Annex

6 Food Processing Criteria

1. INTRODUCTION

From its inception, the retail segment of the food industry has prepared foods in consumer-sized portions, using commercially available equipment for cutting, grinding, slicing, cooking, and refrigeration, and applying herbs and spices readily available to consumers at their local grocery.

Over the past score of years, retail segment operators have expanded into food manufacturing/processing-type operations, often using sophisticated new technologies and equipment that are sometimes microprocessor-controlled. Many now desire to alter the atmospheres within food packages, or apply federally regulated chemical food additives as a method of food preservation. Food processing operations now being conducted or proposed include cook-chill; vacuum packaging; sous vide; smoking and curing; brewing, processing, and bottling alcoholic beverages, carbonated beverages, or drinking water; and custom processing of animals.

The Food Code specifies that a HACCP plan acceptable to the regulatory authority be the basis for approving food manufacturing/processing operations at retail. The HACCP plans are to be provided and accepted in two ways as follows.

(A) Reduced Oxygen Packaging

Section 3-502.12 of the Food Code provides the criteria that are to be met in the HACCP plans of those operators who are conducting reduced oxygen packaging (ROP) operations. Unless prior approval of the HACCP plan is required by the regulatory authority, the HACCP plan covering this operation along with the related records documenting monitoring and corrective actions need only be available and acceptable to the regulatory authority at the time of inspection.

(B) Other Food Manufacturing/Processing Operations

Except for ROP as discussed in (A) above, the Food Code specifies under §§ 3-502.11, 8-103.10, 8-103.11, and 8-201.13 that the food establishment operator must obtain a variance from the regulatory authority for all food manufacturing/processing operations based on the prior approval of a HACCP plan.

The purpose of this Annex is to provide processing criteria for different types of food manufacturing/processing operations for use by those preparing and reviewing HACCP plans and proposals. Criteria for additional processes will be provided as they are developed, reviewed, and accepted.

2. REDUCED OXYGEN PACKAGING

(A) Introduction

ROP which provides an environment that contains little or no oxygen, offers unique advantages and opportunities for the food industry but also raises many microbiological concerns. Products packaged using ROP may be produced safely if proper controls are in effect. Producing and distributing these products with a HACCP approach offer an effective, rational, and systematic method for the assurance of food safety. The purpose of this Annex is to provide guidelines for effective food safety controls for retail food establishments covering the receipt, processing, packaging, holding, displaying, and labeling of food in reduced oxygen packages.

(B) Definitions

The term ROP is defined as any packaging procedure that results in a reduced oxygen level in a sealed package. The term is often used because it is an inclusive term and can include other packaging options such as:

(1) *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.

(2) *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. CAP is defined as packaging of a product in a modified atmosphere followed by maintaining subsequent control of that atmosphere.

(3) *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. 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.

(4) *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:

(a) Preparation of the raw materials (this step may include partial cooking of some or all ingredients);

(b) Packaging of the product, application of vacuum, and sealing of the package;

(c)Pasteurization of the product for a specified and monitored time/temperature;

(d) Rapid and monitored cooling of the product at or below $3^{o}C(38^{o}F)$ or frozen; and

(e) Reheating of the packages to a specified temperature before opening and service.

(5) *Vacuum Packaging* reduces the amount of air from a package and hermetically seals the package so that a near-perfect vacuum remains 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 contours of the food being packaged.

(C) Benefits of ROP

ROP can create a significantly anaerobic environment that prevents the growth of aerobic spoilage organisms, which generally are Gram-negative bacteria such as pseudomonads or aerobic yeast and molds. These organisms are responsible for off-odors, slime, and texture changes, which are signs of spoilage.

ROP can be used to prevent degradation or oxidative processes in food products. Reducing the oxygen in and around a food retards the amount of oxidative rancidity in fats and oils. ROP also prevents color deterioration in raw meats caused by oxygen. An additional effect of sealing food in ROP is the reduction of product shrinkage by preventing water loss.

These benefits of ROP allow an extended shelf life for foods in the distribution chain, providing additional time to reach new geographic markets or longer display at retail. Providing an extended shelf life for ready-to-eat convenience foods and advertising foods as "Fresh – Never Frozen" are examples of economic and quality advantages.

(D) Safety Concerns

Use of ROP with some foods can markedly increase safety concerns. Unless potentially hazardous foods (time/temperature control for safety foods) are protected inherently, simply placing them in ROP without regard to microbial growth will increase the risk of foodborne illnesses. ROP processors and regulators must assume that during distribution of foods or while foods are held by retailers or consumers, refrigerated temperatures may not be consistently maintained. In fact, a serious concern is that the increased use of vacuum packaging at retail supermarket deli-type operations may be followed by temperature abuse in the establishment or by the consumer. Consequently, at least one barrier or multiple hurdles resulting in a barrier need to be incorporated into the production process for products packaged using ROP. The incorporation of several sub-inhibitory barriers, none of which could individually inhibit microbial growth but which in combination provide a full barrier to growth, is necessary to ensure food safety.

Some products in ROP contain no preservatives and frequently do not possess any intrinsic inhibitory barriers (such as, pH, a_w, or salt concentrations) that either alone or in combination will inhibit microbial growth. Thus, product safety is not provided by natural or formulated characteristics.

An anaerobic environment, usually created by ROP, provides the potential for growth of several important pathogens. Some of these are psychrotrophic and grow slowly at temperatures near the freezing point of foods. Additionally, the inhibition of the spoilage bacteria is significant because without these competing organisms, tell-tale signs signaling that the product is no longer fit for consumption will not occur.

The use of one form of ROP, vacuum packaging, is not new. Many food products have a long and safe history of being vacuum packaged in ROP. However, the early use of vacuum packaging for smoked fish had disastrous results, causing a long-standing moratorium on certain uses of this technology.

(1) *Refrigerated Holding Requirements for Foods in ROP*

Safe use of ROP technology demands that adequate refrigeration be maintained during the entire shelf-life of potentially hazardous foods (time/temperature control for safety foods) to ensure product safety.

Bacteria, with the exception of those that can form spores, are eliminated by pasteurization. However, pathogens may survive in the final product if pasteurization is inadequate, poor quality raw materials or poor handling practices are used, or post-

processing contamination occurs. Even if foods that are in ROP receive adequate thermal processing, a particular concern is present at retail when employees open manufactured products and repackage them. This operation presents the potential for post-processing contamination by pathogens.

If products in ROP are subjected to mild temperature abuse, i.e., 5°-12°C (41°-53°F), at any stage during storage or distribution, foodborne pathogens, including ***Bacillus cereus***, ***Salmonella*** spp., ***Staphylococcus aureus***, and ***Vibrio parahaemolyticus***, can grow slowly. Marginal refrigeration that does not facilitate growth may still allow ***Salmonella*** spp., ***Campylobacter*** spp., and ***Brucella*** spp. to survive for long periods of time.

Published surveys indicate that refrigeration practices at retail need improvement. Some refrigerated products offered in convenience stores were found at or above 7.2°C (45°F) 50% of the time; in several cases temperatures as high as 10°C (50°F) were observed. Delicatessen display cases have been shown to demonstrate poor temperature control. Foods have been observed above 10°C (50°F) and above 12.8°C (55°F) in several instances. Supermarket fresh meat cases appear to have a relatively good record of temperature control. However, even these foods can occasionally be found above 10°C (50°F).

Temperature abuse is common throughout distribution and retail markets. Strict adherence to temperature control and shelf-life must be observed and documented by the establishment using ROP. Information on temperature control should also be provided to the consumer. Currently these controls are not extensively used. Additionally, some commercial equipment is incapable of maintaining foods below 7.2°C (45°F) because of refrigeration capacity, insufficient refrigerating medium, or poor maintenance.

Most warehouses and transport vehicles in U.S. distribution chains maintain temperatures in the 0°-3.3°C (32°-38°F) range. It must be assumed, however, for purposes of assessing risk, that occasionally temperatures of 10°C (50°F) or higher may occur for extended periods. At retail, further temperature abuse must also be assumed. For instance, retail display cases can be as high as 13.3°C (56°F) for short periods and some refrigerated foods are provided no refrigeration for short periods of time. These realities point to the need for establishments to implement controls, such as buyer specifications, over refrigerated distribution systems so that better temperature control can be ensured.

(2) *Control of **Clostridium botulinum** and **Listeria monocytogenes** in Reduced Oxygen Packaged Foods*

There has been an increased interest in vacuum packaging or MAP at retail using conventional refrigeration for holding. Refrigerated foods packaged at retail may be chilled either after they are physically prepared and repackaged, or packaged after a cooking step. In either case but primarily the latter, germination of ***Clostridium***

botulinum is the causative agent of botulism, a severe food poisoning characterized by double vision, paralysis, and occasionally death. Sanitary safeguards must be employed to prevent reintroduction of pathogens. Chief among these is ***Listeria monocytogenes***.

Clostridium botulinum is the causative agent of botulism, a severe food poisoning characterized by double vision, paralysis, and occasionally death. The organism is an anaerobic spore-forming bacteria that produces a potent neurotoxin. The spores are ubiquitous in nature, relatively heat-resistant, and can survive most minimal heat treatments that destroy vegetative cells. Certain strains of ***C. botulinum*** (type E and non-proteolytic types B and F), which have been primarily associated with fish, are psychrotrophic and can grow and produce toxin at temperatures as low as 3.3^{o}C (38^{o}F). Other strains of ***C. botulinum*** (type A and proteolytic types B and F) can grow and produce toxin at temperatures slightly above 10^{o}C (50^{o}F). If present, ***C. botulinum*** could potentially grow and render toxigenic a food packaged and held in ROP because most other competing organisms are inhibited by ROP. Therefore, the food could be toxic yet appear organoleptically acceptable. This is particularly true of psychrotrophic strains of ***C. botulinum*** that do not produce tell-tale proteolytic enzymes. Because botulism is potentially deadly, foods held in anaerobic conditions merit regulatory concern and vigilance.

The potential for botulism toxin to develop also exists when ROP is used after heat treatments such as pasteurization, or sous vide, processing of foods which will not destroy the spores of ***C. botulinum***. Mild heat treatments in combination with ROP may actually select for ***C. botulinum*** by killing off its competitors. If the applied heat treatment does not produce commercial sterility, the food requires refrigeration to prevent spoilage and ensure product safety. For this reason, sous vide products are frequently flash frozen in liquid nitrogen and held in frozen storage until use.

There is a further microbial concern with ROP at retail. Processed products such as meats and cheeses which have undergone an adequate cooking step to kill ***L. monocytogenes*** can be contaminated when opened, sliced, and repackaged at retail. Thus, a simple packaging or repackaging operation can present an opportunity for recontamination with pathogens if strict sanitary safeguards are not in place.

Processors of products using ROP should be cautious if they plan to rely on refrigeration as the sole barrier that ensures product safety. This approach requires very rigorous temperature controls and monitored refrigeration equipment. If extended shelf life is sought, a temperature of 3.3^{o}C (38^{o}F) or lower must be maintained at all times to prevent outgrowth of ***C. botulinum*** and the subsequent production of toxin. ***Listeria monocytogenes*** can grow at even lower temperatures; consequently, appropriate use-by dates must be established and readily apparent to the consumer. Since refrigeration alone does not guarantee safety from pathogenic microorganisms, additional growth barriers must be provided. Growth barriers are provided by hurdles such as low pH, a_w, or short shelf life, and constant monitoring of the temperature. Any

one hurdle, or a combination of several, may be used with refrigeration to control pathogenic outgrowth.

(3) *Design of Heat Processes for Foods in Reduced Oxygen Packages*

Heat processes for sous vide or cook-chill operations should be designed so that, at a minimum, all vegetative pathogens are destroyed by a pasteurization process. Special labeling of these products is necessary to ensure adequate warning to consumers that these foods must be refrigerated at 5^{o}C (41^{o}F) and consumed by the date required by the Code for that particular product.

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), chartered by the U.S. Department of Agriculture (USDA) and the Department of Health and Human Services (DHHS), commented on the microbial safety of refrigerated foods containing cooked, uncured meat or poultry products that are packaged for extended refrigerated shelf life and are ready-to-eat or prepared with little or no additional heat treatment. The NACMCF recommended guidelines for evaluating the ability of thermal processes to inactivate ***L. monocytogenes*** in extended shelf life refrigerated foods. Specifically, it recommended a proposed requirement for demonstrating that an ROP process provides a heat treatment sufficient to achieve a 4 decimal log reduction (4D) of ***L. monocytogenes***.

Other scientific reports recommend more extensive thermal processing. Thermal processes for sous vide practiced in Europe are designed to achieve a 12-13 log reduction (12-13D) of the target organism ***Streptococcus faecalis***. It is reasoned that thermal inactivation of this organism would ensure destruction of all other vegetative pathogens.

Food manufacturers with adequate in-house research and development programs may have the ability to design their own thermal processes. However, small retailers and supermarkets may not be able to perform the microbiological challenge studies necessary to provide the same level of food safety. If a retail establishment wishes to use an ROP process, microbiological studies should be performed by, or in conjunction with, an appropriate process authority or person knowledgeable in food microbiology who is acceptable to the regulatory authority.

Finally, if foods are held long enough, even under proper refrigeration, extended shelf life may be a problem. A study on fresh vegetables inoculated with ***L. monocytogenes***, conducted to determine the effect of CAP on shelf life, found that CAP lengthened the time that all vegetables were considered acceptable, but that populations of ***L. monocytogenes*** increased during that extended storage.

(4) *Consumer Handling Practices and In-Home Refrigerator Temperatures*

Extended shelf life provided by ROP is cause for concern because of the potential for abuse by the consumer. Consumers often cannot, or do not, maintain adequate refrigeration of potentially hazardous foods (time/temperature control for safety foods) at home. Foods in ROP that are taken home might not be eaten until enough time/temperature abuse has occurred to allow any pathogens present to increase to levels which can increase the chance of illness. Under the best of circumstances, home refrigerators can be expected to range between 5^{o} and 10^{o}C (41^{o}-50^{o}F). One study reported that home refrigerator temperatures in 21% of the households surveyed were 10^{o}C (50^{o}F). Another study reported more than 1 of 4 home refrigerators are above 7.2^{o}C (45^{o}F) and almost 1 of 10 are above 10^{o}C (50^{o}F). Thus, refrigeration alone cannot be relied on for ensuring microbiological safety after foods in ROP leave the establishment.

Consumers have come to expect that certain packages of foods would be safe without refrigeration. Low-acid canned foods have been thermally processed, which renders the food shelf-stable. Retort heating ensures the destruction of ***C. botulinum*** spores as well as all other foodborne pathogens. Yet consumers may not understand that most products that are packaged in ROP are not commercially sterile or shelf-stable and must be refrigerated. A clear label statement to keep the product refrigerated must be provided to consumers.

The use of ROP has been extensively studied by regulators and the food industry over the past several years. Recommendations have been adapted from the Association of Food and Drug Officials "Retail Guidelines - Refrigerated Foods in Reduced Oxygen Packages" and New York State Department of Agriculture and Markets "Proposed Reduced Oxygen Packaging Regulations." As provided in the Food Code, some ROP operations may be conducted under provision 3-502.12 Reduced Oxygen Packaging, Criteria. Food that is packaged by an ROP method under these provisions is considered safe while it is under the control of the establishment and, if the labeling instructions are followed, while under the control of the consumer.

(E) Safety Barrier Verification

The safety barriers for all processed foods held in ROP at retail must be verified in writing. This can be accomplished through written certification from the product manufacturer. Independent laboratory analysis using methodology approved by the regulatory authority can also be used to verify incoming product and should be used to verify the barriers in a product that is packaged within the establishment by an ROP method. It should be noted that the Association of Food and Drug Officials (AFDO) guidelines recommend that laboratory analysis be conducted by official methods of the AOAC International (AOAC).

The multiple barrier or hurdle efficacy should be validated by inoculated pack or challenge studies. A product should be tested under abuse temperatures to demonstrate product safety during the food's shelf life.

Any changes in product formulation or processing procedures are cause for notification of the regulatory authority and a required approval of the revised ROP process. A record of all safety barrier verifications should be updated every 12 months. This record must be available to the regulatory authority for review at the time of inspection.

(F) USDA Process Exemption

Meat and poultry products cured at a food processing plant regulated by the U.S. Department of Agriculture using substances specified in 9 CFR 424, Preparation and Processing Operations, are exempt from the safety barrier verification requirements. Other ROP operations may be developed that do not meet the provisions of section 3-502.12 of the Code and that will require a variance and prior approval by the regulatory authority under section 3-502.11.

(G) Recommendations for ROP Without Multiple Barriers

(1) *Employee Training*

If ROP is used, employees assigned to packaging of the foods must have documented proof that demonstrates familiarity with ROP guidelines in this Annex 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.

(2) *Refrigeration Requirements*

Foods in ROP that have only one barrier, i.e., refrigeration, to ***C. botulinum***, must be refrigerated to 5^{o}C (41^{o}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. Alternatively, foods packaged by ROP may be kept frozen if freezing is used as the declared primary safety barrier. 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 3^{o}C (38^{o}F).

(3) *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 5^{o}C (41^{o}F)" or "Important - Must be kept frozen," in the case of foods which rely on freezing as a primary safety barrier. The statement must appear on the principal display panel in bold type on a contrasting background. Foods held under ROP which have lower refrigeration requirements as a condition of safe shelf life must be monitored for temperature history and must not be offered for retail sale if the temperature and time specified in the variance are exceeded.

(4) *Labeling - "Use-by date"*

Each container of food in ROP must bear a "use-by" date. This date cannot exceed 14 days from retail packaging or repackaging without a further variance granted by the regulatory authority. The date assigned by a repacker cannot extend beyond the manufacturer's recommended "pull date" for the food. 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 packaging or repackaging, as an acceptable alternative to a 14 day "use-by" date, i.e., for product packaged on November 1, 1999 - "Sell by November 10, 1999" - use within 4 days of sell-by date. Foods that are frozen before or immediately after packaging and remain frozen until use should bear a "Keep frozen, use within 4 days after thawing" statement.

(H) Foods Which Require a Variance Under Code Section 3-502.11 if Packaged in Reduced Oxygen Atmosphere

(1) Processed fish and smoked fish may not be packed by ROP unless establishments are approved for the activity and inspected by the regulatory authority. Establishments packaging such fish products, and smoking and packing establishments, must be licensed in accordance with applicable law. Caviar may be packed on the premises by ROP if the establishment is approved by the regulatory authority and has an approved scheduled process established by a processing authority acceptable to the regulatory authority.

(2) Soft cheeses such as ricotta, cottage cheese, cheese spreads, and combinations of cheese and other ingredients such as vegetables, meat, or fish at retail must be approved for ROP and inspected by the regulatory authority.

(3) Meat or poultry products which are smoked or cured at retail, except that raw food of animal origin which is cured in a USDA-regulated processing plant, or establishment approved by the regulatory authority to cure these foods may be smoked in accordance with approved time/temperature requirements and packaged in ROP at retail if approved by the regulatory authority.

(I) Hazard Analysis and Critical Control Point (HACCP) Operation

All food establishments packaging food in a reduced oxygen atmosphere must develop a HACCP plan and maintain the plan at the processing site for review by the regulatory authority. For ROP operations the plan must include:

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

(2) A list of equipment and food-contact packaging supplies used, including

compliance standards required by the regulatory authority, i.e., USDA or a recognized third party equipment by the evaluation organization such as NSF International;

(3) A description of the lot identification system acceptable to the regulatory authority;

(4) A description of the employee training program acceptable to the regulatory authority;

(5) A listing and proportion of food-grade gasses used; and

(6) A standard operating procedure for method and frequency of cleaning and sanitizing food-contact surfaces in the designated processing area.

(J) Precautions Against Contamination at Retail

Only unopened packages of food products obtained from sources that comply with the applicable laws relating to food safety can be used to package at retail in a reduced oxygen atmosphere. If it is necessary to stop packaging for a period in excess of one-half hour, the remainder of that product must be diverted for another use in the retail establishment.

(K) 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.

(L) Dedicated Area/Restricted Access

All aspects of reduced oxygen packaging shall be conducted in an area specifically designated for this purpose. 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.

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3. SMOKING AND CURING

(A) Introduction

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 424. It is important to use curing methods which achieve uniform distribution of the curing mixture in the meat or poultry product.

(B) Definitions

Cured meat and poultry can be divided into three basic categories: (1) uncomminuted smoked products; (2) sausages; and (3) uncomminuted unsmoked processed meats.

(1) *Uncomminuted smoked products* - include bacon, beef jerky, hams, pork shoulders, turkey breasts, turkey drumsticks.

(2) *Sausages* - include both finely ground and coarse ground products. Finely ground sausages include bologna, frankfurters, luncheon meats and loaves, sandwich spreads, and viennas. Coarse ground sausages include chorizos, kielbasa, pepperoni, salami, and summer sausages.

(3) *Cured sausages* - may be categorized as: (1) raw, cured; (2) cooked, smoked; (3) cooked, unsmoked; and (4) dry, semidry, or fermented.

(4) *Uncomminuted, unsmoked processed products* - include corned beef, pastrami, pig's feet, corned tongues. This category of products may be sold as either raw ready-to-cook or ready-to-eat.

(C) 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 comminuting. Proper and thorough 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 (pickle) solution. These methods depend on slow diffusion of the curing agents through the product. Products must be properly refrigerated during immersion curing.

Several methods may be used to shorten curing times. These include hot immersion curing greater than 49^{o}C (>120^{o}F), injection by arterial pumping (e.g., hams), and stitch pumping by a series of hollow needles. If the injection method is used, injection needles must be frequently monitored during processing to ensure that they are not fouled or plugged.

Tumbling or massaging may also be used as an aid to hasten curing. Proper sanitation must be observed to prevent contamination during this operation.

The dry curing method, a similar process, may also be used. In this case, curing ingredients are rubbed over cuts and surfaces of meat held under refrigeration. Precautions must include wearing sanitary gloves when meat is handled. Product temperature maintenance is critical.

(D) Smoking

Smoking is the process of exposing 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 standard operating procedure must be established to prevent contamination during the smoking process.

(E) 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 which 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 enterotoxin that is heat stable and thus will not be inactivated by subsequent cooking.

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

Some fermented and dry cured products are processed without cooking. The labeling for these products should include instructions to the consumer to cook thoroughly before consumption.

(F) Recommendations for Safe Curing of Meat and Poultry

(1) *Posting of Acceptable Products*

A list of products approved by the regulatory authority, or by an approved knowledgeable authority on curing acceptable to the regulatory authority, must be posted in the processing area of the establishment.

(2) *Employee Training*

Employees assigned to cure meat or poultry must demonstrate familiarity with these guidelines and the potential hazards associated with curing foods. A description of the training and course content provided to the employees must be available for review by the regulatory authority.

(3) *HACCP*

A HACCP plan is needed for all curing operations. The following recommendations must be met to cure meat and poultry products in the establishment. References are available from local USDA extension offices, public libraries, and college or university food or meat science departments to develop HACCP plans for curing meat and poultry.

(a) *Critical Control Points*

The following are critical control points to be addressed:

(i) Purchase of prepared cure mixes; or

(ii) If cure mixes are blended on the premises instead of acquired pre-mixed, mixing must be carefully controlled by using calibrated weighing devices.

(iii) Cure ingredients must be stored in a dry location. Cure must be discarded if the package is wet or appears to have been wetted.

(b) *Raw Material Handling*

(i) Thawing must be monitored and controlled to ensure thoroughness and to prevent temperature abuse. Improperly thawed meat could cause insufficient cure penetration. Temperature abuse can cause spoilage or growth of pathogens.

(ii) Meat must be fresh. Curing may not be used to salvage meat that has excessive bacterial growth or spoilage.

(c) Formulating, Preparation and Curing

(i) A formulation and preparation procedure must be documented.

(ii) All equipment and utensils must be cleaned and sanitized.

(iii) Pieces must be prepared to uniform sizes to ensure uniform cure penetration. This is extremely critical for dry and immersion curing.

(iv) Calibrated scales must be used to weigh ingredients.

(v) A schedule or recipe must be established for determining the exact amount of curing formulation to be used for a specified weight of meat or meat mixture.

(vi) Methods and procedures must be strictly controlled to ensure uniform cure.

(vii) Mixing of curing formulation with comminuted ingredients must be controlled and monitored.

(viii) All surfaces of meat must be rotated and rubbed at intervals of sufficient frequency to ensure cure penetration when a dry curing method is used.

(ix) Immersion curing requires periodic mixing of the batch to facilitate uniform curing.

(x) The application of salt during dry curing of muscle cuts requires that the temperature of the product be strictly controlled between 1.7°C (35^{o}F) and 7.2°C (45^{o}F). The lower temperature is set to limit microbial growth and the upper temperature is set for the purpose of ensuring cure penetration. Refer to USDA regulations 9 CFR 318.10(c)(3)(iv) for specific details on dry curing.

(xi) Curing solutions must be discarded daily unless they remain with the same batch of product during its entire curing process.

(xii) Injection needles must be inspected for plugging when stitch pumping or artery pumping of muscle cuts is performed.

(xiii) Sanitary casings must be provided for sausage, chub or loaf forming.

(xiv) Casings may not be stripped for reuse in forming additional chubs or sausages from batch to batch.

(xv) Hot curing of bacon bellies, hams, or any other products must be performed at >49°C (120°F) as specified in 9 CFR 318.

(d) *Cooking and/or Smoking*

(i) When smokehouses are initially installed or structurally modified, calibration of product heating characteristics must be ascertained by competent food technologists. Tests should be run with full range of anticipated product loading. Verification of even airflow and moisture should be recorded in operational records of the smokehouse for these various loads.

(ii) Procedures for delivering the appropriate thermal treatment of cooked meats in conformance with the *Food Code* must be developed and used. (Also see 9 CFR 318.17 and 318.23 for USDA requirements for meat products.) A minimum of 73.9°C (165°F) should be used for cured poultry products.

(iii) Cooking equipment that provides even temperature control of the heating medium must be used.

(iv) Products must be adequately separated to prevent overlap in the cooking media whether immersed in hot water, sprayed with hot water, steamed, or oven heated.

(v) Calibrated temperature measuring devices must be used for determining internal product temperatures.

(vi) Temperature measuring device probes must be sanitized to prevent contaminating products when internal temperatures are measured.

(vii) Calibrated temperature measuring devices must be used for measuring temperatures of the heating medium.

(viii) Raw products must be separated from cooked products.

(ix) Time/temperature parameters of the cooking process must be monitored and recorded. In some processes, the heating medium temperature should also monitored.

(e) *Cooling*

(i) Cooling must be done in accordance with recommendations in the *Food Code* or under a variance. The USDA Cooling Guideline, FSIS Directive 7110.3 for special procedures for cured products, provides specific guidance.

(ii) Written cooling procedures must be established.

(iii) Chill water used in water sprays or immersion chilling which is in direct contact with products in casings or products cooked in an impervious package must be properly chlorinated.

(iv) Chill water temperature must be monitored and controlled.

(v) Chill water may not be reused until properly chlorinated. Reclaimed chill water must be discarded daily.

(vi) Product must be placed in a manner that allows chilled water or air to uniformly contact the product for assurance of uniform cooling.

(vii) Internal temperatures must be monitored during cooling by using calibrated temperature measuring devices.

(viii) Adequate cooling medium circulation must be maintained and monitored.

(ix) Temperatures of the cooling medium must be monitored and recorded in accordance with a written procedure.

(x) Handling of product must be minimized during cooling, peeling of casing, and packaging. Sanitary gloves must be used in these procedures.

(f) *Fermentation and Drying*

(i) Temperature and time must be controlled and logs must be maintained that record the monitoring of this process.

(ii) Humidity must be controlled by use of a humidistat. Monitoring of the process must be recorded in a written log.

(iii) Product must be kept separated to allow adequate air circulation during the process.

(iv) Use of an active and pure culture must be ensured to effect a rapid pH drop of the product. Use of commercially produced culture is necessary and the culture must be used according to the manufacturer's instructions.

(v) Determination of the pH of fermented sausages at the end of the fermentation cycle must be recorded.

(vi) Handling of products must be minimized and only done with sanitary gloves or sanitized utensils.

(vii) Dry (unfermented) products may not be hot smoked until the curing and drying procedures are completed.

(viii) Semi-dry fermented sausage must be heated after fermentation to a time/temperature sufficient to control growth of pathogenic and spoilage organisms of concern.

(4) *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.

(5) *Equipment Cleaning and Sanitizing*

The procedures for cleaning and sanitization must be accomplished according to parts 4-6 and 4-7 of the Food Code.

(G) References

Judge, M., E. Aberle, J. Forrest, H. Hedrick, and R. Merkel, 1984. *Principles of Meat Science*. Kendall/Hunt Publishing Company, Dubuque, IA.

Price, J. and B. Schweigert, 1978. *The Science of Meat and Meat Products*. Food and Nutrition Press, Inc., Westport, CT.