calibration
    - Pest management
    - Rendering hauler
- Liability Insurance
- Letters of Guarantee

B. Approval Program

A supplier approval program details the actions taken for approval of supplier, initial ingredient evaluation and maintaining of approved supplier status.

An Example of a Supplier Approval Program is as follows:

A. Approval
    1. A minimum of one container of the product will be obtained.
    2. The product will be evaluated against the specific raw material specification criteria.
    3. Criteria may include:
        a. Net weight confirmation
        b. Product physical evaluation
        c. Chemical and bacterial analysis
    4. Probationary Approval
        a. New supplier will be maintained under probationary status for 3 consecutive receipts.
        b. Approved supplier will move to probationary status if any bacterial, chemical or physical hazard is detected or found.
            i. The supplier will be contacted on the issue and preventative action response shall be required.
            ii. Other actions may include: product placed on “hold”, returning product, reconditioning, or other mutually agreeable actions.

B. Assessment
    1. Supplier assessment will include evaluation of an annual third party audit or multi-year assessment.
    2. The supplier assessment will be reviewed at least annually.

C. Monitoring
    1. Each raw meat supplier will be evaluated at least annually on conformance to specification.
    2. Each lot or unit of raw meat will be examined for bacterial and physical hazards.

XXV. Policies

A. Internal Audits

Internal audits are the evaluation and verification that all facets of the facilities programs and processes are being performed as intended. This process is a requirement for any Global Food Safety Initiative (GFSI) scheme.
Internal audits involve:

- Physical observation of SOP's / GMP steps
- Physical confirmation of documentation and records
- Documentation of compliance and non-compliance.
- Documentation of corrective actions (revision to procedure, re-training of employees, etc.)
- Verification that the corrective action were effective.

B. Document Control

1. Records and Retention

A policy needs to identify and explain the recordkeeping and retention of records relevant to the control of the process or evaluation of food safety, food quality and food defense. The following is main points of records and retention.

Records:

- Records should contain effective date and optionally a record control number.
- All hard copy records shall be:
  - Genuine and legible
  - Initialed by operator and verified for accuracy
  - Recorded in ink on a timely basis with accurate date
  - Errors shall be marked with single line-out and initialed
  - Out of compliance or control is recorded
  - Any disposition of product and corrective actions taken
- Electronically recorded records are used for documentation and down loaded. These record may be transcribed to hard copy records.

Retention:

- Records relating to food safety, food quality and food defense are maintained for a minimum of 1 year for refrigerated, 2 years for frozen, or longer based on shelf life. Better Process Control School (FDA) requires 1 year on site and 2 years off-site at an easily accessible location, for a total of 3 years.
- Current records are maintained in designated office. Historical records are maintained in storage.

Responsibility:

Who is responsible for the recordkeeping oversight and retention?

2. Product Change / Amendment

Any product ingredient or process change or amendment needs proper approval by designated facility employee with overall responsibility. Product change refers to a modification to the product. Product amendment relates to substitution of an ingredient or process modification.

The use of a Product Change / Amendment form is recommended. This form would include:

- Date
- Product Name
- Product Number
- Identification if the change or amendment is permanent or temporary
- Description of change or amendment
- List of documents that need revision
- Approval signature(s) of employee with overall authority.