REDUCED OXYGEN PACKAGING HACCP PLAN
REQUIREMENTS AND GUIDELINES FOR DEVELOPING A PLAN

INTRODUCTION

The Hazard Analysis Critical Control Point (HACCP) plan required by the Department of Health and Mental Hygiene (DOHMH) for reduced oxygen packaging (ROP) is a prevention-based food safety system, based on the plan in the 2009 US FDA Food Code. It identifies and tracks the processes food products undergo as they pass from the supplier to the table. HACCP treats receiving, storage, preparation, cooking, cooling, holding and service of food as a continuous system or flow. It is designed to assist in identifying and monitoring Critical Control Points (CCPs) in the process flow. Each step in the process flow is broken down into logical component and is evaluated by principles of risk. Hazard as used in this document is limited to food safety.

HACCP is a management system that helps to assure food safety through the analysis and control of possible biological, chemical, and physical hazards that may contaminate food. It is based on the premise that if each step of the process is carried out correctly, the end product will be safe food. A CCP is a point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels. For the successful implementation of any HACCP plan, management of a food operation must be strongly committed to the HACCP concept.

The implementation of a HACCP plan is most effective when a team approach is used to design and implement a comprehensive plan based on the HACCP principles. A complete team may include, but not be limited to, the owner, managers, chefs, cooks, dishwashers, wait staff, and other staff who are actively involved in any aspect of food preparation within a food service establishment (FSE), from receipt of food products at the “back door” to serving of food in the “front of the house.”

Whenever a HACCP plan is required by the DOHMH it must be approved by DOHMH, determined to be scientifically and technically sound, to identify all hazards and, if properly implemented, will effectively control such hazards. Prior to approval, DOHMH may require additional information that will enable it to determine that food safety is not compromised by any step in the HACCP proposal.

All FSEs using ROP must develop a HACCP plan and maintain the plan at the food establishment for review by the DOHMH inspectors. HACCP plans for ROP must include:

- A flow diagram for each specific food or food category identifying CCPs. A flow diagram is a simple schematic picture of the exact process you use in your establishment to produce the food product.

- A complete description of the preparation, packaging, and storage procedures designated as critical control points, with attendant critical limits, corrective action plans, monitoring, verification schemes and records required;

- A list of equipment and food-contact packaging supplies used, including compliance standards required by the regulatory authority.

- A listing and proportion of food-grade gases used; and

- Standard operating procedures for cleaning and sanitizing food-contact surfaces in the designated food preparation area including:
    - The method and frequency for monitoring each critical control point by a food worker designated by the person-in-charge (PIC)
    - The method and frequency for the PIC of food operations to routinely verify that food workers are following standard operating procedures and monitoring the CCPs,
    - The corrective action to be taken by the PIC if the critical limits for each CCP are not met.
- Records/logs that will be maintained by the PIC to demonstrate that the HACCP plan is being properly implemented.

STANDARD OPERATING PROCEDURE (SOP)

This is a detailed set of instructions, steps or procedures that control the operational conditions within an FSE allowing for environmental conditions favorable to the preparation of safe food. SOPs describe a set of objectives associated with sanitary handling of food and the cleanliness of the food service environment. SOPs can help control bacterial hazards by specifying procedures to:

- Avoid product cross-contamination by proper product flow and limiting food worker's tasks and movement
- Locate hand washing and sanitizing stations near the food preparation area to facilitate proper hand washing
- Ensure appropriate equipment maintenance and cleaning/sanitizing procedures

When SOPs are in place, a HACCP plan can be more effective because it can concentrate on the hazards associated with the food or preparation and not on the food environment or maintenance of facilities. Programs that are valuable in supporting the HACCP system address:

- Personal hygiene
- Maintenance plans
- Pest control
- Equipment and operation design
- Food worker training
- Product identification

Sanitation SOPs cover daily pre-operational sanitation procedures that the FSE must implement to prevent direct product contamination or adulteration. It is a prerequisite to HACCP.

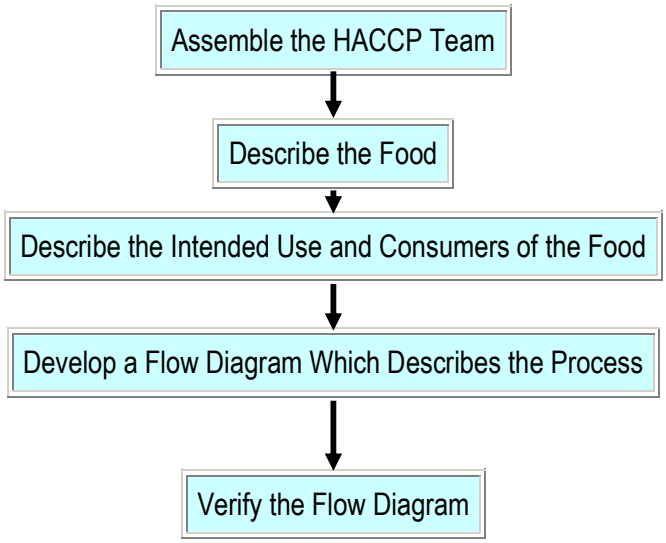
REDUCED OXYGEN PACKAGING

In reduced oxygen packaging (ROP), results in a reduced oxygen level in the sealed food package. The air we breathe has approximately 21% oxygen hence any packaging option that results in less than 21% oxygen is classified as ROP. However, by reducing the oxygen normally found in the package, and the consequent reduction in normal food spoilage bacteria, an environment could be created conducive to the growth of more dangerous pathogenic food microorganisms such as *Clostridium botulinum*. ROP options include processes such as Cook-chill, Controlled Atmosphere (CA) and Modified Atmosphere Packaging (MAP), Sous Vide processing and Vacuum-Packaging. ROP offers unique advantages and opportunities such as extended shelf-life and improved quality retention to the food industry, but also raises many microbiological concerns. Ensuring the safest possible food product to the consumer is the ultimate responsibility of each food service establishment.

PUBLIC HEALTH RATIONALE

Use of reduced oxygen packaging (ROP), with some foods, provides the potential for growth of several important pathogens such as Clostridium Botulinum, thereby increasing safety concerns. Clostridium Botulinum is the causative agent of botulism, a severe food poisoning characterized by double vision, paralysis, and occasionally death. 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. Unless potentially hazardous foods (temperature controlled for safety) are protected inherently, simply placing them in ROP without regard to microbial growth will increase the risk of food-borne illnesses.

In the development of a HACCP plan, five preliminary tasks need to be accomplished before the application of the HACCP principles to a specific product and process. These are:



PRINCIPLE 1: CONDUCT A HAZARD ANALYSIS AND IDENTIFY THE HAZARDS

The first principle of HACCP is to conduct a hazard analysis, describing operational steps (receiving, storage, preparation, cooking, holding, and service) and determining what food safety hazards are likely to occur at each step and whether applicable preventive measures are available. These determinations should be done with the aid of a flow diagram and be based on incidence evaluation and/or scientific data on hazards.

A. DEVELOP A FLOW CHART/DIAGRAM.

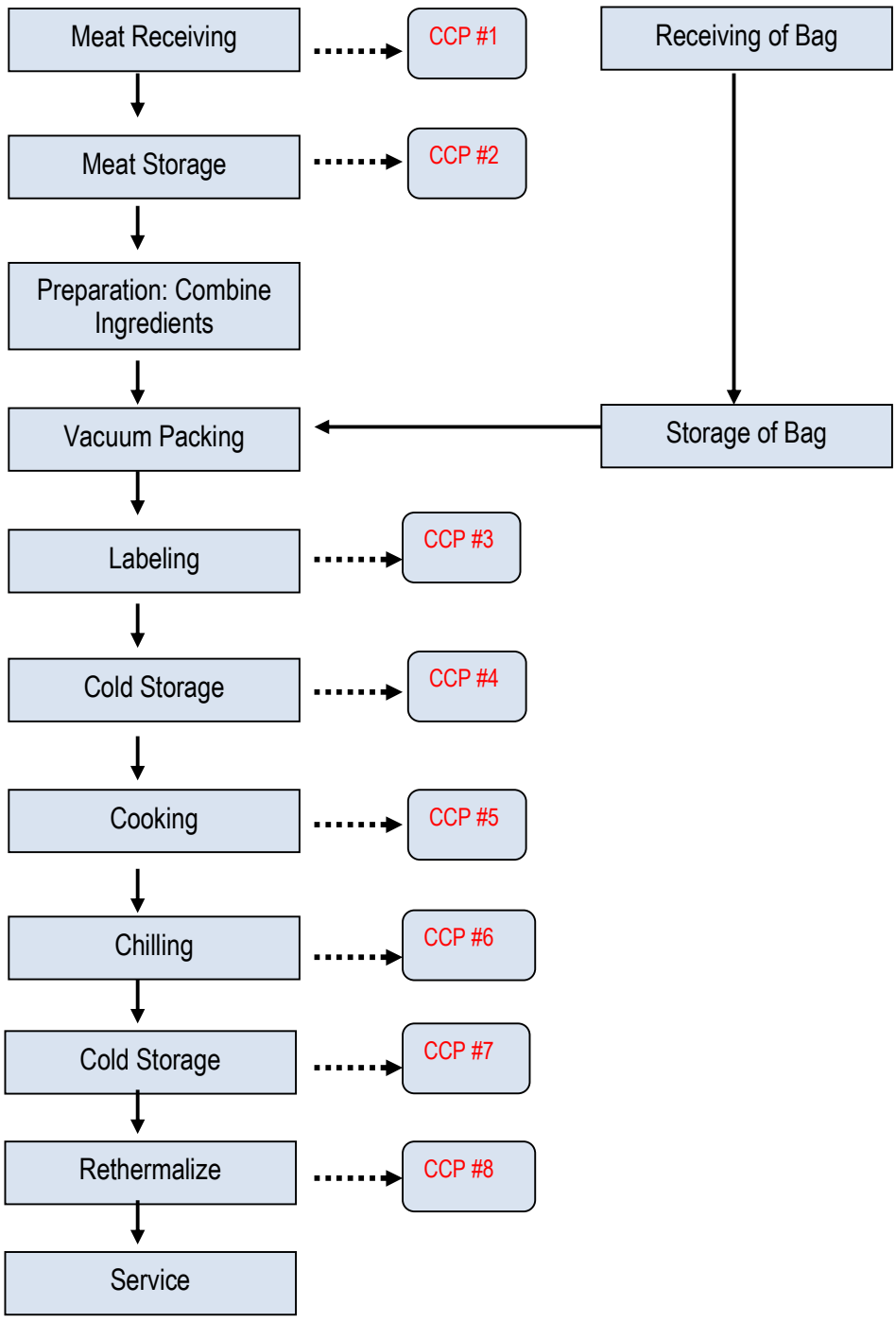
A flow diagram provides a clear simple outline of the steps involved in the process from receipt of raw materials to service of prepared foods. Since the flow chart is the basis for the hazard analysis, it must be correct and complete. Any hazard that is not identified and therefore not controlled may lead to an unsafe product.

A typical process flow diagram for meat preparation with CCPs is shown in Figure 1. The flow chart, which can be product or process specific, covers all the steps in the process, and forms the foundation for applying the seven principles of HACCP.

PRINCIPLE 1. DEVELOP A LIST OF HAZARDS

The purpose of the first HACCP principle is to develop a list of hazards which are of such significance that they are reasonably likely to cause injury or illness if not effectively controlled. The primary goal of food safety is to control food safety hazards. Identifying and controlling the hazards are keys to a successful HACCP system. In the flow diagram, potential biological, chemical and physical hazards associated with receiving, storing, preparing, cooking, holding, reheating, and service of the food product are identified for each process step.

Figure 1. Flow Diagram for Meat Preparation.



B. IDENTIFY POTENTIAL HAZARDS.

Once the flow chart is drawn, each step in the process must be carefully examined and all potential hazards that may occur must be identified. Hazard analysis involves hazard identification and evaluation by the HACCP team. After the list of potential hazards is assembled, the HACCP team must decide which potential hazards must be addressed in the HACCP plan. During this stage, each potential hazard is evaluated based on the severity of the hazard and its likely occurrence. Severity means the risk to the consumer. Hazards associated with each step in the flow diagram are then listed in the hazard analysis table along with preventive measures proposed to control the hazards. Hazards that are low risk and not likely to occur need not be listed on the hazard analysis.

A food safety hazard is any unacceptable contamination by a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control. A preventive measure is the means by which the FSE is able to control the hazard. To properly identify biological, chemical, or physical hazards likely to occur, one needs to know about the chemical, physical, and microbiological characteristics of the ingredients, as well as how various processes affect those characteristics. Each step in the process flow diagram is evaluated to determine whether a biological, chemical and/or physical hazard may be introduced at that step and whether applicable preventive measures are available.

Biological Hazards

Biological hazards are living organisms, including micro-organisms, which can put human health at risk. Biological hazards include bacteria, parasites, protozoa, viruses, and the like. Agricultural products and food animals carry a wide range of bacteria. From a public health standpoint, most bacteria are harmless. However, food-borne pathogenic microorganisms (harmful bacteria) can cause illness, disease or even death in humans. Pathogenic bacteria cause a large proportion (approximately 90%) of all food-borne illnesses. During transportation, receiving, storage, preparation, packaging, and service, any food may be exposed to pathogenic biological contamination. Pathogens can survive when you do not cook food properly to the recommended internal temperatures, multiply if you do not store food at the correct temperature and spread from raw food to cooked/ready to eat foods.

Chemical Hazards

Chemical hazards involve chemicals or deleterious substances contaminating food due to improper storage of food or chemicals, misuse of cleaning or pesticide products, or naturally occurring sources. Chemical hazards fall into two categories:

- Naturally occurring poisons, chemicals or deleterious substances that are natural constituents of foods and are not the result of environmental, agricultural, industrial, or other contamination. Examples include aflatoxins, hypoglycins, and shellfish toxins.
- Added poisonous chemicals or deleterious substances that are intentionally or unintentionally added to foods at some point in growing, harvesting, storage, processing, packing, or distribution. This includes pesticides, fungicides, insecticides, fertilizers, drug residues, and antibiotics, as well as food additives. This group can also include chemicals such as lubricants, cleaners, paints, and coatings.

Physical Hazards

Physical hazards are any physical material not normally found in a food that causes illness or injury to the individual consuming the food. Physical hazards include a variety of foreign materials or objects, such as glass, metal, and plastic. However, foreign objects that cannot or do not cause illness or injury are not hazards, even though they may not be aesthetically pleasing to your customers. A number of situations can result in physical hazards in finished food products. They include, but are not limited to poorly designed or poorly maintained facilities and equipment. An example is paint chips falling from overhead structures onto an exposed food, or pieces of metal from improperly maintained equipment getting into the food product. Physical hazards may be caused by improper procedures or improper food worker training and practices. Examples are broken glass, plastic, wood, metal, hair, jewellery, pests and/or their droppings.

PRINCIPLE 2. DETERMINE THE CRITICAL CONTROL POINTS

The information developed during the hazard analysis is used by the HACCP team to identify which steps in the process are critical control points (CCPs). A CCP is a step at which a control can be applied to prevent or eliminate a biological, chemical or physical hazard or reduce it to an acceptable level. A complete and accurate identification of CCPs is necessary to control food safety hazards. For example, cooking that must occur at a specific temperature and for a specified time in order to destroy microbiological pathogens are a CCP. Cooking, cooling and storage are a few examples of CCPs, and each requires a control to reduce the risk to the consumer.

PRINCIPLE 3. ESTABLISH THE CRITICAL LIMITS

A critical limit is defined as a criterion that must be met for each preventive measure associated with a CCP. A critical limit may be a temperature limit at which potentially hazardous food must be cooked, re-heated, or held hot. A critical limit could also be a food hygienic practice that prevents the spread of harmful bacteria from raw food to ready-to-eat food such as the use of different coloured knives and boards. Critical limits are boundaries and measurements that define safety for CCPs and can be found in the New York City Health Code (HC) or the New York State Sanitary Code (SSC). Example HC§ 81.09(a)(2) sets a critical limit of 155^{o}F (68.3^{o}C) for 15 seconds as the minimum internal temperature required for cooking pork and pork products. Similarly chicken and chicken products are considered safe when the internal temperature reaches 165^{o}F (73.9^{o}C). When critical limits are not met, it could mean that the food is not safe to eat.

Table 1: ROP Processes and Critical Limits

PROCESS	CRITICAL LIMIT
Receiving	Food that arrives in the FSE that is not at the required temperature should not be accepted. Food must come from identifiable and approved source. Limit the amount of time potentially hazardous foods are in the temperature danger zone (41° F - 140° F) or (5° C - 60° C).
Cold Holding	Potentially hazardous raw food must be kept at or below 41° F prior to placing in a ROP bag. Raw meat or poultry placed in ROP may be kept at 38° F (3° C) or below without being cooked for no more than 14 calendar days, and must be discarded after 14 days. All *aquatic animals must be kept at 32°F (0°C) or below for the entire process. Once cooked, refer to the health code for cold holding temperatures. All other ROP food must be cooked immediately.
Cooking	Cook all ROP foods until the internal temperature reaches the required cooking temperatures set in the NYC Health Code. For example, poultry should be cooked so that all parts are at least 165° F (73.9°C) and held for at least 15 seconds.
Cooling	Immediately after cooking, ROP food can be cooled in any of the following ways: 1. Cool to 34°F or less within 6 hours, hold at that temperature and consume or discard within 30 days 2. Cool to 34°F or less within 6 hours, hold at 41°F or less and consume or discard within 72 hours 3. Cool to 38°F or less within 2 hours, hold at that temperature and consume or discard within 72 hours 4. Hold ROP food frozen with no shelf life restriction until consumed or used.
Cold Holding After ROP	Cooked ROP foods held at 41° F (5° C) or below are to be consumed within 72 hours or discarded. Cooked ROP foods held at 34° F (1° C) or below are to be consumed or discarded within 30 days of preparation.
Holding	All aquatic animals raw or frozen must be kept at 32° F (0° C) or below during the entire process
Rethermalization	Rethermalize (heat) all ROP foods until all internal parts of the product reaches 140° F (60° C).
Labeling	All ROP products must be labeled to include at a minimum; product name, date packaged, required storage temperature, and discard date. Label should always be in accordance with approved HACCP plan.
Natural Inhibitors used	Foods with a pH of 4.6 or lower wouldn't allow growth of bacteria. Foods with a Water Activity (Aw) of 0.85 or less do not permit bacterial growth. These inhibitors will affect the length of time that food can be held in reduced oxygen packaging

*Aquatic animal means fresh or saltwater finfish, crustaceans and other forms of aquatic life (including but not limited to alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, if such animal life is intended for human consumption.

PRINCIPLE 4. ESTABLISH MONITORING PROCEDURES

Once you have decided which process steps are CCPs and have set the critical limits, a food worker from the HACCP team must be assigned to take necessary measurements and record the observations.

Monitoring is a planned sequence of observations or measurements to assess whether the CCP is under control and to produce an accurate record for future use in verification. When it is not possible to monitor a critical limit on a continuous basis, it is necessary to establish that the monitoring interval will be reliable enough to indicate that the hazard is under control. Monitoring is intended to prevent deviations from occurring or to indicate when one has actually occurred, so that corrective action can be initiated.

Food workers from the HACCP team who are responsible for the monitoring process must:

- be trained in the monitoring technique for which they are responsible
- fully understand the purpose and importance of monitoring
- be unbiased in monitoring and reporting, and
- accurately report the results of the monitoring

For example: Checking the temperature of a refrigerator to ensure it is within its critical limit. In this example, the control measure (to inhibit bacterial growth) is to control the temperature. If the critical limit has been set at no higher than 38° F (3.3° C) the purpose of monitoring is to verify that the critical limit of 38° F (3.3° C) has been met.

Certain control measures may have critical limits that cannot be easily measured. For example: how would you monitor the activities of the food worker to prevent cross contamination? The use of differently colored cutting boards for raw and cooked products is one way of providing the control measure for hazards such as cross contamination in preparation. In this case, the effective monitoring is a visual check by the supervisor of the operations. All records and documents associated with CCP monitoring should be dated and signed or initialed by the person doing the monitoring.

PRINCIPLE 5. ESTABLISH CORRECTIVE ACTIONS

Whenever there is a deviation from established critical limits, corrective actions are necessary. Specific corrective actions should be developed in advance for each CCP and included in the HACCP plan. As a minimum, the HACCP plan should specify what is done when a deviation occurs, who is responsible for implementing the corrective actions, and that a record will be developed and maintained of the actions taken. Only food workers who have a thorough understanding of the process, product and HACCP plan should be assigned the responsibility for oversight of corrective actions.

Here are a few examples of corrective action:

- If your refrigerator temperature Critical Limit is 38° F (3.3° C) but your “monitoring” check finds that the refrigerator is running at 53.6° F (12° C), your “corrective action” could be: "call the maintenance engineer and discard the food".
- If your cross contamination critical limit is to "keep raw and cooked ready-to-eat foods separated" but your “monitoring” check finds blood on the board to be used for chopping vegetables, then your

"corrective action" could be: "thoroughly clean and sanitize the board, retrain your food workers and dispose of affected food."

PRINCIPLE 6. IMPLEMENT VERIFICATION PROCEDURES

Verification is defined as those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan. Verification involves taking an overview of your HACCP based system to ensure it is working. Verification also involves establishing that your procedures are effective in controlling hazards and checking to see that your procedures are being applied in practice.

Verification activities are carried out by the person in charge of food operations who routinely verifies that the food worker is following the HACCP plan. All verification actions undertaken must be recorded. One aspect of verification is evaluating whether the FSE's HACCP system is functioning according to the HACCP plan. The person in charge of food operations should rely on:

- frequent reviews of the HACCP plan,
- verifying that the HACCP plan is being correctly followed, and
- review of CCP monitoring and corrective action records.

Examples of verification activities include checking to see that:

- control measures at CCPs are being consistently applied
- appropriate corrective actions have been taken
- monitoring records are consistent and accurate, and
- procedures are still relevant and up to date.

PRINCIPLE 7. ESTABLISH AND IMPLEMENT A RECORD-KEEPING SYSTEM

Accurate record keeping is an essential part of a successful HACCP program. Written records or other kinds of documentation approved by the Department will be needed in order to verify that the system is working. Records provide documentation that the critical limits have been met or that appropriate corrective actions were taken when the limits were exceeded. Likewise, they provide a means of monitoring so that process adjustments can be made to prevent a loss of control.

Record keeping should be as simple as possible to facilitate accurate data collection by the designated food worker.

Records to be kept as part of the HACCP system include:

1. HACCP plan and support documentation used in developing the plan
2. Records of CCP monitoring
3. Records of corrective action
4. Records of verification activities

Specifically these records are:

- HACCP Plan Form
- Approved Source
- Receiving Log
- Damaged and Discarded product Log
- Daily Storage Temperature Log
- Daily cooking and Reheating Log
- Cooling Temperature Log
- Thermometer Calibration Log
- Corrective Action Log
- Food worker training record

All records need to be kept on site for at least 90 days after consumption of the food prepared pursuant to the HACCP plan to demonstrate that the HACCP plan has been properly implemented. (Copies of all forms to be used are attached to these guidelines. These forms are suggestions. If more documentation is required at a specific FSE, by the PIC or the DOHMH, the form should be adapted.)

RECOMMENDATIONS FOR ROP

(1) EMPLOYEE (FOOD WORKER) TRAINING

If ROP is used, food workers assigned to packaging and/or processing the food must be trained, and must demonstrates familiarity with ROP guidelines and the potential hazards associated with these foods.

(2) REFRIGERATION REQUIREMENTS

The use of refrigeration to ensure food safety in ROP requires very rigorous temperature controls and monitored refrigeration equipment. The refrigeration unit should be equipped with an electronic system that continuously monitors time and temperature and should be visually examined for proper operation twice daily.

A food that has an A_w 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 United States Department of Agriculture using substances specified in 9 CFR 424.21, or successor regulation, and is received in an intact package; or is a food with high level of competing organisms such as raw meat or raw poultry, may be held at 38 degrees Fahrenheit (3.3 degrees Celsius) without being cooked for no more than 14 calendar days, and must be discarded after 14 days.

Food cooked in ROP packages should be properly cooled to an internal temperature of 38° Fahrenheit (3.3° Celsius) or below within two hours of cooking and further cooled to an internal temperature of 34° Fahrenheit (1.1° Celsius) or less within six hours of reaching 38° Fahrenheit (3.3° Celsius). Refrigerated ROP food should be held at an internal temperature of 34° Fahrenheit (1.1° Celsius) and consumed or

discarded within 30 days after the date of preparation. However, if cooled to an internal food temperature of 38° Fahrenheit (3.3° Celsius), the food may be held at an internal temperature of 38° Fahrenheit (3.3° Celsius) or less for no more than 72 hours before consumption, and if not consumed, must be discarded.

(3) LABELING

Each ROP packaged food must bear the product name, date packed, and date to be discarded and stored in accordance with a "First-in" "First-out" storage rotation procedure in accordance with the HACCP plan.

Below are examples of Hazard Analysis and HACCP plan summary tables:

Table 2: Hazard Analysis

PROCESS STEP					
Processing Step	**Potential Hazards (C) Chemical (P) Physical (B) Biological**	**Is this potential food safety hazard significant?**	**Justification of Decision**	**Preventive Measures**	**Is this step a CCP?**
Meat Receiving	(B) Pathogens Salmonella & E. coli 0157:H7 Clostridium botulinum (C) and (P) None	Yes	May be present on in-coming raw meat. Proper storage & handling at subsequent steps can reduce the growth of E. coli if present.	Approved supplier showing that the meat has met regulatory standards	CCP #1
Storage					
Preparation					
Vacuum Packaging					
Labeling					
Cold Storage					
Cooking					
Chilling					
Rethermalize					
Service					

Name of Food Establishment: ……..
Address: ……
Signature & Date: ……

Brief Product Description: ……
……
……

Table 3: ROP HACCP Plan Summary

CCP									
Critical Control Point (CCP)	**Hazard Description**	**Critical Limits for each Control Measure**	**Monitoring**				**Corrective Action**	**Verification Activities**	**Record-keeping Procedures**
			What	**How**	**Frequency**	**Who**			
1 Receiving raw Beef	Salmonella and E. coli bacteria	Supplier Certification that product has been sampled for Salmonella must accompany shipment	Check each shipment	Visual examination of records	Every day meat is supplied	Designated food worker	Will not receive meat unaccompanied by Salmonella certification	Receiving Log will be reviewed every month to ensure compliance	In Receiving Log
2 Storage temperature	Pathogens	41°F (5°C) or less	Storage room & Meat temperature	Temperature monitoring device	Daily	Designated food worker	Identify & eliminate cause of deviation. Discard, Prevent recurrence.	Storage Log will be reviewed every month to ensure compliance	In Storage Log
3 Labeling									
4 Cold Storage									
5 Cooking									
6 Chilling									
7. Cold Storage									
8 Rethermalize									

NAME OF FOOD ESTABLISHMENT:_____ BRIEF PRODUCT DESCRIPTION:_____

ADDRESS:_____.

SIGNATURE:_____ DATE:_____

Downloadable Blank Forms & Flow Chart

1. Hazard Analysis Table

PROCESS STEP					
Processing Step	**Potential Hazards (C) Chemical (P) Physical (B) Biological**	**Is this potential food safety hazard significant?**	**Justification of Decision**	**Preventive Measures**	**Is this step a CCP?**

NAME OF FOOD ESTABLISHMENT:_____ BRIEF PRODUCT DESCRIPTION:_____

ADDRESS:_____.

SIGNATURE:_____ DATE:_____

2. ROP HACCP Plan Summary

CCP									
Critical Control Point (CCP)	Hazard Description	Critical Limits for each Control Measure	Monitoring				Corrective Action	Verification Activities	Record-keeping Procedures
			What	How	Frequency	Who			

NAME OF FOOD ESTABLISHMENT:_____ BRIEF PRODUCT DESCRIPTION:_____

ADDRESS:_____.

SIGNATURE:_____ DATE:_____