Establishment Responsibilities

Note: *This section is informational material to give you a basis for understanding what the establishment responsibilities are related to HACCP. It includes a review of the 7 HACCP Principles and hazards of concern for NRTE/RTE products.*

Introduction

Hazard Analysis and Critical Control Point, or HACCP, is a systematic approach to the identification, evaluation, and control of food safety hazards. The HACCP Plan is the written document which is based upon the principles of HACCP and which delineates the procedures to be followed by the official establishment. The HACCP system is the result of the implementation of the HACCP plan.

HACCP is an establishment management's system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from all steps in production, including raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product. For successful implementation of a HACCP plan, an establishment management must be strongly committed to the HACCP concept sustaining a sense of the importance of producing safe food.

HACCP is designed for use in all segments of the food industry from growing, harvesting, processing, manufacturing, distributing, and merchandising to preparing food for consumption. Food safety systems based on the HACCP principles have been successfully applied in food processing plants, retail food stores, and food service operations. The seven principles of HACCP have been universally accepted by government agencies, trade associations and the food industry around the world.

FSIS has the overall authority and oversight to regulate meat/poultry products intended for distribution into commerce. The official establishment's responsibility is to produce safe wholesome meat/poultry products. When the Pathogen Reduction/HACCP System Final Rule was published in July 1996, and the regulation was first implemented in large establishments in January 1998, in Small establishments in January 1999, and in very small establishments in January 2000, FSIS required all establishments that produce federally inspected meat and poultry products to design and operate HACCP systems. HACCP provides a framework for establishments to conduct science-based process controls that can be validated as effective in eliminating, preventing, or reducing to an acceptable level, the food safety hazards that are reasonably likely to occur in an official establishment's particular production processes. Under the HACCP regulatory system, establishments assume full responsibility for producing products that are safe for consumers.

The 7 HACCP Principles

The National Advisory Committee on Microbiological Criteria for Food (NACMCF) working group created guidelines and redefined the seven basic principles of HACCP as an effective and rational means of assuring food safety from harvest to consumption. The working group created the HACCP principles and application guideline document which was adopted in August 1997. This paper is not a regulatory document. However, it is a document that was utilized by FSIS when the HACCP regulation was developed and then published in the Federal Register. As regulators, you will be responsible for verifying compliance with the HACCP regulation. The HACCP guideline with the seven principles is not an enforceable document; however, it is helpful for inspection personnel to be familiar with the basis for the development of the HACCP plan which will be regulated under Title 9 Code of Federal Regulation (CFR) Part 417. The Inspection Methods and Regulatory Decision-making section later in this training will cover your regulatory responsibilities.

The 7 HACCP Principles

The seven principles of HACCP, which encompass a systematic approach to the identification, prevention, and control of food safety hazards include:

1. Conduct a Hazard Analysis
2. Determine Critical Control Points
3. Establish Critical Limits
4. Establish Monitoring Procedures
5. Establish Corrective Actions
6. Establish Recordkeeping and Documentation Procedures
7. Establish Verification Procedures

The National Advisory Committee on Microbiological Criteria for Food (NACMCF) describes the seven principles in its HACCP document. The document and its revisions are currently on the NACMCF webpage, http://vm.cfsan.fda.gov/~comm/nacmcfp.html.

Principle 1: Conduct a hazard analysis

A thorough hazard analysis is the key to preparing an effectively designed HACCP plan. The NACMCF identified the purpose of the hazard analysis in the guidance document as a process used 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. It is important to consider in the hazard analysis the ingredients and raw materials, each step in the process, product storage and distribution, and final preparation and use by the consumer. When conducting a hazard analysis, safety concerns must be differentiated from quality concerns.

A hazard is defined by NACMCF as a biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control. Establishments

must consider all three types of hazards – biological, chemical, and physical – at each step of the production process. A food safety hazard that is reasonably likely to occur is one for which a prudent plant would establish controls because the hazard has historically occurred in the product/process or because there is a reasonable probability that the hazard would occur in the absence of these controls.

The hazard analysis and identification of associated control measures accomplish three objectives: (1) hazards and associated control measures are identified, (2) the analysis may identify needed modifications to a process or product so that product safety is further assured or improved, and (3) the analysis provides a basis for determining Critical Control Points (CCP) in Principle 2.

Hazards identified in one operation or facility may not be significant in another operation producing the same or a similar product. A summary of the HACCP team decisions and the rationale developed during the hazard analysis should be kept for future reference. Upon completion of the hazard analysis, the hazards associated with each step in the production of the food should be listed along with any measure(s) that are used to control the hazard(s). The term control measure is used because not all hazards can be prevented, but virtually all can be controlled. More than one control measure may be required for a specific hazard. On the other hand, more than one hazard may be addressed by a specific control measure.

Federally inspected establishments must conduct hazard analyses for their processes. The plant can either conduct the hazard analysis itself or have an outside source conduct it. This first principle is the key to a successful food safety system within the establishment. If the identification of the food safety hazards in the hazard analysis is not thorough and not well thought-out, and hazards warranting control within the HACCP system are not identified, then HACCP plan when executed will not result in an adequate food safety system due to the original design flaw in the hazard analysis. In other words, products may be produced and distributed into commerce that pose a food safety hazard to the consumer.

These concepts from the first principle will be discussed further in the next section.

Flow Charts

The establishment should have a flow chart accurately depicting the flow of product through the process. The flow chart should include all the steps in the process and should match the steps in the hazard analysis. The CSI should verify that the flow chart accurately depicts the steps in the process by walking through the process while it is in operation.

Hazard Analysis

At each step, the establishment must determine what food safety hazards may be associated with that step, if that hazard is reasonably likely to occur in the process, and what controls will be used to prevent, eliminate, or reduce the hazard to an acceptable level. The control point for a hazard may be further along in the process than the point at which the hazard occurs. For example, the cooking step is the most common control for biological hazards that have been introduced into the product at previous steps.

Each establishment is responsible for identifying the hazards reasonably likely to occur in its process, and for determining how it will control those hazards to prevent, eliminate, or reduce them to an acceptable level. Different establishments may have identified different hazards as reasonably likely to occur and different control measures for them, even though their processes may appear to be similar. For example differences may exist in the type of equipment, incoming product, employee training, or production practices.

When completed, the hazard analysis should have

- Identified hazards reasonably likely to occur, and
- Identified the associated preventive measures that can be applied to control these hazards.

The hazard analysis shall include hazards that can occur before, during and after entry into the plant.

This provides a basis for determining the critical control points (CCPs).

Principle 2: Determine critical control points

The hazards that were identified in the hazard analysis must be addressed in the HACCP plan. A hazard is controlled by one or more critical control points (CCPs).

A ***critical control point*** is defined as 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. Critical control points are locations in a process at which some aspect of control can be applied to control food safety hazards that have been determined reasonably likely to occur.

Examples of CCPs include cooking (lethality), chilling/cooling (stabilization), thermal processing, testing for foreign objects such as metal contamination, the chemical concentration of a carcass rinse or spray, and other such parameters.

The step of the process at which the critical control point is located does not necessarily have to be at the point where the hazard is introduced into the system. It is the plant's responsibility to determine the location of its CCPs. They may be placed at any location deemed adequate to prevent, eliminate, or effectively control the hazard in the meat/poultry product produced.

Control may actually be achieved as a cumulative affect. There may be several steps in the process that together attain complete control, but individually do so only partially. For example, an official establishment produces RTE product. The plant may keep storage temperatures low to control bacterial growth; however this control measure does not entirely eliminate the identified hazard. Next the plant may use an antimicrobial spray to reduce the bacterial load; however this control step is still not entirely eliminating the identified hazard. Next the plant may use salt or other food additives to lower the water activity; however this control step still is not entirely eliminating all the pathogens. Heat may be applied, but not sufficient to be a lethality step. The product may be dried to further reduce the water activity. The finished product is considered RTE by the plant because the combined process control steps actually eliminated the pathogens of concern and the food safety hazard. Another plant uses sufficient cooking temperatures to achieve lethality of the pathogens in one step. In both examples the plants need to have documentation to support that the process produces RTE product.

For ***each*** hazard that is determined to be reasonably likely to occur, the establishment must identify critical control points and corresponding critical limits that are measurable or observable. Establishments must have documentation supporting all of these decisions, and they must be able to demonstrate that their plan designs are valid and effective in operation.

Principle 3: Establish critical limits

The next step in the development of a HACCP plan is to establish critical limits for each critical control point. ***Critical limits*** (CL) are the parameters that indicate whether the control measure at the CCP is in or out of control. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) states that a CL is **a maximum or minimum value** to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard. The HACCP team must consider the food safety standard that must be met at each CCP. Critical limits are designed to ensure applicable targets or performance standards pertaining to the specific process or product. Critical limit design should be based on applicable FSIS **regulations** or guidelines, FDA tolerances and action levels, scientific and technical literature, surveys, experimental studies, or the recommendations of recognized experts in the industry, academia, trade associations, or processing authorities. Critical limits should not be

confused with operational limits which are established for reasons other than food safety.

Critical limits are most often based on process parameters such as temperature, time, physical dimensions, humidity, moisture level, water activity, pH, titratable acidity, salt concentration, available chlorine, viscosity, preservatives, or survival of target pathogens. Critical limits must be actual values that can be measured or quantified. Regardless of the parameter used, the critical limit must be sufficient to prevent, eliminate, or reduce to an acceptable level the occurrence of the food safety hazard it is designed to control. The establishment must be able to provide the basis for their decision documents regarding the selection and development of the critical limits. The HACCP team must develop CLs that work effectively given the capabilities and limitations of the plant's processes.

Principle 4: Establish monitoring procedures

Once critical limits are set for each CCP during the HACCP plan development, procedures must be established to monitor the CCPs to determine whether the critical limits are being met. ***Monitoring*** is a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification. Every CCP that is in the HACCP plan must be monitored to ensure that the critical limits are consistently met and that the process is producing safe product. Establishments are responsible for determining the procedure used to monitor each CCP. Monitoring procedures usually involve either a measurement or an observation. If the critical limit is a numerical value, then monitoring usually involves a measurement. If the critical limit is defined as the presence or absence of an attribute, then the monitoring procedure may involve observation. Monitoring procedures should be designed to determine when deviations from the critical limit occur so that appropriate corrective actions can be initiated.

Establishments must determine how often they need to monitor CCPs. Ideally, the monitoring frequency would be continuous whenever possible. An example is the continual recording of cooking temperatures on temperature recording charts. The advantage of continuous monitoring is that it allows a plant to see what is occurring at a CCP throughout the production process at any given time.

When it is not possible to monitor a CCP on a continuous basis then it is monitored intermittently and the frequency must be determined. The frequency selected should be adequate to determine that the CCP is under control. Statistically designed data collection or sampling systems are used to establish the frequency when monitoring is not on a continuous basis. Establishments can select any employee to conduct monitoring activities. Assigning monitoring responsibilities is an important consideration for establishment management. HACCP monitors are often production employees or quality control personnel. Employees selected to be HACCP monitors should be adequately trained and should understand the purpose and significance of monitoring.

They should also be trained to immediately report unusual occurrences to the individual responsible for initiating corrective actions. The HACCP plan does not have to specify ***who*** will do the monitoring.

From a practical consideration, monitoring has three objectives:

- ***To track control of the process*****.**
  Monitoring the process allows the establishment to identify situations in which a trend is developing that may lead to loss of process control. If monitoring detects such a trend, plants can take appropriate measures to restore process control ***before*** a deviation occurs.

- ***To determine when there is a loss of control and a deviation occurs*****.** Monitoring serves to determine when the process has deviated from the critical limit. This information lets the establishment know appropriate corrective actions must be taken to restore process control and to effectively address all affected product.

- ***To provide a written document to be used in verification*****.**
  Monitoring results must be recorded on official HACCP records, and such records serve as the basis for verification activities.

Principle 5: Establish corrective actions

Next, the HACCP team determines corrective actions for each CCP that must be taken in cases where the CL is not met. The specific corrective actions depend upon the process used and type of food produced.

When there is a deviation from the critical limit, corrective actions are required to prevent potentially hazardous foods from reaching consumers.
The HACCP plan must include corrective actions to be taken when a deviation from the critical limit occurs at a critical control point. The corrective actions consist of

- Identifying and eliminate the cause of the deviation,

- Ensuring that the CCP is under control after the corrective action is taken,

- Ensuring that measures are established to prevent recurrence, and

- Ensuring that no product affected by the deviation is shipped.

HACCP plans should specify what is to take place when a deviation occurs, who is responsible for implementing corrective actions, and that corrective actions will be documented as part of the HACCP records. When designing their HACCP plans, establishments can either specify particular corrective actions they will take when a deviation occurs, or can simply state that they will address the regulatory requirements

in Title 9 CFR Section 417.3 Corrective Action. As appropriate, experts may be consulted to review the information available and to assist in determining disposition of non-compliant product.

Principle 6: Establish recordkeeping and documentation procedures

When developing the HACCP plan, the HACCP team must ensure that the HACCP system has an effective recordkeeping system. ***Records*** are written evidence documenting the operation of the HACCP system. All measurements taken at a CCP, and any corrective actions taken, should be documented and kept on file. These records can be used to trace the production history of a finished product. If any questions arise about the product, a review of records may be the only way to determine whether the product was produced in a safe manner according to the HACCP plan.

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF, 1998) recommends that the establishment maintain four types of records. *Remember that these are recommendations which may be in addition to the regulatory requirements as outlined in 9 CFR Part 417.*

- Summary of the hazard analysis including the rationale
- HACCP plan
- Support documentation such as validation records
- Daily operational records generated during the operation of the HACCP plan

The **summary of the hazard analysis** covers the basis and justification for an establishment's HACCP plan. This includes information about decisions the HACCP team made during the hazard analysis process. It contains all the information about the hazard analysis, including justification for CCPs and critical limits.

The **HACCP plan** outlines the formal procedures the establishment will follow to meet the seven principles. The NACMCF recommends that the HACCP plan records a

- List of the HACCP team and assigned responsibilities
- Description of the food, its distribution, intended use, and consumer
- Verified flow chart for the entire manufacturing process with CCPs indicated
- HACCP Plan Summary Table that lists the following for each hazard of concern—the CCP, critical limit, the monitoring procedures and frequencies, the corrective actions, the verification procedures and frequencies, and the recordkeeping system.

The **supporting documentation** includes the rationale used to establish CCPs, critical limits, monitoring procedures and frequencies, corrective action procedures, and

verification procedures and frequencies. This includes all scientific references, regulatory resources, and materials from other sources (e.g., extension services, academic experts, consultants, industry trade associations) that have been used in the development of the HACCP plan.

The **daily operational records** are what most of us think of when we think of HACCP records. These include the actual records from the implementation of the HACCP plan (monitoring, corrective actions, and verification).

The HACCP regulation requires that HACCP records:

- Contain the date and time of the activity reflected on the record
- Contain the signature or initials of the employee making the entry
- Have the information entered on the record at the time it is being observed
- Contain actual observations or data values obtained

Principle 7: Establish verification procedures

HACCP systems must be systematically verified. In the NACMCF explanation of the verification principle, which FSIS is following, four processes are involved in the verification of the establishment's HACCP system. The establishment is responsible for the first three; FSIS is responsible for the fourth. The first is the scientific and technical process, known as ``validation,'' for determining that the CCPs and associated critical limits are adequate and sufficient to control likely hazards. The second process is to ensure, initially and on an ongoing basis, that the entire HACCP system functions properly. The third process consists of documented, periodic, reassessment of the HACCP plan. The fourth process defines FSIS's responsibility for certain actions (Government verification) to ensure that the establishment's HACCP system is functioning adequately.

Verification establishes the accuracy of, or confirms the monitoring of, the critical control points. The verification procedures demonstrate that the HACCP system is adequately controlling food safety hazards. After initial validation that the HACCP system can work correctly and effectively with respect to the hazards, the system must be verified periodically. Periodic verification involves the use of methods, procedures, or tests in addition to those used for monitoring, to determine whether the HACCP system is in compliance with the HACCP plan and/or whether the HACCP plan needs modification and revalidation to achieve its food safety objective. Establishments must also be able to provide supporting documentation for the verification procedures and frequencies specified in the HACCP plan.

Ongoing verification activities consist, at a minimum, of calibration procedures (if there are instruments that require calibration), direct observations of monitoring and corrective actions, and records review. All three of these will be described in the HACCP plan, as applicable.

The goal of **calibration procedures** is to ensure that all measurements are accurate. If the findings from the procedures show that the measuring device is incorrect, then the device must be recalibrated or replaced. The establishment should determine if the inaccurate process-monitoring instrument permitted the production of products that did not meet the critical limit. If it is determined that the critical limit was not met, the establishment would have to implement corrective actions.

The **direct observation** procedures and frequency for this type of verification procedure usually involve observing the monitor.

The purpose of **records review** is to ensure that the records were prepared correctly, that all activities were performed as required by the HACCP plan, that no activity was missed, and that all results were within the critical limits.

Not all CCPs require the calibration of process-monitoring equipment. Establishments are not limited to only these three types of verification activities. Other types of verification procedures that establishments may use include independent checks or measurements to verify the accuracy of monitoring and microbiological testing.

Let's go back and discuss in more detail the hazards of concern.

Hazards of Concern for NSS NRTE/RTE 03G, 03H, or 03I Products

During the development and design of the HACCP plan, the official establishment determines if there are any biological, chemical, or physical hazards that are reasonably likely to occur before, during, or after entry into the establishment.

A food safety hazard is defined as any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

Biological Hazards in Meat and Poultry

(1) Examples

Potential biological hazards in meat and poultry include bacteria, toxins, viruses, protozoa, and parasites. Of the biological hazards, the most important are bacteria which can cause either food borne infections or intoxications. Bacteria cause a large proportion of all food borne illnesses. Bacteria that cause human illness, including disease, are termed pathogenic. Most food borne illness can result in diarrhea, nausea, vomiting, stomach cramping, and in more serious cases, organ damage, stillborn births, and death.

The pathogens that are most likely to be found in commonly slaughtered livestock (cattle, sheep, and swine) and poultry (chicken and turkey) include *Salmonella*, *Campylobacter*, and *Listeria monocytogenes*. In addition, *Yersinia enterocolitica* has been isolated from swine as well as being detected in the environment. *Listeria monocytogenes* also is widespread in the environment and is often present in soil, water, and silage. Although *Escherichia coli* also is found in livestock and poultry, most forms of *Escherichia coli* are not pathogenic. *Escherichia coli* O157:H7 is pathogenic. The ultimate source for all of these pathogens is apparently healthy animals that may shed these bacteria in their feces. While dressing the carcasses during the slaughter process, these bacteria may be transferred from the hide and offal to the carcass causing contamination. All of these pathogens have been implicated in widely publicized food borne disease outbreaks associated with the consumption of meat and poultry products. In the production of the not shelf stable (NSS) NRTE/RTE products pathogenic bacteria and zoonotic agents should be considered while conducting the hazard analysis. Proper cooking, fermentation, cooling, and storage of food can destroy and/or prevent growth of these bacteria. Zoonotic agents are biological hazards that cause disease in animals which can be transmitted to and cause disease in humans.

Some types of bacteria produce toxins in NRTE/RTE products as a by-product of their growth. Toxins of most concern are produced by *Clostridium botulinum*, *Clostridium perfringens, Bacillus cereus,* and *Staphylococcus aureus*. All are the result of the growth of bacteria and the production of toxins in foods that have been mishandled. These bacteria are common in the environment and are often found on carcasses. The environment (air, water, and soil) is the common source of these types of bacteria. An exception is *Staphylococcus aureus,* which is commonly found in association with human skin, and sometimes in poultry bruises. The hazard is the toxin (e.g., enterotoxin, neurotoxin, hemotoxin) produced by the organisms. The organism may contaminate the product if improper handling occurs after the product has been cooked. Proper cooking, fermentation, cooling, and storage of food can prevent growth of these bacteria and, more importantly, the production of their toxins. However, cooking will not destroy several of these toxins once they are formed in food.

Parasites (parasitic worms) of public health importance are the beef and pork tapeworms (*Cysticercus bovis* [the larvae of the human tapeworm,-*Taenia saginata*] and *Cysticercus cellulosae* [the larvae of the human tapeworm - *Taenia solium*] respectively) and the roundworm that causes trichinosis (*Trichinella spiralis*). Federal and state inspection program personnel can observe the immature stages (cysts) of tapeworms in carcasses of animals with severe infection and when detected by government inspection personnel or plant employees such product cannot be further processed for human consumption. When the cysts are less severe or evident, infected meat may enter the human food chain after it has been appropriately treated. Humans consuming undercooked meat infected with these tapeworms become ill generally after the mature stages of the tapeworms invade the intestinal tract.

Trichinella spiralis is an intestinal worm that produces larvae that migrate to and encyst in muscles of a number of animals, particularly swine. Humans consuming infected pork which is undercooked may get ill from the cysts which then live in the muscles of the human hosts. Pork muscle tissue may carry *Trichinella spiralis*, better known as trichinae. Specific regulatory requirements that outline procedures to control Trichinella are found in 9 CFR §318.10. *Trichinella spiralis* is an additional biological hazard that may be addressed in the manufacturing of processed pork product, especially if the product is intended to be eaten without thorough cooking by the consumer.

Tapeworms and roundworms generally are readily destroyed at cooking temperature and time combinations less rigorous than the combinations necessary to destroy pathogenic bacteria.

Viruses can cause gastroenteritis and diseases such as hepatitis and polio in humans. The presence of viruses in food and water is generally associated with a contaminated food worker, usually in the retail or food service arena. In general, healthy animals do not serve as carriers of viruses. Viruses do not normally grow or reproduce in meat and poultry products. Meat and poultry products may serve as vectors for viruses.

Protozoa can cause diseases such as sarcocystosis, toxoplasmosis and cryptosporidiosis. These organisms are not usually considered under food safety concerns for meat and poultry products.

(2) Public Health Concerns

It is particularly important for establishments to identify and control these biological hazards in RTE products, because the consumer is not expected to cook these products further. In not shelf stable (NSS) RTE products, the lethality step is the intervention that protects the consumer from most biological pathogens. However, *Listeria monocytogenes* can pose a food safety risk in NSS RTE products if this pathogen is not properly controlled post lethality in the processing environment. Products that are NSS heat-treated (such as products in the 03H and some in the 03I regulatory processing category) can pose a food safety risk if some pathogenic bacteria remain on the product which must be controlled. In addition, products that are NSS and produced with secondary inhibitors, especially those that may be RTE, can pose a food safety risk if the pathogenic bacteria are not prevented, eliminated, or reduced to acceptable levels as many of these products have not had heat applied but rely on other strategies to control the food safety hazards.

Type of bacteria of concern for NSS NRTE/RTE products

Species harboring organism	Organisms				
	Salmonella	*E. coli* O157:H7	*Campylo bacter*	*Listeria monocytogenes*	*Yersinia enterocolitica*
Beef	+	+		+	
Lamb	+			+	
Pork*	+			+	+
Poultry	+		+	+	

* Trichinae control may be required in certain products

There are definite public health concerns associated with bacterial toxins in NRTE/RTE products. Toxins may be produced during the growth phase of some bacteria. These are called preformed toxins, such as *C. botulinum* toxin, and when they are ingested, they may cause headaches, disorientation, neurological damage, paralysis, and possibly death. The toxins may affect the nerve endings and interfere with nerve impulses. In the case of botulism toxin, the diaphragm is affected and death results from suffocation. Other toxins are formed when the vegetative cell produces a spore. Some spore-forming bacteria form spores in the human digestive tract because the digestive juices are too harsh for the vegetative cell and the self-preservation mechanism (spore formation) is turned on. This is true for *C. perfringens*. The common form of perfringens poisoning is characterized by intense abdominal cramps and diarrhea which begin 8-22 hours after consumption of foods containing large numbers of those *C. perfringens* bacteria capable of producing the food poisoning toxin.

Type of toxin producing bacteria of concern for NSS NRTE/RTE products

Species harboring organism	**Organisms**			
	Staphylococcus aureus	**Clostridium perfringens*	**Clostridium botulinum*	**Bacillus cereus*
Beef	+	+	+	+
Lamb	+	+	+	+
Pork	+	+	+	+
Poultry	+	+	+	+
Primary 03 HACCP Element	03I	03G/03H	03G/03H	03G/03H

* Spore formers

A public health concern associated with zoonotic agents is trichinosis, a disease that results from ingesting pork cysts in undercooked pork products. Due to improvements in animal production processes, trichinosis is quite rare in this country. Once ingested with the meat, the larvae bore through the intestinal wall and travel through the blood and lymph to encyst in muscles. If there is a heavy enough infestation, based on the amount of *Trichinella spiralis* ingested, the encysting process within muscles is painful. If the worms encyst in the diaphragm, they may interfere with breathing.

(3) Control methods

It is crucial to avoid the contamination of meat and poultry whenever possible. This includes inadvertent contamination from the live animal, processing procedures and equipment, employees, and the environment. Contamination can be minimized or avoided altogether by following appropriate sanitation procedures, good manufacturing practices, and procedures for employee hygiene. The term "cross-contamination" generally refers to the transfer of organisms from a contaminated source to a previously uncontaminated surface. A particular concern is the cross-contamination of ready-to-eat foods with not-ready-to-eat (raw or partially cooked) meat or poultry, or with purge from not-ready-to-eat meat or poultry. It is particularly important to ensure complete separation of not-ready-to-eat and ready-to-eat products.

Some bacteria, such as *Listeria* (including *Listeria monocytogenes*), can be found in the processing environment. Although most forms of *Listeria* are not pathogenic, *Listeria monocytogenes* is a pathogen. This emphasizes the need for adequate sanitation, not only of the equipment and product contact zones, but also the floors, walls, drains, etc. Employee hygiene, air flow, and traffic flow of people and equipment between areas used for not-ready-to-eat processing and ready-to-eat processing is very important and should be strictly controlled.

Recontamination with bacteria (e.g., *Listeria monocytogenes* and *Salmonella*) must be considered as cooked products are exposed to the environment, food contact surfaces, or raw product prior to final packaging.

Recognizing that bacteria will be present on meat and poultry, it is important to keep the overall number of bacteria very low in order that pathogens can be minimized. Temperature, acidity, salt and drying, and combinations of these can be used to restrict growth of pathogens.

- **Temperature** -- The growth of most bacteria can be slowed (controlled) by maintaining the product at refrigeration temperatures (less than 41^{o}F), or by freezing. Some bacteria survive freezing, so freezing cannot be considered a method to eliminate bacteria. Holding products at higher temperatures (greater than 130^{o}F) also restricts the growth of the bacteria.

- **Acidity** -- Fermentation restricts the growth of bacteria of public health concern by increasing the acidity (lowering the pH) of the product. Generally a pH of less than 5 will severely restrict or completely stop the growth of harmful bacteria. Some bacteria can survive in acidic conditions, so fermentation alone cannot be relied upon to completely eliminate all harmful bacteria.

- **Salt and Drying** -- Some products contain high levels of salt. Salt and low moisture content in a product can be effective in controlling growth of some harmful bacteria, but some organisms (e.g., *Staphylococcus aureus*) survive in high salt environments.

Most pathogenic bacteria, including *Salmonella, Escherichia coli* O157:H7*, Listeria monocytogenes*, *Yersinia enterocolitica*, and *Campylobacter*, can be fairly easily destroyed using a rather mild cooking process--maintaining a minimum temperature within the range of 130 ^{o}F to 165 ^{o}F for a specific amount of time. However, cooking at this temperature range and for the specified dwell time will not destroy the heat resistant forms (spores) of certain bacteria, nor will some types of toxins be destroyed if they have already been formed in the product. Thermal processing (canning) at a minimum retort temperature of greater than 240 ^{o}F for a specific amount of time is necessary to destroy most spores and toxins. These bacteria are killed by proper cooking. Regulatory requirements contained in 9 CFR §318.17 and in 9 CFR §381.150 require the establishment operators to address a lethality performance standard for certain products for *Salmonella*. Generally, *Escherichia coli* O157:H7 and *Campylobacter* are easily controlled when the lethality procedure is at least sufficient to destroy *Salmonella*. *Salmonella* generally is present in higher numbers than are most other pathogens.

Spore-forming bacteria (*Clostridium perfringens* and *Clostridium botulinum*) can survive cooking when in the heat-resistant spore form, and these organisms need to be considered as the products are chilled. Growth (sometimes referred to as "outgrowth") of these bacteria is slowed by proper cooling. Regulatory requirements contained in 9 CFR §318.17 for cooked roast beef, in 9 CFR §318.23 for cooked uncured patties, and in 9 CFR §381.150 for cooked poultry require establishment operators to address a stabilization (cooling) performance standard for both *Clostridium perfringens* and *Clostridium botulinum*.

The types of controls used for products in the 03G, 03H, and 03I regulatory processing categories will vary because they represent different production processes. For example, the controls used for products in the 03G processing category will include cooking (lethality), because by definition, this processing category is fully cooked and ready-to-eat. The controls used for products in the 03I processing category involve secondary inhibitors, such as those that affect pH level or lower water activity (e.g., added salt).

Some plants use post-lethality pasteurization, which involves running the intact package through steam or hot water to bring the product surface up to a temperature sufficient for the purpose of destroying *Lm*. However, only the surfaces in contact with the outer packaging material reach these temperatures. If the product is sliced, those sliced surfaces in contact with another sliced surface do not reach the required temperature. Likewise, hot dogs in a package would not reach the temperature required to ensure the destruction of *Lm*. So for sliced product, or for packages with multiple pieces of product, post-lethality pasteurization will not heat all product surfaces sufficiently to ensure the destruction of *Lm*. Therefore, the antimicrobial inhibitors are currently the control method of choice. Whatever control measure is used for *Lm*, the establishment should validate their process to demonstrate that the finished product are produced and distributed under conditions that will prevent or inhibit the growth of the pathogen.

Antimicrobial sprays are an example of a control measure used by establishments. Certain antimicrobials are approved as food additives (9 CFR §424.21(c)) for meat and poultry products (which means their use must be declared on the label). These compounds can be formulated in the product to inhibit the growth of certain pathogens. Some antimicrobials may be used as sprays or immersion dips at room temperature. Some of antimicrobials are considered incidental additives as defined in the Food and Drug Administration regulations (21 CFR §101.100(a)(3)). Incidental additives are substances present in foods at insignificant levels and that do not serve a technical or functional effect in that food (their use is not declared on the finished product label). These antimicrobial agents are effective against *E. coli* O157:H7*, Salmonella,* and *Listeria monocytogenes.*

Salmonella, *E. coli* O157:H7, *Campylobacter*, and *Listeria monocytogenes* may all be effectively controlled (destroyed) by cooking to an internal temperature of 158° F for meat and 160°F for poultry products. Time and temperature may also be combined so that product held for longer periods of time at lower temperatures (130° F or more) may receive the same lethality benefit.

Listeria monocytogenes (*Lm*) raises different concerns in the hazard analysis than do the other bacteria affecting NRTE/RTE products. While *Lm* may enter the establishment on/in the commonly slaughtered species, the lethality step destroys it. But *Lm* is commonly found in the plant environment too, which is a primary concern in RTE products. The results of microbiological testing show that *Lm* can be found in vents and drains and on equipment, including product contact surfaces. It thrives in warm to cool, moist environments, which is typical in an RTE processing area. Slicers and peelers are key locations which can serve as harborage sites or niches in which *Listeria monocytogenes (Lm)* can recontaminate fully cooked product. Both pieces of equipment provide a moist environment and contain crevices where the bacteria can accumulate. The moving parts come into direct contact with product that has already received a lethality treatment. Because of the lethality treatment, the competitive microbes have been destroyed, leaving a virtually sterile surface exposed to any contaminant that contacts it. Plants must be vigilant in equipment sanitation and keep the area as dry and free of product residue as possible. Product residue may protect bacteria from harsh cleaning or sanitizing agents. When product picks up contaminants from other sources, it is referred to as cross-contamination. Even though the lethality step destroys *Lm* in the product, post-lethality handling and processing may result in recontamination of exposed product, and there is usually not a sufficient kill step after that. *Lm* contamination is often a result of post-lethality contamination.

Toxins are stable under most conditions, so for non-thermally processed foods, preventing toxin formation is the only true control that establishments can apply. Most of the bacteria that produce toxins are spore-formers. Spore-forming bacteria pose particular problems because they may survive cooking when in their heat-resistant spore form. The bacterial sporulation is inhibited at cooler, refrigerated temperatures, and should be considered during the chilling step of production. For this reason,

stabilization is important in controlling spore-formers. For some products, proper cooking and fermentation may control toxins. Post-lethality handling of product is also important in controlling contamination with *Staphylococcus aureus* (e.g., employee hygiene).

For zoonotic agents, the establishment may have little to no impact on preventing this hazard from entering the plant. However, the plant can destroy the parasite in NRTE/RTE products during the production process through various processing interventions (cooking, freezing, manipulating the water activity with salt, etc.). In fully cooked products, parasites are destroyed during the lethality step (9 CFR §311.23, §311.24, §318.10).

Chemical hazards

(1) Examples

Chemical hazards that may affect NRTE/RTE products usually originate from five general sources: (1) Agriculture chemicals: pesticides, herbicides, animals drugs, fertilizers, (2) Plant chemicals: cleaners, paint, sanitizers, oils, lubricants, pesticides, (3) Naturally occurring toxicants: products from plant , animal, or microbial metabolisms such as mycotoxins, aflatoxins, lupin alkaloids, ergot, erucic acid, phomopsins, phytoestrogens, allergens, etc., (4) Food chemicals: preservatives, acids, food additives, sulfating agents, processing aids, etc., (5) Environmental contaminants: lead, cadmium, mercury, arsenic, tin, dioxins, or polychlorinated biphenyls (PCBs).

The potential health consequences of exposure to chemicals in food can be serious, are often inadequately understood, and deserve consideration. The long-term and cumulative effects of exposure associated with chemicals in food pose special difficulties in identifying and addressing these risks. The constant introductions of new chemicals that find their way into food also continue to present management challenges. It is apparent that at least some of the identified chemical hazards are of concern because they exert particular effects. For example, pesticides such as organochlorines, industrial chemicals such as dioxins and chemicals present naturally in food such as phytoestrogens may be of concern because they have the potential to cause endocrine effects and/or interfere with the immune system. Similarly some chemicals are of concern because of their potential to act as allergens. When food additives exceed approved amounts or when used in higher concentrations, these chemicals may create a food safety hazard. For example, nitrites and nitrates can be toxic in high concentrations. Some hazards such as lead contamination can affect a certain population- infants or young children-causing toxic effects. Lead, in addition to being a chemical hazard, may be a physical hazard.

(2) Public health concerns

The most common well documented public health concerns associated with chemical hazards in NRTE/RTE products relate to the short-term affects of allergens. Food allergies are responses of the immune system to naturally occurring proteins in certain foods that most individuals can eat without any adverse effect. Frequently such reactions occur because the presence of the allergenic substances in the foods is not declared on the food label. Evidence indicates that some food allergens can cause serious reactions in sensitive individuals upon ingestion of very small amounts, therefore, the presence of an ingredient that contains an allergen must be declared on the product label. For instance, allergens that are ingested by persons who are sensitive to them can cause a range of symptoms that may affect breathing, cause skin rashes, result in digestive disorders, and in more serious cases result in death due to anaphylactic shock. The symptoms usually begin with breathing difficulties and may progress to the point of death by suffocation.

There is scientific consensus that the following foods can cause serious allergic reactions in some individuals and account for more than 90% of all food allergies. The “Big 8”, or top 8 foods that most people with food allergies are allergic to, are peanuts, soybeans, milk, eggs, fish, crustacean, tree nuts and wheat gluten.

Other potential causes of adverse reactions (food intolerances) in sensitive individuals are due to ingredients such as monosodium glutamate, sulfites, lactose, and Yellow 5 (tartrazine). The adverse reactions to these substances are due to the ingredients itself or its chemical composition.

Long-term effects of chemicals are associated with exposure over a period of years (e.g., lead poisoning in infants or nitrites and nitrates, which have been determined to be carcinogenic). When product that contains excessive amounts of residual nitrites and nitrates is ingested, the health consequences may be deadly. Chemical residues have been linked through research to various types of cancers. The public health concerns associated with the long-term effects of exposure to chemicals from ingestion of food is not well understood or well documented.

3) Control methods

Under the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA), under which FSIS operates, all ingredients used to formulate a meat, poultry, or egg product must be declared in the ingredients statement on product labeling. A product is ***misbranded*** under the Acts when it contains ingredients that are permitted, but are not declared on product labeling.

Manufacturers are responsible for ensuring that food is not adulterated or misbranded as a result of the presence of undeclared allergens. There may be situations where these substances are added intentionally to food, but not declared on the label. Other

situations involve substances unintentionally introduced into a food product and consequently not declared on the label. When an allergen, not formulated in the product, is identified as likely to occur in the food due to the firms' practices (e.g., use of common equipment, production scheduling, rework practices), then you should determine if the establishment has identified and implemented controls to prevent potential allergen cross-contact, e.g., dedicated equipment, separation, production scheduling, sanitation, proper rework usage (like to like).

Some establishments may consider food allergens in their hazard analyses if there is a potential, but may address this issue through SSOP or other prerequisite programs (e.g., segregation and labeling).

The basic controls that the plant may apply for other chemical hazards include using chemicals as approved, using them for the intended use, using them at the appropriate amount or concentration, and properly storing the chemicals. The establishment should use in-house control of all chemicals by maintaining the identity of the chemical or by properly labeling processed products to identify any known allergens that may be present in the food. Prevention may be achieved when the plant institutes a specification program for incoming materials, such as suppliers' letters of guaranty on packaging material or non-meat ingredients. In order to be applicable for use in meat and poultry plants, the label on chemicals must include directions and precautions for such use as required by Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regulations. Accordingly, any such preparation offered for use in federally inspected meat and poultry plants must be labeled in compliance with those requirements. Documentation substantiating the safety of a chemical's use in food-processing will vary with the nature and intended use of that chemical. For example, for a pesticide, an establishment should have documentation showing that the compound is registered with Environmental Protection Agency (EPA) and the label information for the pesticide.

For a chemical sanitizer used on food contact surfaces, an establishment should have documentation showing that the compound complies with the relevant Food and Drug Administration(FDA) regulations in 21 CFR §178.1010. (Sanitizers meeting this requirement are usually identified as "Food Grade.") Meat and poultry establishments are responsible for ensuring that all proprietary substances and nonfood compounds are safe for their intended use and used appropriately. In some cases, other Federal Agencies require that chemicals meet their regulatory requirements. For example, EPA requires that pesticides be registered with EPA, labeled as such, and used only in accordance with approved instructions. An establishment should have documentation indicating that they meet these requirements.

Also, many chemicals, such as food contact surface sanitizers and lubricants used in food processing areas must meet FDA requirements. Again, the establishment must have documentation demonstrating this. Often, the statement "Food Grade" on the label of these and other chemicals indicates that they meet FDA requirements. Many chemical uses (anti-slip compounds, laundry soaps, etc.) are not approved for use by

any Federal agency. An establishment will likely have labels, instructions, or letters of guarantee from the manufacturer to substantiate the safety of these chemicals in a food processing environment. In some cases, documentation will state that the chemical use was previously approved by USDA or FSIS and that the formulation and use has not changed since that approval.

Nitrites/nitrates are interesting in that while they are needed for food safety (to prevent *C. botulinum* spores from germinating and forming the botulism toxin), in excess they can be lethal. So in the case of nitrites/nitrates, adding too little may actually be a food safety hazard because these food additives are in some products to impart a measure of food safety. Therefore, strict control over the storage and application of these chemicals is essential. A plant must have creditable supporting data for the chemicals it uses in its facility.

Physical hazards

(1) Examples

Physical hazards include a variety of materials referred to as extraneous materials or foreign particles or objects. A physical hazard can be defined as any physical material not normally found in a food that can cause illness or injury to a person consuming the product.

Physical hazards in finished products can arise from several sources, such as contaminated raw materials, poorly designed or maintained facilities and equipment, faulty procedures during processing, and improper employee training or practices.

The types of physical hazards that can be found in NRTE/RTE products include metal fragments (from nails, screws, needles, seals, knives, equipment parts, shroud pins, wire, jewelry, buckshot, etc.); glass shards (from broken jars, bottles, light bulbs, thermometers, windows, eye glasses, etc.); wood pieces or chips (from broken pallets, handles, boards, etc.); stones (from driveways, etc.); plastic pieces (from packaging material, food/candy wrappers, gloves, etc.); bone fragments (from the cut-up and fabrication of carcasses), and other foreign materials (pens, trash, etc.). In some cases, physical hazards enter the plant with the live animal (e.g., buckshot). But in many cases, these physical hazards are introduced to NRTE/RTE product as a result of events that occur during the production process (e.g., metal from a blade or wood chips from a broken pallet). The size, shape, and consistency of the foreign object should be considered in determining whether it is or is not a hazard.

(2) Public health concerns

Typical public health concerns associated with physical hazards in NRTE/RTE product include broken teeth and damage, such as tears, to the mouth, esophagus, stomach, and intestines. These physical hazards may obstruct air passages or intestines. In

some cases, death may result due to suffocation or infections (intestinal blockages). Small children are particularly susceptible to problems brought on by physical hazards since their body structures are smaller, and the physical objects may have a greater effect. RTE products pose the greatest risk when physical hazards are embedded in them, because the consumer has a lower likelihood of identifying and removing the hazard prior to consumption if they do not further handle (e.g., mix) the product.

(3) Control methods

Methods that establishments use to control physical hazards include visual observation of product as it is unboxed or mixed, sanitation procedures, SOPs for product handling, GMPs to ensure proper maintenance and inspections of facilities and equipment, and foreign materials detection equipment (inline magnets, screens, traps, filters, etc.) used during the production process. Establishments may implement controls to prevent physical objects from entering the plant in incoming product by instituting specifications for incoming material and requiring suppliers' letters of guaranty.

Note: Biological, chemical, and physical food safety hazards although discussed separately, can share properties that span more than one hazard classification.