Validation and Verification of HACCP Plans in Retail Food Establishments (Food Service and Retail Food Stores)

Cape May County Department of Health

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During the past decade, retail food establishments have expanded their operations to include specialized food processing-type operations, such as smoking and curing, acidification, and reduced oxygen packaging, often using sophisticated new technologies and equipment. Such operations present a significant health risk if not conducted under strict operational procedures.

A HACCP Plan is required because specialized processes have historically resulted in more foodborne illnesses than standard processes and, therefore, present a significant health risk if not conducted under strict operational procedures. These types of operations may require the person-in-charge and food employees to use specialized equipment and demonstrate specific competencies. An approved HACCP Plan is necessary to ensure that the proposed process is carried out safely.

The Cape May County Department of Health is responsible for ensuring that HACCP plans and plans based on HACCP principles (i.e. Time as a Public Health Control, acidification, etc) are effectively implemented to eliminate or significantly reduce targeted hazards that may contribute to foodborne illness. The Cape May County Department of Health is responsible for ensuring that such plans as written are valid, in addition to verifying their effective implementation in the field.

HACCP plans are mandatory for the following processes and operations:

1. Use of food additives or adding components such as vinegar as a method of food preservation or to render a food so that it is not potentially hazardous
2. Reduced oxygen packaging (ROP) with barriers
3. Custom processing animals
4. Molluscan shellfish tanks
5. Smoking for preservation
6. Curing
7. Time as a public health control.

Index

Key Terms 1
Contents of a HACCP Plan 3
  Principle 1: Conduct a Hazard Analysis 3
  Principle 2: Identify Critical Control Points 4
  Principle 3: Establish Critical Limits 4
  Principle 4: Establish Monitoring/Inspection Requirements 5
  Principle 5: Establish Corrective Actions 5
  Principle 6: Establish Verification Procedures 5
  Principle 7: Establish a Record Keeping System 6
Specialized Processes and Procedures Requiring A HACCP Plan 7
Acidification/adding components to Render Food Non-Potentially Hazardous 8
  Public Health Rationale 8
  Controls and Guidelines 8
Reduced Oxygen Packaging (ROP) 10
  Public Health Rationale 12
  Controls and Guidelines (Reduced Oxygen Packaging) 13
  Safety Barrier Verification 13
  Recommendations for ROP Without Multiple Barriers 13
    Employee Training 13
    Refrigeration Requirements 13
    Labeling – Refrigeration Statements 13
    Labeling – “Use-by date” 14
    Disposition of Expired Product at Retail 14
    Dedicated Area/Restricted Access 14
Custom Processing Animals 15
  Public Health Rationale 15
Molluscan Shellfish Tank 16
  Public Health Rationale 16
    Controls and Guidelines 16
Smoking and Curing 21
  Public Health Rationale 22
  Controls and Guidelines 22
    Incorporation of Cure Ingredients 22
    Smoking 22
    Fermentation and Dehydration 23
    Dedicated Area/Restricted Access 23
Time as a Public Health Control 24
  Public Health Rationale 24
  Controls and Guidelines 25
    Holding Hot Food without Temperature Control 25
    Holding Cold Food with Temperature Control 25
Non-compliant HACCP Systems 26
  Enforcement/Corrective Actions 26
  Follow-up Field Verification Inspection 27
Hazard Analysis Critical Control Point (HACCP) Plan Review Application 28

Key Terms

aw – means water activity which is a measure of the free moisture in a food, is the quotient of the free moisture in a food, is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature, and is indicated by the symbol aw.
Control Point – Any point in a specific food system at which loss of control does not lead to an unacceptable health risk.
Critical Control Point – means a point or procedure in a specific food system where loss of control may result in an unacceptable health risk.
Critical Limit – The maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize risk, that the identified food safety hazard may occur.
Deviation – Failure to meet a required critical limit for a critical control point.
Good Retail Practices (GRPs) – Preventative measures that include practices and procedures to effectively control the introduction of pathogens, chemicals, and physical objects into food, that are prerequisites to instituting a HACCP or Risk Control Plan and are not addressed by the Food Code interventions or risk factors.
Hazard Analysis Critical Control Point (HACCP) – An acronym for Hazard Analysis Critical Control Point, means a written document that delineates the formal procedures for following the HACCP principles (July, 2005) incorporated herein by reference, as amended and supplemented, and available through the Division of Cooperative Programs (HFS-625), Office of Compliance, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, telephone (301)436-2350 and website address http://www.cfsan.fda.gov/~dms/hret2toc.html.
HACCP Plan – a written document that delineates the formal procedures for following the Hazard Analysis Critical Control Point principles developed by the National Advisory Committee for the Microbiological Criteria for Foods.
HACCP System – The result of implementing the HACCP principles in an operation that has foundational comprehensive prerequisite programs in place. A HACCP system includes the HACCP plan and all prerequisite programs.
Hazard – means a biological, chemical, physical property that may cause an unacceptable consumer health risk.
Hazard Analysis – The process of collecting and evaluating information about hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.
Monitoring – A planned sequence of observations or measurements of critical limits designed to produce an accurate record and intended to ensure that the critical limit maintains product safety. Continuous monitoring means an uninterrupted record of data.
pH – means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution. Values between 0 and 7 indicate acidity and values between 7 and 14 indicate alkalinity. The value for pure distilled water is seven, which is considered neutral.
Potentially Hazardous Food – means a food that is natural or synthetic and that requires temperature control because it is in a form capable of supporting:

1. the rapid and progressive growth of infectious or toxigenic microorganisms;
2. the growth and toxin production of Clostridium botulinum; or
3. In raw shell eggs, the growth of Salmonella enteritidis.

Prerequisites for HACCP – Practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety.
Preventative Measures – An action to exclude, destroy, eliminate, or reduce a hazard and prevent recontamination through effective means.
Risk – The likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.
Risk Factor – One of the factors identified by the Centers for Disease Control and Prevention (CDC) as a contributor to the foodborne outbreaks that have been investigated and confirmed. The factors are unsafe sources, inadequate cooking, improper holding, contaminated equipment and poor personal hygiene.
Severity – The seriousness of the effect(s) of a hazard.
Standard Operating Procedures (SOP) – A detailed set of instructions, steps or procedures that control the operational conditions within a food establishment allowing for environmental conditions that are favorable to the production of safe food. These written procedures are often equivalent to prerequisite programs of HACCP. The extent to which operators employ various SOPs will determine which critical control points need to be controlled.
Validation – Validation is that element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.
Verification – Verification means those activities other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to plan.

Contents of a HACCP Plan

For a food establishment that is required to have a HACCP plan, the plan and specifications shall indicate:

a) A categorization of the types of potentially hazardous foods that are specified in the menu such as soups and sauces, salads, and bulk, solid foods such as meat roasts, or of other foods that are specified by the regulatory authority;
b) A flow diagram by specific food or category type identifying critical control points and providing information on the following:
   (1) Ingredients, materials, and equipment used in the preparation of that food, and
   (2) Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved;
c) Food employee and supervisory training plan that addresses the food safety issues of concern;
d) A statement of standard operating procedures for the plan under consideration including and clearly identifying:
   (1) Each critical control point (CCP)
   (2) The critical limits for each CCP,
   (3) The method and frequency for monitoring and controlling each CCP by the food employee designated by the person-in-charge (PIC),
   (4) The method and frequency for the PIC to routinely verify that the food employee is following standard operating procedures and monitoring CCPs,
   (5) Action to be taken by the PIC if the critical limits for each CCP are not met, and
   (6) Records to be maintained by the PIC to demonstrate that the HACCP plan is properly operated and managed; and
e) Additional scientific data or other information, as required by the regulatory authority, supporting the determination that FOOD safety is not compromised by the proposal.

HACCP is defined as a systematic approach to the identification, evaluation and control of food safety hazards based on the following seven principles:

Principle 1: Conduct a Hazard Analysis

A **food hazard** is any unacceptable contamination by a biological, chemical, or physical agent at sufficient level to cause a food to be unsafe for human consumption. By far the most common agents are biological, mainly pathogenic bacteria, other microorganisms and parasites.

Biological hazards include: bacteria, bacterial toxins, viruses and parasitic organisms that could survive, grow or contaminate food products/raw materials, and potentially cause foodborne illness. (See chart entitled: *Selected Factors Influencing Growth of Common Foodborne Pathogens* following Principle #7.)

Chemical hazards could result from a number of sources: agricultural chemicals, insecticides, fungicides, etc.; cleaning/sanitizing agents and chemicals, certain naturally-occurring toxins such as Scombrotoxin (histamine), Ciguatoxin, mycotoxins from mold, shellfish toxins, etc. and misuse of food chemicals (preservatives, additives, etc.)

Physical hazards include: inadvertent field matter (stones, wood, metal fragments, etc.); inadvertent processing residues (glass, metal fragments, etc.); intentional materials (employee sabotage) and miscellaneous particulates and fragments.

Principle 2: Identify Critical Control Points

A **Critical Control Point (CCP)** means a point or procedure, in a specific food system, where loss of control may result in an unacceptable health risk.

CCPs are not limited to those processes or operations which eliminate hazards.

CCPs can also be identified where hazard prevention or reduction can occur (e.g., ingredient or raw material specifications, sanitation programs, etc.).

Identification of a CCP is an important process and provides the backbone of HACCP. In addition to the element of hazard control at a CCP, it is equally important that such control can be monitored and adequately verified (see Principles 4 and 7).

Thoroughly discuss the selection of CCPs. Once identified, CCPs should be clearly labeled on product flow chart(s).

Principle 3: Establish Critical Limits

A **Critical Limit (CL)** is a safe limit or tolerance that must be met for each identified CCP. These are the boundaries of safety for the microbiological, chemical and physical hazards. Exceeding these boundaries indicates that a health hazard may exist or could develop.

The most obvious examples of such limits are specific temperature/time relationships for either processing or storage that are necessary to prevent, eliminate or reduce microbial hazards. Food composition information such as acidity may also be used.

Other examples of critical limits include: specifications on raw material/ingredients (e.g., an ingredient shall be free of *Salmonella* or parasites).

Care must be exercised; critical limits must be identified for each CCP and these critical limits must be realistic and be measurable.

Principle 4: Establish Monitoring/Inspection Requirements

Monitoring is a scheduled observation or measurement of a CCP and its limits. The purpose of monitoring is two-fold: to assess whether a CCP is under control and to generate data that will be used to produce an accurate record for future verification. Monitoring procedures should be accurate and done at appropriately established frequency.

Visual observations are usually based upon a predetermined inspection checklist, which usually involves observing temperatures, or cleanliness of equipment. Chemical testing may include measuring pH or acidity, or sanitizer levels. Sensory monitoring involves examining raw materials for "off" odors, presence of molds, or other defects.

Microbiological testing has a limited but important role due to the time delay involved for results. While it is not possible to use microbial data to stop a process on the spot or to bring a CCP under control, microbial testing is used to set/maintain acceptance standards on raw materials and ingredients in hazard analysis. Microbial data may also be used in HACCP verification (see Principle 7).

Principle 5: Establish Corrective Actions

A **Corrective Action** is a procedure followed when a deviation occurs. Corrective actions must be taken whenever monitoring indicates that limits or tolerances are not met. Based upon the severity of hazard and the individually defined situation, corrective action may involve: notifying a supervisor, process line shut down, reprocessing, adjusting process temperature and times, rejecting raw materials or ingredients, and holding or recalling product in distribution. Corrective actions must be identified and documented in the HACCP plan and should specifically address each CCP. It is fundamentally important to specifically delineate responsibility and authority with regard to corrective action.

Principle 6: Establish Verification Procedures

A working HACCP system is dynamic and flexible, and allows for change. It should have provisions for verification of its effectiveness.

Verification is a process designed to:

- Review the HACCP plan
- Establish whether the CCPs and CLs are being adequately controlled and monitored
- Determine if the procedures for product deviations and record keeping are being followed correctly

Verification involves actual observation of procedures and a thorough review of records. On-going verification should be on a well-defined and established frequency, i.e. once per shift, daily, weekly, etc. However, a comprehensive HACCP system verification should be conducted at least annually or whenever there is a change in the HACCP system. If the results of that comprehensive verification identify deficiencies, the HACCP plan must be modified, as necessary, to ensure the HACCP plan is controlling the hazards.

Principle 7: Establish a Record Keeping System

An **adequate record keeping system** is the heart of a HACCP program.
Records are the documentation needed to verify effectiveness of the HACCP plan. They are the only reference available to trace the production history of a finished product. If questions arise concerning the product, a review of the records may be the only way to prove that the product was prepared and handled in a safe manner in accordance with all the HACCP principles outlined in the establishment's HACCP plan.

Adherence to the specific critical limits (CLs) set at each CCP is the best assurance of product safety. Documenting the data, from those measurements, results in a permanent record. Records provide a dual function by providing a history of performance, as well as any actions taken to prevent a problem.

In order to assure product safety and to document processes and procedures, **HACCP records must contain the following information**:

- Title and date of record
- Product identification
- Materials and equipment used
- Operations performed
- Critical criteria and limits
- Corrective action to be taken and by whom
- Operator identification
- Monitoring data
- Reviewer's initials and date of review

Specialized Processes and Procedures Requiring A HACCP Plan

In this section, you will be able to identify preventative measures commonly used for controlling hazards associated with specialized processing methods and high risk procedures including:

- Use of food additives or adding components such as vinegar as a method of food preservation or to render a food so that it is not potentially hazardous
- Reduced oxygen packaging (ROP) with barriers
- Custom processing animals
- Molluscan shellfish tanks
- Smoking for preservation
- Curing
- Time as a public health control

Acidification/adding components to Render Food Non-Potentially Hazardous

Regulation: 8:24-3.5 (h) – **Limitation of growth of organisms of public health concern**
3. – using food additives or adding components such as vinegar: as a method of food preservation rather than as a method of flavor enhancement; or to render a food so that it is not potentially hazardous.

Public Health Rationale

A Hazard Analysis Critical Control Point (HACCP) plan is necessary when conducting specific food processes such as acidification. Such processes have historically resulted in more foodborne illnesses than standard processes. They present a significant health risk if not conducted under strict operational procedures. The HACCP plan must be maintained at the retail site for review by the regulatory authority.
Cooked rice is a potentially hazardous food (phf). If the pH of the rice is not brought down below 4.6, it may be able to support the growth of Bacillus cereus when stored at room temperature. The preparation of acidified (adding vinegar) sushi rice shall require the person in charge and food employees to use specialized equipment and demonstrate specific competencies. An approved HACCP Plan is designed to ensure that the proposed method of operation is carried out safely.

Controls and Guidelines

Example: Making sushi rice

<u>The HACCP plan must include the following:</u>

1) The 7 Principles listed on pages 3 – 6 must be addressed.
2) There must be a written recipe or formulation for acidifying the rice.
   a) The recipe must contain the weights of rice and water needed prior to cooking.
   b) The concentration of vinegar, (for example: 5%)
3) Cooked rice must be cooled in a shallow container that is less than 4” deep to promote rapid cooling of product and uniform acidification.
4) One of the CCPs must be the pH of the cooked rice.
5) A calibrated pH meter must be used, according to manufacturer’s instructions, to monitor the pH of every batch of acidified rice.
   a) Conduct the pH test with in 30 minutes after acidification of the cooked rice
   b) Make a rice slurry: ¼ cup sample of the cooked acidified rice taken from various locations in the batch and add ¾ cup of distilled water in a clear plastic cup and blend the slurry for 20 seconds.
   c) Insert a pH probe into the liquid portion of the slurry
6) The target pH should be 4.1 but must not exceed 4.6.

7) The results of the pH measurement of each batch of rice and the pH meter calibration log must be properly recorded, and the records must be retained for 90 days.

Reduced Oxygen Packaging (ROP)

Regulation: 8:24-3.5 – Limitation of growth of organisms or public health concern

(i) The criteria for reduced oxygen packaging shall include the following:

1. A retail food establishment that packages food using a reduced oxygen packaging method and Clostridium botulinum is identified as a microbiological hazard in the final packaged form shall ensure that there are at least 2 barriers in place to control the growth and toxin formation of Clostridium botulinum, except for a retail food establishment that obtains prior approval from the health authority as specified under (h) above.
2. A retail food establishment that packages food using a reduced oxygen packaging method and Clostridium botulinum is identified as a microbiological hazard in the final packaged form shall have a HACCP plan that contains the information specified under N.J.A.C. 8:24-9.1(e) and that:
   i. Identifies the food to be packaged;
   ii. Limits the food packaged to a food that does not support the growth of Clostridium botulinum because it has an aw of 0.91 or less; has a pH of 4.6 or less; is a meat or poultry product cured at a food processing plant regulated by the U.S.D.A., using substances specified in Use of Food Ingredients and Sources of Radiation, 9 CFR §424.21, incorporated herein by reference, as amended and supplemented, and is received in an intact package; or is a food with a high level of competing organisms such as raw meat or raw poultry;
   iii. Specifies methods for maintaining food at 41°F or below;
   iv. Describes how the packages shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to maintain the food at 41°F or below, and to discard the food if within 14 calendar days of its packaging it is not served for on-premises consumption, or consumed if served or sold for off-premises consumption;
   v. Limits the shelf life to no more than 14 calendar days from packaging to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first;
   vi. Includes operational procedures that prohibit contacting food with bare hands; identify a designated area and the method by which physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination, and how access to the processing equipment is restricted to responsible trained personnel familiar with the potential hazards of the operation; and delineate cleaning and sanitization procedures for food-contact surfaces; and
   vii. Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the concepts required for a safe operation; equipment and facilities; and the procedures specified under N.J.A.C. 8:24-9.1(e).
3. A retail food establishment shall not package fish using a reduced oxygen packaging method, except for fish that is frozen before, during, and after packaging.

Key Terms

"Reduced Oxygen Packaging" includes:
1.Vacuum packaging, in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package, such as sous vide;
2. Modified atmosphere packaging, in which the atmosphere of a package of food is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the packaging material or the respiration of the food. Modified atmosphere packaging includes: reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen; and
3. Controlled atmosphere packaging, in which the atmosphere of a package of food is modified so that until the package is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement oxygen, nonrespiring food, and impermeable packaging material.

Cook-chill is a process that uses a plastic bag filled with hot cooked food from which air has been expelled and which is closed with a plastic or metal crimp.

Controlled Atmosphere Packaging (CAP) is an active system which continuously maintains the desired atmosphere within a package throughout the shelf-life of a product by the use of agents to bind or scavenge oxygen or a sachet containing compounds to emit a gas. Controlled Atmosphere Packaging (CAP) is defined as packaging of a product in a modified atmosphere followed by maintaining subsequent control of that atmosphere.

Modified Atmosphere Packaging (MAP) is a process that employs a gas flushing and sealing process or reduction of oxygen through respiration of vegetables or microbial action. Modified Atmosphere Packaging (MAP) is defined as packaging of a product in an atmosphere which has had a one-time modification of gaseous composition so that it is different from that of air, which normally contains 78.08 % nitrogen, 20.96% oxygen, 0.03% carbon dioxide.

Sous Vide is a specialized process of ROP for partially cooked ingredients alone or combined with raw foods that require refrigeration or frozen storage until the package is thoroughly heated immediately before service. The sous vide process is a pasteurization step that reduces bacterial load but is not sufficient to make the food shelf-stable. The process involves the following steps:

1. Preparation of the raw materials (this step may include partial cooking of some or all ingredients);
2. Packaging of the product, application of vacuum, and sealing of the package;
3. Pasteurization of the product for a specified and monitored time/temperature;
4. Rapid and monitored cooling of the product at or below (38 F) or frozen; and
5. Reheating of the packages to a specified temperature before opening and service.

Vacuum Packaging reduces the amount of air from a package and hermetically seals the package so that a near-perfect, vacuum remain inside. A common variation of the process is Vacuum Skin Packaging (VSP). A highly flexible plastic barrier is used by this technology that allows the package to mold itself to the contour of the food being packaged.

Public Health Rationale

Use of reduced oxygen packaging (ROP), with some foods, provides the potential for growth of several important pathogens, thereby markedly increasing safety concerns.

An anaerobic environment, usually created by ROP, prevents the growth of aerobic spoilage organisms. These aerobic organisms are responsible for off-odors, slime, and texture changes, which are signs of spoilage. The inhibition of these spoilage organisms is significant because, without them, tell-tale signs signaling that the product is no longer fit for consumption will not occur.

ROP processors and regulators must assume that during distribution of foods, or while being held by retailers or consumers, refrigerated temperatures may not be consistently maintained. A serious concern is that the increased use of vacuum packaging at retail and supermarket deli-type operations may be followed by temperature abuse in the establishment or by the consumer.

If products in ROP are subjected to mild temperature abuse, i.e., 41-53 degree F, at any stage during storage or distribution, foodborne pathogens, including *Bacillus cereus, Salmonella* spp*., Staphlococcus aureus,* and *Vibrio parahaemolyticus* can grow slowly. Also, marginal refrigeration, that does not facilitate growth, may still allow *Salmonella* spp., *Campylobacter* spp., and *Brucella* spp. to survive for long periods of time.

Consequently, one or more growth barriers must be used with refrigeration to control pathogenic outgrowth. Growth barriers are provided by hurdles such as low pH, aw, or short shelf life, and constant monitoring of the temperatures.

Controls and Guidelines (Reduced Oxygen Packaging)

All food establishments packaging food in a ROP atmosphere must develop a HACCP plan and maintain the plan on-site for review by the regulatory authority. In addition, those foods being packaged using a ROP method, but do not have at least two safety barriers, also require a variance.

Safety Barrier Verification

The safety barriers for all processed foods held in ROP at retail must be verified in writing. This can be accomplished in two ways:

- Written certification form the product manufacturer
- Independent laboratory analysis using methodology approved by the regulatory authority.

Recommendations for ROP Without Multiple Barriers

Employee Training

If ROP is used, employees assigned to packaging of the foods must have documented proof that demonstrates familiarity with ROP guidelines and the potential hazards associated with these foods.

At the discretion of the regulatory authority, a description of the training and course content, provided to the employees, must either be available for review or have prior approval by the regulatory authority.

Refrigeration Requirements

Foods in ROP that have only one barrier, i.e. refrigeration, to *C. botulinum*, must be refrigerated to 41 degree F or below and marked with a use-by-date within either the manufacturer's labeled use-by date or 14 days after preparation at retail, whichever comes first.

Any extension of shelf life past 14 days will require a further variance that considers lower refrigeration temperatures. Foods that are intended for refrigerated storage beyond 14 days must be maintained at or below 38 degree F.

Labeling – Refrigeration Statements

All foods in ROP which rely on refrigeration as a barrier to microbial growth must bear the statement "Important – Must be kept refrigerated at 41 degree F" or "Important – Must be kept frozen," in the case of foods which rely on freezing as a primary safety barrier.

Labeling – “Use-by date”

- Each container of food in ROP must bear a “use-by” date.
- This date may not exceed 14 days from retail packaging or repackaging without a further variance granted by the regulatory authority.
- The “use-by” date must be listed on the principal display panel in bold type on a contrasting background
- Any label must contain a combination of a “sell-by” date and use-by instructions which, makes it clear that the product must be consumed within 14 days of retail date.
- Foods that are frozen, before or immediately after packaging, (and remain frozen until use) should bear “Keep frozen, use within 4 days after thawing” statement.

Disposition of Expired Product at Retail

Processed reduced oxygen foods that exceed the “use-by” date or manufacturer’s “pull date” cannot be sold in any form and must be disposed of in a proper manner.

Dedicated Area/Restricted Access

- All aspects of reduced oxygen foods that exceed the “use-by” date or manufacturer’s “pull date” cannot be sold in any form and must be disposed of in a proper manner.
- There shall be an effective separation to prevent cross contamination between raw and cooked foods.
- Access to processing equipment shall be restricted to responsible trained personnel who are familiar with the potential hazards inherent in food packaged by an ROP method.
- Some ROP procedures such as sous vide may require a “sanitary zone” or dedicated room with restricted access to prevent contamination.

The HACCP plan must also include a listing and proportion of food-grade gasses used and a standard operating procedure for method and frequency of cleaning and sanitizing food-contact surfaces in the designated processing area.

Custom Processing Animals

Regulation: 8:24-3.5 Limitation of growth of organisms of public health concern
(h) A retail food establishment shall obtain approval from the health authority to conduct specialized food processing activities before engaging in any of the following activities:
6. Custom processing of animals that are for personal use as food and not for sale or service in a retail food establishment.

Key Terms

Custom Processing - Preparing/processing of animals who have died by means other than slaughtering and whose product is not to be sold or given away and is only for the use of the owner of the animal, his family, and/or non-paying guests

Field dressed - Field dressed means that the body cavity has been opened and the internal organs removed.

Game Animals – means an animal, the products of which are food, that is not classified as poultry, fish, cattle, sheep, swine, goat, horse or equine. The term includes mammals such as reindeer, elk, deer, antelope, water buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat, and non-aquatic reptiles such as land snakes. The term excludes ratites such as ostrich, emu, and rhea.

Public Health Rationale

The purpose of requiring a variance and a HACCP plan, when custom processing animals that are for personal use as food is to ensure that this process is conducted in a sanitary manner. It is also necessary to ensure that these animals, intended for private use, do not get into the food chain, as they are considered an unapproved food source.

The primary concern regarding this type of specialized process is that these animals may be carriers of viruses, rickettsia, bacteria, or parasites that cause illness in humans. Some of these diseases can be severe in the human host.

It is imperative, to avoid cross-contamination, that these animals, which are not inspected under USDA, be processed separately from all other products for sale to the consumer. Strict adherence to proper hand washing techniques and cleaning and sanitizing procedures is also required to prevent microbiological contamination and prevent cross-contamination.

Although when discussing sanitation, the emphasis is placed on the environment, the products themselves must not be over-looked. Dirty or spoiled meat products entering a sanitary environment are not only unacceptable in themselves, but place the environment at risk as well.

Molluscan Shellfish Tank

Regulation: 8:24-6.5 Maintenance and operation

6.5(k)2 – Live animals may be allowed in the following situations if the contamination of food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles cannot result:

i. Edible fish or decorative fish in aquariums, shellfish or crustacean on ice or under refrigeration, and shellfish and crustacean in display tank systems.

2.4(d)2. – Food employees with service animals may handle or care for their service animals and food employees may handle or care for fish in aquariums or molluscan shellfish or crustacean in display tanks if the food employees wash their hands.

Key Terms

Molluscan shellfish – means any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the scallop product consists only of the shucked abductor muscle.

Public Health Rationale

Shellfish are filter feeders allowing concentration of pathogenic microorganisms that may be present in the water. Due to the number of shellfish and the limited volume of water used, display tanks may allow concentration of pathogenic viruses and bacteria.

Since many people eat shellfish either raw or lightly cooked, the potential for increased levels for pathogenic microorganisms in shellfish held in display tanks is of concern. If shellfish stored in molluscan shellfish tanks are offered for consumption, certain safeguards must be in place as specified in a detailed HACCP plan that is approved by the regulatory authority. Opportunities for contamination must be controlled or eliminated. Procedures must emphasize strict monitoring of the water quality of the tank including the filtering and disinfection system.

Controls and Guidelines

Retail Molluscan Shellfish Tanks (Live Fish Holding)

The design and operation of a Live Fish Holding System can play a major role in the prevention of foodborne illness. Proper design will facilitate cleaning and sanitizing of the equipment. In addition, hydraulic design of the unit is important to assure an adequate quantity and quality of water for the intended purpose.

Inadequate flow or “dead spots” can lead to bacteriological growths and/or oxygen deficiency and fish mortality. Minimum turbulence will permit feces and other organic matter generated by active fish to settle out without being suspended and ingested. Use of food grade materials for all construction materials and additives will prevent possible adulteration by chemicals.

Handling Molluscan Shellfish

1. Cull out dead, cracked, and weak molluscan shellfish daily (CCP)
2. Before adding molluscan shellfish to the system, make sure they are cleaned thoroughly and that you cull out all dead, cracked, and weak animals.
3. Never mix molluscan shellfish with other fish species
4. If the tank is ever used for crab, lobster, etc. it must be sanitized before molluscan shellfish may be added. To sanitize the tank, follow the instructions for cleaning the UV bulb (adding bleach solution to tubes, etc.) At the end of the 30 minute soaking period do not open the drain. Fill tank to normal operating level with fresh water and turn system on for 30 minutes. Turn system off and thoroughly flush out tubes, bio-mix, and tank sides. Make sure all bleach smell is gone before adding molluscan shellfish.
5. Never mix lots of molluscan shellfish which come from different shipping containers and are marked with different shipping tags. If molluscan shellfish are added to a tank which already has the same species, then the two lots must be kept separated with a non-absorbent, easily cleaned divider or by the use of non-toxic, single use mesh bags. (These requirements are designed to facilitate a food poisoning investigation and/or food recall).
6. Every shipment, or portion thereof, should be visually inspected to ensure that shellfish is tagged with information as required under 8:24-3.2(o). (CCP) In addition, shellstock tags are to be retained for 90 days from the date the container is emptied and filed in chronological order correlated to the date when, or dates during which, the shellstock are sold or served.

System Design

1. Equipment and utensils must be constructed with materials that are durable, non-absorbent, non-toxic, and easily cleanable.
2. Hold at least 100 gallons of water per 75 pounds of shellfish
   - Re-circulation systems should include:
   - A filtration system capable of maintaining a clean and healthy environment.
   - Refrigeration units that can maintain water temperatures between 40-60 degree F.
   - An accurate thermometer.
   - An adequately designed aeration system (see manufacturer’s instructions)
   - Units which store bivalve mollusks require a UV disinfecting unit (or similarly approved device) capable of maintaining the water quality at a bacteriological count of 2 coliform/100 ml or less.
3. Water must be tested upon initial set-up and on a regular basis thereafter.
4. Dead-ended pipes or hoses that could fill with stagnant water should be avoided.
5. Systems should be equipped with back-flow prevention devices to protect potable water supplies.

System Operation

1. Operational maintenance instructions plus a notice of public health concerns should be attached to each live holding unit.
2. Marine water used in a live holding system must not be taken from an area closed to bivalve harvesting or an area subject to contamination (i.e. sewer/storm drain out-falls, industrial site areas) or within a 125 meter radius of any docks or wharves. If artificial sea water is prepared, the ingredients must be food grade materials and the water from an approved water system.
3. Defoamers, if used, must be of food grade quality
4. The turbidity of the water should not exceed 20 NTU.
5. Product loading my not exceed the manufacturer's recommended limits.
6. Prior to placement in tanks, all shellfish shall be washed and culled to remove dead, broken or weak animals and culled on a daily basis thereafter.
7. Bivalve mollusks must not be mixed with other fish species or share common water systems.
8. Bivalve mollusks from different suppliers, harvest areas or harvest dates must not be commingled. Vertical plastic dividers, mesh bags, etc. may be used to maintain lot identity

Maintenance and Records

1. Designated employees should be responsible for maintenance. Maintenance instructions, operating manuals and checklists should be made available.
2. Maintenance procedures should include:
    a. A weekly cleaning and servicing of the holding unit (draining not required) to include spray nozzles, filtration system, etc.
    b. Daily check to ensure the light is functioning, cleaning the Ultra-violet disinfection system every 6-8 weeks, and replacement of the UV bulbs every 9-10 months. (Spare UV bulbs should be readily available). (CCP)
3. Maintenance and operational logs (water quality, temperature, etc) are to be complete and accurate and should be kept a minimum of one year
4. Records of each lot of bivalves (indicating where purchased and as which plant they were processed) must be kept on site for a minimum of 1 year and made available upon request.

Maintenance Guidelines

Oysters, clams and mussels in a living state must be adequately protected to remain safe, wholesome and attractive to the customer. Federal, state and local health codes usually have specific sanitary controls and record-keeping requirements that are to be applied to the shellfish by all wholesalers and retailers. These requirements usually specify that:

- Shellfish are to be stored and handled so as not to become contaminated
- Storage equipment is to be properly designed, constructed, and cleaned
- Different lots must be stored separately
- Health officials must be able to trace a lot of shellfish to the original shipper and harvest area of origin.

Proper use of holding tanks will ensure that these requirements are met or exceeded. Therefore, the following additional operating instructions must be followed to conform to federal and state requirements.

Care of the UV Unit

1. **Clean the bulb** (every 6-8 weeks) - The UV Unit is a white tubular appliance that is connected to the water circulation hose lines. The unit contains an ultra-violet (UV) bulb which kills bacteria as they pass by. For this reason, clean the bulb every 6-8 weeks.

2. **Drain tank** - Do not remove bio-mix. Mix ½ cup bleach with one gallon fresh water. Remove spray tops from riser tubes. Pour ½ of bleach solution down each riser tube using funnel or container with pour spout. Leave tank drain closed and allow solution to stand in tubes for 30 minutes. Open tank drain and flush out solution by running water from hose down each riser tube. Flush system completely.

3. **Change the UV bulb** (every 9-10 months) - Unplug unit! Remove protective end caps from chamber. Disconnect bulb-pin plugs from both ends of bulb. Remove "o" rings from each end and save for new bulb. Remove old bulb and replace with new. Replace "O" rings and reconnect plugs and end caps.

Additional System Procedures

Maintenance log
One of the welded panels on the system's base should contain a summary of critical instructions as well as a maintenance log. The summary of critical instructions as well as a maintenance log. The log allows the establishment to track the frequency of critical maintenance procedures. The log should be filled out regularly.

Dividers
Removable dividers used in the tank to keep different lots of molluscan shellfish or different species separated must be smooth, non-toxic, non-absorbent, and easily cleaned. Dividers left in the system should be cleaned every time the system is cleaned and be washed, rinsed, and sanitized in an approved manner.

Cleaning Tank Interior
It is important that the tank interior be kept free of algae and slime build-up. To prevent this build-up, the tank interior should be wiped down with a clean rag or towel every time you clean the filter bed (at least once a week).

Troubleshooting Operational Problems
Proper maintenance is the key to the health and longevity of the aquatic animals within the tank. Routine maintenance such as dusting shelves or rotating stock needs to be done regularly. Proper cleaning of the filter system, cleaning and replacement of the ultraviolet lights and disinfection of the tank are major concerns.

Problems to look for are listed below:

1. *Foam* is caused by a build-up of organic proteins and other material in the water. Usual cause is from bleeding of an aquatic animal into the water.
    a. Remove foam by scraping off surface with fine mesh screen or siphon and vacuum.
    b. Look for cause. Remove injured animals and check for missing body parts (i.e. fins, legs, cracked or broken shells, etc.)
2. *Ammonia smell* – foul odor indicates that organics have built up to a level that anaerobic bacteria have started to digest the matter.
    a. Clean tank
    b. Clean filters
    c. Remove organic solvents
    d. Change the water
    e. Check the ultra violet light
3. *Algae* is normal when tanks are in areas with lots of natural light.
    a. Clean algae off with a clean soft cloth.
    b. Rinsing shellfish thoroughly with cold running water will remove the algae spores from their bodies.
    c. Do not use chemicals to remove the algae from tanks when animals are in the tanks.
4. *Cloudy or yellow hazy* water indicates a build-up of organic proteins (will lead to foaming).
    a. Change the filter's activated carbon unit.
    b. Check for damaged or sick animals.
    c. Check for clogged filter units or clogged air stores.
    d. Install a properly designed filter system if one is not in place.
5. *High mortality* may be caused by several reasons such as:
    a. Animals damaged or suffering from temperature shock during transportation or transfer to tanks.
    b. Toxic substance added to tank, i.e. cleaning chemicals, insect spray, non-food grade glues, non-approved algaecides.

Smoking and Curing

Regulation: 9:24-3.5 – Limitation of growth of organisms of public health concerns
Section (h) – a retail food establishment shall obtain approval from the health authority to conduct specialized food processing activities before engaging in any of the following activities:

1. smoking food as a method of food preservation rather than as a method of flavor enhancement;
2. curing food;

Key Terms

Acceptable Product List – means a list of meat or poultry products for which a HACCP Plan has been approved by a process authority.
Casings – means natural animal stomachs, intestines or bladders or manufactured casings of cellulose or collagen, which are used to contain comminuted meat, or poultry product mixtures for sausages.
Cold Smoking – means a smoking process used to apply smoke or a smoke flavor at or near ambient temperature to food products not sufficiently darkened or flavored in the original cooking process.
Curing – is a process of preserving meat by the application of salt, nitrite and seasonings to meat and is characterized by the interaction of nitrite and meat pigments resulting in the development of a “cured” pink color.
Cure Accelerator – means compounds such as ascorbic acid or erythorbic acid or their derivatives, sodium ascorbate and sodium erythorbate as defined for us in 9CFR 318.7 (c)(4), which shorted the time required for the distinctive pink color to develop in cured meat and poultry products.
Injected – means manipulating a meat so that infectious or toxigenic microorganisms may be introduced from its surface to its interior through tenderizing with deep penetration or injecting the meat such as with juices which may be referred to as “injecting,” “pinning,” or “stitch pumping.”
Massaging – means subjecting meat chunks to a mechanical treatment to facilitate protein extraction from muscle fibers. This process accelerates the even dispersal of cure solution and increases yield.
Process Authority – is a person or organization with expert knowledge in meat or poultry production, process control and relevant regulations.
Showering – means a potable water spray with or without liquid smoke in the smoke house which, depending on when the water spray is applied, maintains humidity, flavors, decreases cooking time, promotes rapid cooling or reduces casing shrinkage.
Smokehouse – means a piece of equipment or room sized enclosure used to conduct the smoking and cooking process which has a smoke source, adequate ventilation, heat and humidity source if necessary, approved plumbing and waste lines if necessary, support structure for the food products to be smoked and a method to determine internal product temperature.

Public Health Rationale

Meat and poultry are cured by the addition of salt alone or in combination with one or more ingredients such as sodium nitrite, sugar, curing accelerators, and spices. These are used for partial preservation, flavoring, color enhancement, tenderizing and improving yield of meat.

The process may include dry curing, immersion curing, direct addition, or injection of the curing ingredients. Curing mixtures are typically composed of salt (sodium chloride), sodium nitrite, and seasonings. The preparation of curing mixtures must be carefully controlled.

A number of proprietary mixtures, which are uniform in composition, are available. The maximum residual sodium nitrite in the finished product is limited to 200 ppm by the USDA Food Safety and Inspection Service (FSIS). A sodium nitrite concentration of 120 ppm is usually sufficient for most purposes. Specific requirements for added nitrite may be found in USDA regulations, 9 CFR 318 and 381. It is important to use curing methods that achieve uniform distribution of the curing mixture in the meat or poultry product.

Controls and Guidelines

Incorporation of Cure Ingredients

Regardless of preparation method, cure ingredients must be distributed throughout the product. Cure ingredients may be introduced into sausage products during mixing or comminution. Proper and through mixing is necessary whether the cure is added to the formulation in dry or solution form. Muscle cuts may be cured by immersion into a curing (pickling) solution. These methods are slow to diffuse curing agents through the product. Products must be properly refrigerated during immersion curing.

Smoking

Smoking is the process of exposing the meat products to wood smoke. Depending on the method, some products may be cooked and smoked simultaneously, smoked and dried without cooking, or cooked without smoking.

Smoke may be produced by burning wood chips or using an approved liquid smoke preparation. Liquid smoke preparations may also be substituted for smoke by addition directly onto the product during formulation in lieu of using a smokehouse or another type of smoking vessel.

As with curing operations, a SOP must be established to prevent contamination during the smoking process.

Fermentation and Dehydration

Meat may be fermented or dehydrated for preservation. The purpose of fermentation is to reduce the pH to below 4.6 and inhibit bacteria harmful to health as well as bacteria that can cause spoilage.

Meat products may also be cured and then dehydrated to prevent germination and growth of bacterial spores. Many fermented and dehydrated meats are made without a cooking step.

Sanitary practices in the production of these products are extremely important because *Staphylococcus aureus* can be introduced. *Staphylococcus aureus* produces an entertoxin that is heat stable and thus will not be inactivated by subsequent cooking.

Processed pork products require treatment to destroy *Trichinella spirilla*. At retail, products which contain raw pork and which are not subsequently cooked must be produced from trichina-free certified pork or treated to destroy trichina. USDA regulations, 9 CFR 318.10(c)(3), establish various requirements for destroying trichnia in pork by heating, freezing, drying or smoking.

Dedicated Area/Restricted Access

All aspects of curing operations must be conducted in an area specifically designated for this purpose. There must be an effective separation to prevent cross contamination between raw and cooked foods or cured and uncured foods. Access to processing equipment shall be restricted to responsible trained personnel who are familiar with the potential hazards inherent in curing foods.

Time as a Public Health Control

Regulation: 8:24-3.5 – Limitation of growth of organisms of public health concern
(g) If time only, rather than time in conjunction with temperature, is used as the public health control for a working supply of potentially hazardous food before cooking, or for ready-to-eat potentially hazardous food that is displayed or held for service for immediate consumption:

1. The food shall be marked or otherwise identified to indicate the time that is four hours past the point in time when the food is removed from temperature control;
2. The food shall be cooked and served, served if ready-to-eat, or discarded, within four hours from the point in time when the food is removed from temperature control;
3. The food in unmarked containers or packages or marked to exceed a four hour limit shall be discarded; and
4. Written procedures shall be submitted to the health authority for approval prior to using time as a public health control and shall be maintained in the retail food establishment to ensure compliance with:
   i. Paragraphs (g)1 through 3 above; and
   ii. Subsection (d) above, for food that is prepared, cooked, and refrigerated before time is used as the public health control.

(h) A retail food establishment shall obtain approval from the health authority to conduct specialized food processing activities before engaging in any of the following activities:

7. Using time as a public health control.

Public Health Rationale

The Food Code permits the use of time, rather than time and temperature, as a public health control when the potentially hazardous food (PHF) will be cooked and/or held for immediate consumption. However, these foods may only be stored without temperature control for up to 4 hours, after which they must be discarded or consumed.

Food kept without temperature control allows product to warm or cool as it equilibrates with the environment. Each temperature scenario incurs different risks in regard to the type of foodborne pathogens able to grow and the rate of growth likely to occur. For both cooling and warming conditions, growth depends on the amount of time the food spends in an optimum growth temperature range during is equilibration with its surroundings. Several factors influence the rate of temperature change in a food, such as the type of food, thickness of the food, and temperature differential between the food and its surroundings.

When evaluating the safety of a 4-hour limit for food with no temperature control, products and environmental parameters must be selected to create a worst-case scenario for pathogens growth and possible toxin production.

Controls and Guidelines

Holding Hot Food without Temperature Control

When food is cooked according to the Food Code recommendations and is then kept at room temperature for 4 hours before discarding, spore forming organisms *Clostridium perfringens* and *Bacillus cereus* are of primary concern.

This is because food cooked according to the Food Code guidelines should be free of vegetative cells. However, the heat requirements are not sufficient to kill spores of *C. perfringens* or *B. cereus* and may actually serve as a heat shock that activates the spores.

B. cereus is found commonly in outbreaks attributed to inadequate hot holding of starchy foods like rice, and has been isolated in a multitude of food products. *C. perfringens* is found commonly in outbreaks attributed to inadequate hot holding of meat and poultry.

Holding Cold Food with Temperature Control

When a food is removed from refrigerated storage and begins to warm to room temperature, *Listeria monocytogenes* is a primary organism of concern. Even while food is held at refrigeration temperatures, the growth potential of *L. monocytogenes* warrants concern for potentially hazardous RTE foods.

Salmonella is also a concern especially with products containing eggs. However, *L. monocytogenes* grows more rapidly than *Salmonella* at refrigeration and room temperatures. By ensuring minimal *Listeria* growth in food, the threat from *Salmonella* would be negligible. Warming conditions will allow food to remain exposed to temperatures that allow *B. cereus* to produce emetic toxin. However the 4-hour time constraint in the Food Code is sufficient to prevent any toxin formation.

Non-compliant HACCP Systems

A HACCP system may be found inadequate if, during the field verification inspection, the regulator finds that actual procedures, corrective actions, records, critical limits, or verification procedures are not in compliance with regulations or the validated HACCP Plan. Some of these inadequacies may include:

- The HACCP Plan in operation does not meet the requirements as stated in the validated HACCP Plan
- Establishment personnel are not performing tasks specified in the validated HACCP Plan
- The establishment fail to take corrective actions, as required by regulation, or as stated in the validated HACCP Plan
- HACCP records are not being maintained as required by regulation or as stated in the validate HACCP Plan
- Adulterated product is being produced or transported

Enforcement/Corrective Actions

During the field verification inspection, any finding, considered to have an immediate impact on public health and safety, must be assessed. When necessary, immediate corrective, or compliance action, must be taken to control the hazard and/or the product.

On-site corrective actions, or subsequent enforcement actions, should be appropriate to the type of violation and could include one or more of the following:

- Accelerated cooling of foods when cooling time limits can still be met
- Reheating when small deviations from hot holding have occurred
- Continued cooking when proper cooking temperatures have not been met
- Initiated use of gloves/tongs/utensils to prevent hand contact with ready-to-eat foods, or required hand washing when potential contamination was observed
- Required hand washing when potential contamination is observed
- Modifications to the HACCP Plan
- Disposal of foods that have experienced extreme temperature abuse or do not comply with critical aspects of the HACCP Plan
- Embargo or disposal of foods from unapproved sources
- Warning letters
- Re-Inspection
- Citations/Administrative fines
- Permit suspension
- Hearings
- Suspension
- Emergency closure

Follow-up Field Verification Inspection

It is recommended that follow-up verification inspections be conducted:

- Routinely or on an unannounced basis, to ensure that selected CCPs are under control
- When established criteria have not been met
- Patterns of non-compliance/non-conformance noted, indicating a systematic failure of management control
- When foods prepared at the establishment have been implicated as a vehicle of foodborne disease
- To verify that changes have been implemented correctly after a HAACP plan has been modified
- When requested on a consultative basis and resources allow accommodating the request

Review of changes to the initial HACCP plan should be carried out during a follow-up regulatory inspection. The establishment's records will form the basis to validate and verify the HACCP plan changes.

Prior to the follow-up inspection, the regulator may wish to contact a regional expert for clarification or direction with regard to HACCP plan changes.

Following a successful inspection for changes to the HACCP Plan, the regulator should issue an acceptance letter to the establishment.

GERALD M. THORNTON
Freeholder

KEVIN L. THOMAS, M.A.
Health Officer
Public Health Coordinator

JOSEPH R.TORDELLA, D.O.
Medical Director

CAPE MAY COUNTY DEPARTMENT of HEALTH

4 Moore Road
Cape May Court House, N.J. 08210-1601
(609)465-1209 after hours (609) 465-1190
Fax: (609) 465-6564

Hazard Analysis Critical Control Point (HACCP) Plan Review Application

Establishment Name: _____

Site Address: _____

Telephone #: _____

Owner/Person-in-Charge: _____

HACCP Plan Contact: _____

Telephone #: _____

Email: _____

Please review/use this checklist to verify that you have included the following in your plan:

- Name of food product and process for which the plan is being submitted.
  - Include formulation of ingredients
  - Include facility layout
  - Include copy of labeling
- A flow chart, showing how the product flows through the establishment, including an accurate description of how the food is prepared, held, served, transported, etc.
- Identification of each Critical Control Point (CCP) in the process.

For *Each* CCP……

- A description of the hazard(s)
- The critical limit for each control point
- A description of monitoring procedure(s) and a sample of form(s) that will be used to document the monitoring activities
- A description of corrective action(s) and sample of form(s) that will be used to document the corrective action(s).
- A description of verification procedure(s) and sample of form(s) that will be used to document verification activities by PIC.

- Page 29
  - A description of plan verification and validation procedures (ex. Annual review, scientific data, modifications to plan.) Please include:
    - A statement that an updated, signed copy of the plan will be maintained on the premises for review by the regulatory authority.
    - Name of person responsible for administering and updating plan
    - A statement that the regulatory authority will be informed of any significant changes in the process that may affect the accuracy or effectiveness of the plan prior to implementation, and
    - A statement that updated plans will be submitted to the regulatory authority, upon request.
    - Laboratory data, if required.
  - Employee training plan and sample form(s) that will be used to document employee training.

All of the information submitted is accurate to the best of my knowledge. All violations noted during previous food safety inspections have been corrected and the operation is in compliance with Chapter 24 "Sanitation in Retail Food Establishments and Food and Beverage Vending Machines".

I understand that failure to comply with this plan and/or falsification of monitoring, corrective action, or verification records may result in a suspension of operations in accordance with Chapter 24.

_____

Permit Holder or Person-in-Charge Signature/Title/Date

For Board of Health Use:

Date	Reviewer	Comments	Accepted	Rejected

Implementation Date:	