

RECOMMENDATIONS
OF THE
NATIONAL ADVISORY COMMITTEE ON
MICROBIOLOGICAL CRITERIA FOR FOODS

FOR

REFRIGERATED FOODS CONTAINING COOKED, UNCURED MEAT
OR POULTRY PRODUCTS THAT ARE PACKAGED FOR EXTENDED
REFRIGERATED SHELF LIFE AND THAT ARE READY-TO-EAT
OR PREPARED WITH LITTLE OR NO ADDITIONAL HEAT TREATMENT

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Executive Summary

The first meeting of the National Advisory Committee for Microbiological Criteria for Foods was held April 5-6, 1988, bringing together scientific experts in the areas of microbiology, epidemiology and food processing. The Committee was divided into two working groups--meat and poultry, and seafood.

This document was drafted by the Meat and Poultry Working Group and contains advice and recommendations for incorporation into food protection programs responsible for assuring the microbiological safety of foods. The primary focus being:

"Refrigerated foods containing cooked, uncured meat or poultry products that are packaged for extended refrigerated shelf life and that are ready-to-eat or prepared with little or no additional heat treatment."

Even though this type of product is relatively new and epidemiological data are lacking, the potential for microbial contamination and recontamination were deemed sufficient to warrant the preparation of these recommendations as a first priority. The reasons for the heightened concern over these products are related to the growth of foodborne pathogens at refrigeration temperatures, toxin production from Clostridium botulinum, and other hazards associated with temperature abuse:

After a thorough review of the various product types falling within this category, common characteristics of the products, process flows and packaging systems, specific recommendations were formulated. These recommendations would require that producers operate under a verified Hazard Analysis Critical Control Point program. Producers would be required to demonstrate a process sufficient to achieve a minimum 4 log reduction for Listeria monocytogenes and that toxin production by nonproteolytic and proteolytic Clostridium botulinum, including psychrotrophic species, is controlled. Additional sections are included to address packaging systems, distribution, refrigeration equipment, labeling, education and research.

This document also contains recommendations for the production of these type products in nonfederally inspected establishments. Rather than banning production for such operations, the document outlines criteria that would need to be met by the producer prior to manufacture. The regulatory authority licensing the establishment would then determine whether to grant permission for unlimited production, limited production, or to prohibit production entirely.

The National Advisory Committee for Microbiological Criteria for Foods adopted this document on January 31, 1990.

MISSION STATEMENT

The National Advisory Committee on Microbiological Criteria for Foods (Committee) is charged with providing advice and recommendations that can be incorporated into food protection programs to assure the microbiological safety of foods provided consumers. For meat and poultry products, this can best be achieved through the development of an integrated product safety systems approach from slaughter through processing to consumption. This approach involves the application of Hazard Analysis Critical Control Point (HACCP) principles, and includes microbiological risk assessment, the judicious use of product sampling, microbiological testing, and acceptance/rejection criteria, for both domestic and imported product.

PREPARED REFRIGERATED PRODUCTS CONTAINING COOKED, UNCURED MEAT AND POULTRY

1.0 Background

1.1 Introduction

This document addresses those issues regarding prepared refrigerated products of the meat and poultry industry. The development of pasteurized uncured meat and poultry products in sealed containers designed for extended refrigerated storage has raised questions pertaining to their microbial safety. Of particular concern are pathogenic microorganisms capable of growth at refrigeration temperatures and the safety of these products when they are temperature abused. These recommendations focus on those products under the regulatory authority of the U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS). It does, however, incorporate recommendations for products produced in nonfederally inspected establishments, including retail markets. This document includes advice and recommendations for consideration by federal, state, and local authorities.

The Committee recognizes that some types of prepared refrigerated foods may exclude meat and poultry items in their formulation, e.g., seafood and vegetable or pasta entrees. It is the desire of the Committee that these products be the subject of a review at a later date.

1.2 Selection of Issues

In formulating the attached recommendations, the Committee has considered a number of issues including increased awareness of the potential for the nation's food supply to harbor organisms of public health concern. For example, incidents involving Salmonella spp. and Listeria monocytogenes in dairy products, and Salmonella spp. in raw poultry have received a great deal of attention.

Three reports of the National Academy of Sciences address, in part, the increasing need to better evaluate and assess the microbial safety of meat and poultry products--"An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients," 1985; "Meat and Poultry Inspection: The Scientific Basis of the Nation's Program," 1985; and "Poultry Inspection: The Basis for a Risk-Assessment Approach," 1987.

Additionally, the changing American lifestyle has prompted corresponding changes in the way meat and poultry products are produced and marketed. The development of pasteurized, uncured meat and poultry products in hermetically-sealed containers designed for extended refrigerated storage is a specific example. The microbial safety of these prepared refrigerated foods has been questioned because of pathogens capable of growth at refrigeration temperatures and under conditions of temperature abuse.

In light of the foregoing, and a review of epidemiological data (including opportunities for contamination), processing procedures, growth and survival capabilities, and susceptibility of probable consumers, the Committee has prepared its first recommendations to address Prepared Refrigerated Food Products Containing Cooked, Uncured Meat and Poultry.

2.0 Product Definition

The products addressed in this document are defined as:

Refrigerated foods containing cooked, uncured meat or poultry products that are packaged for extended refrigerated shelf life and that are ready-to-eat or prepared with little or no additional heat treatment.

Of particular concern are those products that rely on refrigeration as the primary barrier to the growth of microbial pathogens or for those products not having some form of secondary barriers, such as a water activity (a_w) ≤ 0.93 or a pH ≤ 4.6 . Included are products containing cured meat or poultry as an ingredient where the nitrite in the meat or poultry ingredient is insufficient to protect the entire food product, e.g., ham salad, beans and franks. Excluded are certain perishable products for which there is extensive commercial experience, the processes are well known, the products are under regulatory control, and there is a favorable record of safety (e.g., cooked beef and roast beef products--including sectioned and formed roasts, chunked and formed roasts, cooked poultry rolls and similar comminuted products). This exclusion should be reconsidered if a new process is used, there is evidence of an increased public health risk, or if verification programs indicate a failure to control and a need for corrective action.

This document is further divided into sections addressing: epidemiological and microbiological information, and the processing and packaging of these products. Section 5 contains recommendations relative to the production, packaging and distribution of these products. Even though the principle targets are those products that fall primarily under FSIS jurisdiction, a segment of the recommendations focuses on those producers regulated by state and local authorities. Recommendations regarding labeling, education, and research are also included.

This document presents the recommendations of the Committee for the manufacture and handling of prepared refrigerated products containing uncured meat or poultry.

3.0 Epidemiological and Microbiological Considerations

3.1 Foodborne Illness Attributed to Meat and Poultry

In preparing its recommendations, the Committee has relied upon data supplied by the Centers for Disease Control (CDC), which tabulate foodborne disease outbreaks as reported by state epidemiologists. Although the products under consideration are a relatively new market entrant for which epidemiological information is lacking, meat and poultry products have historically represented a significant percentage of foods implicated as the cause of foodborne illness. Between 1973 and 1982, meat and poultry products accounted for 28% of all reported outbreaks of foodborne disease in the United States for which an etiological vehicle was identified. The primary etiological agents for meat related outbreaks were Staphylococcus aureus (21%), Salmonella spp. (15%), and Clostridium perfringens (11%). For poultry related outbreaks, the etiological agents were Salmonella spp. (22%), S. aureus (16%), and C. perfringens (13%). From 1982 to 1989, CDC data indicate two sporadic cases of listeriosis related to meat and poultry in the United States.

The presence of E. coli 0157:H7, a recently recognized foodborne pathogen, is also of concern. While it is not a particularly heat resistant microorganism, the temperature during the cooking process must be adequate to kill the pathogen. Outbreaks have been associated with meat and dairy products and may have been caused by low levels of the organism. Children and the elderly may be particularly vulnerable to infection with E. coli 0157:H7, which may cause serious illnesses such as hemorrhagic colitis, hemolytic uremic syndrome and thrombotic thrombocytopenic purpura.

3.2 Bacterial Pathogens of Meat and Poultry

Pathogenic microorganisms (e.g., Salmonella spp., Staphylococcus spp., C. perfringens, L. monocytogenes, E. coli 0157:H7, and Campylobacter jejuni) occur in raw meat and poultry and must be controlled during processing. As these products receive little or no subsequent heat treatment prior to consumption, a failure to eliminate infectious organisms and control sporeformers during and after processing may lead to illness should temperature abuse or other improper handling occur. Since naturally occurring competitive microflora are destroyed during heat processing, pathogenic microorganisms would be allowed to proliferate.

Psychrotrophic pathogens such as L. monocytogenes are of particular concern. Failure to destroy these organisms during processing or prevent their reentry after processing may lead to an unsafe product even though subsequent handling and storage are carried out properly.

3.3 Potential for Microbial Contamination/Recontamination

The products under consideration share one or more of the following characteristics: (1) pre-cooked packaged products intended to receive little or no additional heat treatment prior to consumption, (2) extended refrigerated shelf life, (3) not typically prepared using a conventional preservation system, e.g., water activity or acidification, and (4) marketed under vacuum, modified atmosphere packaging (MAP), and/or in sealed containers. The safety of these products is dependent upon: (1) sufficient heating during processing to destroy vegetative cells of pathogens, (2) avoidance of recontamination with bacterial pathogens, (3) proper refrigeration temperatures throughout the life of the product, and/or (4) appropriate shelf life.

Vacuum packaging and MAP have the effect of diminishing the growth of most bacteria commonly associated with fresh foods except the lactic acid bacteria, Brochothrix spp. and the clostridia. The most important of these for sensitive refrigerated products are the nonproteolytic strains of C. botulinum (types B, E, and F) because they can grow below 5°C. The proteolytic strains (types A, B, F, and G) do not grow below 10°C. The prevalence of proteolytic C. botulinum strains in fresh and processed meat and poultry products examined in the United States and Canada has been found to be about 0.2%. A recent CDC review of botulism in the United States indicates that no cases of botulism from nonproteolytic strains have been attributed to foods stored at refrigeration temperature. Temperature abuse has been a common error in perishable foods implicated in botulism.

Research during the past 20 years employing inoculated packs for a variety of meat and seafood products using proteolytic and nonproteolytic strains of C. botulinum with storage in MAP of varying composition and incubation temperatures from 4° to 30°C report the following:

- toxigenesis is positively related to numbers of C. botulinum spores and increasing temperature and time of incubation. To develop toxigenesis at 4°C required more spores and/or longer periods of incubation than at higher temperatures.

- while product spoilage often precedes toxigenesis, it is not always the case.

- product storage at 4°C for up to 3 weeks should be safe provided that the spore load is <1 spore/g.

- toxin production by C. botulinum in foods in MAP is affected by the interrelationship of MAP, pH, a_w , temperature, nutrients, salt, time, and microbial competition, the spore level, and the type and strain of C. botulinum.

3.4 Population Groups of Special Concern

At this time, the minimum infective dose for most foodborne pathogens cannot be accurately ascertained. Infective dose is, at a minimum, a function of the sum total of virulence factors possessed by a microorganism and frequently ill-defined or poorly understood host susceptibility.

However, some generalities are possible. For example, the elderly, particularly the institutionalized elderly, frequently experience more severe outcomes, even death, from certain pathogens such as S. enteritidis, S. dublin, and L. monocytogenes. Foods likely to be consumed by these and other high at-risk groups (e.g. infants, cancer patients, individuals with extreme neutropenia, transplant recipients) require that particular care be taken in establishing, monitoring, and verifying critical control points to prevent low level contamination.

3.5 Temperature Controls

As a result of the foregoing, proper temperature controls are essential to the safety of these products. While we recognize that temperature abuse can occur at all stages of product manufacture, storage and distribution, the greatest potential occurs throughout the distribution cycle, including consumer purchase, storage and preparation. Temperature must be controlled and monitored by the manufacturer, distributor, and retailer. Since prepared refrigerated products will be promoted to consumers as requiring little, if any, additional heat treatment, the manner of their preparation, packaging, distribution, and storage is critical. Not only must the manufacturer, distributor, and retailer understand that these products require particular care to ensure their safety, but so must the consumer.

Current USDA cooking and cooling requirements are included as Appendix A.

4.0 Processing and Packaging

4.1 Process Types

"Refrigerated foods containing cooked, uncured meat or poultry products that are packaged for extended refrigerated shelf life and that are ready-to-eat or prepared with little or no additional heat treatment."

These processes may be categorized into at least nine types. The Committee recognizes that individual manufacturers may employ variant procedures, however, the following examples are outlined to provide a basic understanding of the manner in which these processes are utilized.

Type 1.

Example--sous vide
Raw ingredients --- Pre-cook (optional) --- Formulate ---
Vacuum package --- Pasteurize --- Chill* --- Distribute

Type 2.

Examples: rolls and roasts
Raw ingredients --- Formulate --- Vacuum package --- Cook
--- Chill* --- Distribute

Type 3.

Examples: roast or fried chicken, other roasts, and
uncured sausages.
Raw ingredients --- Cook --- Chill* --- Package ---
Distribute

Type 4.

Examples: Some uncured luncheon meats and diced meats.
Raw ingredients --- Formulate --- Cook --- Chill* ---
Slice or dice --- Package --- Distribute

Type 5.

Examples: Meat and pasta, meat and sauces, dinners,
sandwiches, pizza
Raw ingredients --- Cook --- Chill* --- Assemble ---
Package --- Distribute

Type 6.

Examples: Chef salad, chicken salad, and sandwiches
or pizza with raw ingredients.
Raw ingredients --- Chill* --- Formulate --- Recook and
chill (optional) --- Package --- Distribute

Type 7.

Examples: Meat pies, quiches, patties, and pates
Raw ingredients --- Formulate --- Cook (optional) ---
Fill into dough --- Cook (optional) --- Chill* ---
Package --- Distribute

Type 8.

Examples: Uncured jellied meats
Raw ingredients --- Cook --- Chill* --- Add raw
ingredients --- Final chill --- Package --- Distribute

Type 9.

Examples: Stews, sauces, and soups
Raw ingredients --- Formulate --- Cook --- Fill while hot
--- Seal --- Hold (optional) --- Chill* --- Distribute

* Denotes continuous chilling at the given step with the asterisk and through all subsequent steps to consumption.

4.2 Process Categories

These nine process types can be further delineated into three categories relative to the inherent microbial risks during pre- and post-processing:

Category 1--Assembled and cooked.

For these products, after the ingredients are prepared and packaged, a final heat treatment is applied to cook the product which will destroy contaminating organisms. When properly controlled, the final heat treatment can assure the destruction of nonsporeforming pathogens, as well as the normal spoilage flora, resulting in products with a relatively long refrigerated shelf life. However, if the final heat treatment does not destroy sporeformers, the possibility of germination and outgrowth exists, resulting in a potential botulinal hazard, particularly if temperature abused. Category 1 includes sous vide and cook-in-bag products with raw or slightly precooked components assembled and packaged, then cooked.

Category 2--Cooked and assembled.

In the case of these products, the ingredients are prepared and then assembled into the final package with no heat treatment being applied after final packaging. Thus, the microbial flora of the packaged product reflects the flora associated with the various ingredients and any flora acquired during the assembly and packaging steps. The refrigerated shelf life of these products is strongly influenced by the number and type of microbial flora in the packaged product. The potential hazard from sporeformers is the same as in category 1 products. However, there is the additional risk of contamination with nonsporeforming pathogens prior to or during packaging. Category 2 includes products with all components cooked individually then assembled and packaged. These products are not further heated before distribution.

Category 3--Assembled with cooked and raw ingredients.

Category 3 includes products with components cooked individually, combined with raw ingredients, then assembled and packaged. The steps in the process for these products are very similar to category 2 products. The major difference is that raw ingredients (e.g. raw vegetables) are added prior to final packaging. This provides the additional risk that the raw ingredients will introduce pathogens into the product that would not otherwise be present if the ingredients were cooked. The potential hazards for these products are very similar to those in category 2 products. These products might not be further heated before distribution.

4.3 Packaging

The manner in which these products are manufactured illustrates that the packaging system used is very important in assuring the stability and safety of these products. Packages and packaging systems are designed to meet marketing and production needs, with specific packaging media being dictated by the product itself and shelf life required to move it through distribution for ultimate consumption. Obviously, the packaging system can be determinative of the type and rate of microbial growth. Product in packages with defective seals would be expected to spoil more quickly and thereby could become contaminated with pathogens in the environment.

The package may be as simple as a moisture barrier for some refrigerated products or a controlled moisture barrier to permit evaporation of moisture from the surface; or it may be more complex, such as MAP using high moisture and gas barrier films. Regardless of the medium used, the packaging system must be designed to assure product safety.

A detailed description of packaging materials and systems is included as Appendix B.

5.0 Recommendations

5.1 HACCP

Based on the preceding analyses, the Committee recommends that a HACCP system be used in the production and distribution of these prepared refrigerated foods. Such systems must be based on sound scientific principles following a thorough risk assessment. (See: Hazard Analysis Critical Control Point System, National Advisory Committee on Microbiological Criteria for Foods, November 1989, Sec. 4.0.) In order to develop a HACCP plan, the producer should follow these essential guidelines:

1. Assess hazards and risks associated with growing, harvesting, raw materials and ingredients, processing, manufacturing, distribution, marketing, preparation and consumption of the food.
2. Determine critical control points (CCP) required to control the identified hazards.
3. Establish the critical limits that must be met at each identified CCP.
4. Establish procedures to monitor CCP.
5. Establish corrective action to be taken when there is a deviation identified by monitoring a CCP.
6. Establish effective recordkeeping systems that document the HACCP plan.
7. Establish procedures for verification that the HACCP system is working correctly.

A detailed example outlining the application of the HACCP principles to the products under consideration is included as Appendix C.

5.2 Process Controls

Microbiological challenge studies or alternative procedures, such as integrated lethality calculations of thermal processes demonstrating that cooked products have been heated sufficiently to achieve a minimum 4-D kill for Listeria monocytogenes should be considered adequate to validate the cooking process (See: Appendix D). The heat treatment used to cook these products must be sufficient to kill vegetative bacterial pathogens, especially those types that may be infectious at low levels.

Listeria monocytogenes is one of the most heat resistant vegetative bacterial pathogens known. Initial loads of L. monocytogenes of around 100/g may be possible; therefore, thermal processes should be designed to kill a minimum of 10^4 L. monocytogenes per gram.

A guideline for evaluating the efficacy of a thermal process for killing L. monocytogenes is provided in Appendix E.

Similarly, it is incumbent upon the processor to verify that production of botulinal toxin in these products can be controlled from the time of production to consumption. In the absence of adequate scientific evidence documenting the safety of the product, appropriate challenge studies with C. botulinum should be conducted. Because both proteolytic and nonproteolytic C. botulinum have been associated with meat and poultry, both types of this organism must be controlled. Secondary barriers such as salt, water activity, and approved preservatives, may serve as an effective alternative to full thermal processing. A guideline for determining the potential for C. botulinum toxin in refrigerated foods is provided in Appendix F. The procedures in Appendix F are intended to serve only as guidelines and may not be suitable for all types of refrigerated foods; other protocols that provide assurance of safety are also acceptable.

If the product supports the formation of botulinal toxin within the timeframe described in the attached guidelines or other acceptable protocol, then the processor must either reformulate the product to prevent botulinal toxin production or design a strategy to assure that the consumer can identify that a product has been temperature abused before the point that botulinal toxin may be produced. If a time/temperature integrator is to be used, studies must be done to correlate safety with temperature abuse and the response of the integrator.

5.3 Process Categories

With respect to individual process categories, it is recommended that special attention be given to the following points in the development and review of the producer's HACCP plan.

Category 1. Assembled and cooked products.

Even though a portion of the normal spoilage flora has been eliminated by the heating process applied after packaging; the heat treatment may be insufficient to destroy C. botulinum spores. Consequently, the time/temperature control procedures applied to these products must assure their ultimate safety.

Category 2. Cooked and assembled, and Category 3. Assembled with cooked and raw ingredients.

Cooked ingredients must receive a heat treatment sufficient to destroy nonsporeforming pathogens, e.g., L. monocytogenes and Salmonella. The lethal treatment required should take into account a number of factors including the initial raw ingredient quality and microbial load, distribution temperature of the product, shelf life and final product use. Of particular concern is that cooked products are not contaminated by pathogens during assembly and packing. It is essential that raw ingredients and the assembly process be controlled to prevent recontamination by pathogens.

5.4 Packaging

Since the packaging systems for these products are important in assuring safety, the producer's HACCP system must ensure that:

1. Approved packaging materials are stored and handled in a manner consistent with maintaining microbiological integrity.
2. Equipment sanitation programs, employee practices, and product handling procedures must minimize product contamination during the packaging process.
3. Key factors such as product temperature, vacuum level, modified atmosphere delivery systems, etc., must be monitored and controlled.
4. Packages must be clearly identified as to production lot in the event of a process deviation.
5. The use of containers which have been traditionally used for the marketing of shelf stable foods is not recommended for these keep refrigerated products until such time as appropriate safeguards are in place to avoid consumer confusion and the risk of temperature abuse. This concern centers on the possibility that consumer misconception may lead to temperature abuse and a botulism hazard.

5.5 Product Distribution

As a result of the perishable nature and finite shelf life of fresh prepared refrigerated products, the manufacturer should also be required to adequately address product distribution in the HACCP plan. Monitoring and verification parameters demonstrating temperature control during distribution must be included. The manufacturer should also be required to include a plan for handling and removing suspect, outdated, or failed product.

5.6 Equipment Monitoring

The use of temperature monitoring devices should be required during refrigerated storage of these temperature-sensitive products. Instruments used for monitoring should also be capable of recording temperatures. These records should be maintained. The temperature recording devices should be made of materials other than glass since glass is easily broken. Glass thermometers may, however, be used for calibration. Additionally, calibrations should be performed at regular intervals using certified thermometers.

5.7 Regulatory Inspection and Review

Processors must have, and maintain on file, a verified HACCP plan prior to production and marketing. Further, the HACCP plan must be sufficient to assure that the processing procedures outlined in the plan are sufficient to control microbial pathogens. In the case of these products, a demonstrated control of C. botulinum, L. monocytogenes, and Salmonella spp. would normally be sufficient to control the presence of the other pathogens of concern. Both C. botulinum and L. monocytogenes have been classified by the International Commission on Microbiological Specifications for Foods (ICMSF) as severe direct health hazards. (See: ICMSF (International Commission on Microbiological Specifications for Foods) 1986. Microorganisms in Foods 2. Sampling for Microbiological Analysis: Principles and Specific Applications. Univ. of Toronto Press. Buffalo, NY). For organisms in this classification, no practical sampling plans can be devised that would be sufficient to guarantee consumer safety. The optimal way to control the occurrence of these organisms is through process control such as that provided through a HACCP system.

Verification procedures are needed to ensure that the HACCP system is operating correctly (See: HACCP, sec. 4.7). Such procedures should be product and/or process specific and should be a part of the approved HACCP plan to assist in assuring a safe product. Microbiological testing and criteria have limitations in a HACCP system but can be valuable as a means of establishing and verifying the effectiveness of CCP's. The frequency of microbiological testing should be based on the regulatory compliance history of the product and/or process. Evidence of a problem may require the utilization of a different process. Since the sensitivity of microbiological tests and the anticipated low prevalence of pathogens will greatly influence the results of verification testing, negative results obtained with a sample lot must be interpreted with care.

Specific tests for individual pathogens and/or indicator organisms may be appropriate but will be product or process specific. Routine analysis of product for total bacterial count or indicator organisms that grow at refrigeration temperature are inappropriate at retail level. Regulatory agencies,

including state and local governments, must assure that the HACCP plan addresses appropriate verification procedures, including microbiological tests and criteria, if appropriate, throughout the processing, distribution and retail sale process.

In instances where the product or process significantly varies from known systems, or for which there is a limited historical record, we would encourage the reviewer to seek validation and verification data from the producer to assure that the product is safe.

5.8 Production Guidelines for Nonfederally Inspected Establishments

5.8.1 Introduction

The Committee recognizes that the preparation and handling of fresh prepared refrigerated foods containing uncured meat and poultry by institutional food service and retail establishments can increase the potential food safety problems associated with these products. Specific concerns relate to:

1. The ability of the producer to control C. botulinum where no barrier to its outgrowth exists, and
2. The manufacturer's knowledge of microbiological control, microbiological sensitivity of these products, quality control, and HACCP systems, and the processing capability and equipment needed to produce these products under good manufacturing practices.

The ability of establishments to assure product safety will differ depending upon the type of operation. Although size is not necessarily a governing factor, it would be expected that larger establishments are better able to provide the resources needed to assure product safety.

5.8.2 Unlimited Production

It is recommended that size of the establishment not be the determining factor in allowing the production of these products. Rather, the determining factor should be the application of microbiological control procedures that assure product safety. It is recommended that unlimited production be extended to any institutional, retail, food service, or similar establishment that can provide demonstrated assurances to the appropriate regulatory authority that the manufacturing is adequate to control C. botulinum, L. monocytogenes, and Salmonella spp. In addition to a HACCP system, the establishment must have a verifiable control plan that includes:

1. (a) A complete written description of the processing, packaging, and storage procedures. CCP's and monitoring and control procedures must be included for each. Those steps that are being taken to minimize excessive handling are to be reflected in the plan, as are the physical barriers or separations that are in place to minimize cross-contamination from raw products.
 - (b) Procedures and frequencies for cleaning and sanitizing food contact surfaces, including documentation to verify compliance.
 - (c) The name(s) of the responsible individual(s) for acceptance/rejection and/or rework of products including a description of procedures to be followed if a process deviation occurs.
 - (d) A description of the lot identification system.
 - (e) A description of initial and continuing employee training program.
 - (f) Procedures and documentation for assuring microbiological adequacy of incoming ingredients and final manufactured products.
2. Maintenance of proper product temperature control, including maintenance of product temperatures not to exceed 40°F and procedures to document that such temperatures have not been exceeded from manufacturing through point of sale.
3. Establishment of a specific product shelf life and use of product "sell by" or "use by" dates as appropriate. Shelf life is to be determined and documented by the manufacturer. In the event documentation cannot be provided, shelf life from manufacturer to retail sale shall not exceed 10 days at 40°F.
4. Establishment of initial and continuing employee training to ensure adequate knowledge of product processing and handling procedures.
5. Development and utilization of clear product labeling to communicate to the consumer the need for proper refrigeration of these products and the need for utilization of the product by the "use by" date.
6. Cross contamination hazards must be carefully monitored in manufacturing and during retail display of products. Cooked and raw products and preparation utensils are to be clearly separated for manufacture and display. Cooked and raw products should be displayed in separate sections.

7. Procedures and requirements for manufacturer use and/or sale of these products must be reviewed and approved by the regulatory authority licensing the establishment for food handling.

8. The manufacturer or owner shall certify that the individual responsible for the processing and vacuum packaging operation is knowledgeable and has been trained in the monitoring and control of critical points in the processing and vacuum packaging operation, as well as all other parts of the control program. The individual responsible shall supervise all processing and vacuum packaging.

5.8.3 Limited Production

Establishments not able to satisfy the requirements outlined in 5.8.2 for control of C. botulinum other than through the use of secondary barriers shall be limited to the production of products that have:

1. An a_w of \leq than 0.93;
2. A pH of 4.6 or less; or
3. Been otherwise formulated to prevent the outgrowth of C. botulinum as determined by the regulatory authority licensing the establishment for food handling.

Additionally, the establishment shall utilize a HACCP based control plan to ensure compliance with the critical limits that have been established for botulinal control.

5.8.4 Excluded from Production

Failure of the establishment to meet all of the requirements outlined for unrestricted production or for limited production will preclude the operation from manufacturing products within this class.

It is the intent of these recommendations to prohibit institutional, food service, and retail establishments from producing these microbiologically sensitive products unless adequate facilities, personnel, and quality control programs exist to consistently ensure microbiological safety.

5.9 Distributors and Retailers

Because of the temperature sensitivity of these products, we recommend that distribution and retail sale also be restricted to only those firms that meet the following conditions:

1. Ability to maintain adequate facilities to ensure the temperature of the product at 40°F or less and establish procedures and documentation to assure temperature maintenance.
2. Program to monitor "sell by" or "use by" dates and procedures whereby products exceeding those dates are removed from retail sale.
3. Assignment of a permanent full-time employee, preferably an assistant manager or other management representative, who is responsible for assuring product handling.

5.10 Imported and Exported Products

1. The Committee recommends that imported products and products for export be produced according to the requirements of federally inspected plants.
2. The Committee also recommends that, where appropriate, sampling plans be based on the recommendations and lot acceptance criteria of ICMSF.

5.11 Labeling

Evidence suggests that consumers have difficulty distinguishing the differences between various food label instructions and their relationship to product safety. For that reason, and because of the greater temperature sensitivity of these products, the Committee recommends that retail and consumer packages carry a uniform standardized label statement and corresponding logo. More specifically, it is recommended that the following label be used on packaged foods that pose a safety hazard when subject to temperature abuse.

* IMPORTANT *
MUST BE KEPT
REFRIGERATED

For products shipped frozen, the shipping carton should be labeled--"KEEP FROZEN."

As is the case with uniform labeling and logo systems, time/temperature integrators (TTIs) can provide retailers and consumers with additional information regarding product storage and handling. TTIs appear to be a means whereby potentially unsafe food could be easily recognized and disposed of before consumption.

The use of appropriate TTIs is recommended wherever feasible. However, the Committee does not believe their use should be mandated at the present time. Rather, it encourages the further development of these products.

5.12 Education and Training

Effective education and training programs could greatly reduce the risks associated with the production, storage, distribution, and handling of these temperature sensitive foods. Appendix G (ICMSF (International Commission on Microbiological Specifications for Foods) 1988. Microorganisms in Foods 4. Chapter 8. Knowledge Required by Personnel and the Public. Blackwell Scientific Publications, London, England) provides a guideline for educating consumers and personnel involved in regulatory inspection, production, and distribution.

5.13 Research

The Committee recommends that additional resources be devoted to research:

1. To determine the true incidence of disease related to the consumption of meat and poultry by funding active surveillance programs that include microbiological, patient, and food data. To establish on the basis of these data a baseline for evaluating the effectiveness of various controls or interventions, e.g., the implementation of the Committee's recommendations.
2. To determine microbiological criteria for each of these products based on prevalence and survival studies of pathogens and other microorganisms in modified atmosphere and under extended periods of refrigeration. To address organisms of particular concern at this time, in priority order, e.g., L. monocytogenes, E. coli 0157:H7, Salmonella spp., and C. botulinum.
3. To develop reliable, consumer-friendly, TTIs, or similar indicators, specifically adapted to the extended refrigerated product shelf life.
4. To determine fundamental microbiological data and improved diagnostic approaches for those pathogens known or thought to exist in the components or environmental conditions unique to these products.

APPENDIX A

Cooking and Cooling Parameters

Cooking Parameters

USDA/FSIS has established minimal internal temperatures required for cooking perishable uncured meat and poultry products. These temperature requirements are referenced in Title 9 of the CFR's (CFR 301-390) or in policies disseminated through the FSIS Policy Book or Notices.

Cooking Requirements

- Cooked beef and roast beef
(9CFR 318.17)
(121 min. at 130°F. to instantaneous at 145°F) 130° - 145°F
(54.4° - 62.7°C)
- Baked meatloaf
(9CFR 317.8) 160°F
(71.1°C)
- Baked pork cut
(9CFR 317.8) 170°C
(76.7°C)
- Pork (to destroy trichinae)
(9CFR 318.10)
(21 hrs. at 120°F. to instantaneous at 144°F) 120° - 144°F
(48.9° - 62.2°C)
- Cooked poultry rolls and other
uncured poultry products
(9CFR 381.150) 160°F
(71.1°C)
- Cooked duck, salted
(FSIS Policy Book) 155°F
(68.3°C)
- Jellied chicken loaf
(FSIS Policy Book) 160°F
(71.1°C)
- Partially cooked, comminuted products
(FSIS Notice 92-85)
 - ≥151°F for 1 min.
 - ≥148°F for 2 min.
 - ≥146°F for 3 min.
 - ≥145°F for 4 min.
 - ≥144°F for 5 min.

Cooling Parameters

Similarly, parameters for cooling and storing refrigerated products including temperatures and times, are reflected in agency regulations (9 CFR) and policies.

Cooling Requirements

- Guidelines for refrigerated storage temperature and internal temperature control point. 40°F (4.4°C)
- Recommended refrigerated storage temperature for periods exceeding one week (FSIS Directive 7110.3) 35°F (1.7°C)
- Cooling procedures require that the product's internal temperature not remain between 130°F (54.4°C) and 80°F (26.7°C) for more than 1.5 hrs. nor between 80°F (26.7°C) and 40°F (4.4°C) for more than 5 hrs. (FSIS Directive 7110.3)
- Cooling procedures for products consisting of intact muscle (e.g., roast beef) require that chilling be initiated within 90 min. of the cooking cycle. Product shall be chilled from 120°F. (48°C.) to 55°F. (12.7°C.) in not more than 6 hrs. Chilling shall continue and the product shall not be packed for shipment until it has reached 40°F. (4.4°C.). (9 CFR 318.17)
- Roast beef for export to the United Kingdom must be chilled to 68°F. (20°C.) or less within 5 hrs. after leaving the cooker and to 46°F. (7°C.) or less within the following 3 hrs.

APPENDIX B

Packaging Materials and Packaging Systems

Fibrous Casings are manufactured from casings coated with cellulose. Generally, the product is heat processed in the casing. The nonmoisture proof casing permits smoke to penetrate through the casing into the product and evaporation of moisture from the product during processing. In many cases, this processing package is also the final package for shipment and distribution. This is most commonly used for deli and food service product but is used for some specialty consumer products like Kosher salami. The casing is relatively impervious to microorganisms when it is dry. Because the casing is nonmoisture proof, moisture evaporates relatively fast and the surface stays dry retarding the development of spoilage organisms. Spoilage, when it does occur, is generally yeasts and molds and some slime forming bacteria. With the evaporation of moisture from the product, some case hardening occurs that further restricts growth of microorganisms. Commonly, shrinkage will amount to 1% a day depending on storage conditions.

Barrier shrink bags are most commonly used for irregularly shaped products, such as primal cuts of beef, hams, and deli loaves. Barrier bags are moisture proof and have low oxygen permeability. To use, the product is inserted into the bag, the air evacuated from the bag with a snorkel or vacuum chamber, sealed using an aluminum slip or a heat seal, then passed through a hot water shrink tunnel (95° to 100°F) that shrinks away the excess film. The final package has an intimate contact to the product providing an anaerobic condition. The resident time in the hot water shrink tunnel is very short and does not provide enough time to surface pasteurize the product.

Form-Fill-Seal Modified Atmosphere Packaging (MAP)

Vacuum packaging is the most common form of MAP used to extend the shelf life and maintain the natural integrity of fresh and cured meats. The vacuum package using oxygen barrier films provides an intimate contact of the film to the product and subsequently provides an anaerobic condition. One of the big advantages of vacuum MAP is that it is easy to identify leaker packages and police the packaging operation.

In form-fill-seal packaging, thermoformable film or rigid plastic is heated to a soft pliable condition and thermoformed into a pocket essentially the same shape and size of the product to be packaged. The product is placed in the pocket and a lidding film is hermetically sealed under vacuum or with vacuum and a gas backfill. With the vacuum package there is a small amount of air containing 20% oxygen entrapped in the product and

the package. Within 24 to 48 hours this residual oxygen is dissipated by the product and anaerobic conditions exist in the package. With gas backfill packages, the residual oxygen in the package is diluted by the backfill gas. The final residual oxygen is directly related to the amount of residual oxygen in the package and amount of backfill gas. Various types of gas mixtures are being used depending on the product. With cured meats and some uncured white meats, the gas may be pure nitrogen or mixture of nitrogen and carbon dioxide. The carbon dioxide gas and the carbonic acid formed from the reaction of carbon dioxide and water does extend shelf life. With fresh red meats, a high concentration of oxygen (40 to 45%) is used to maintain the bloom; 20% CO_2 to extend shelf life and remainder N_2 . MAP packages can also be made using preformed pouches or trays.

Cook in vacuum packages are primarily used for cooked ham for slicing or deli using preformed bags or form-fill-seal packages. The cured tumbled macerated meats are vacuum packaged in the bar or form-fill-seal, placed in mold and cooked. As a result of the processing, the film adheres to the meat creating an anaerobic package.

Tray shrink wrap packages generally use a moisture proof and high oxygen permeable film. They are generally used for fresh sausage, fresh meat, and frozen precooked patties that are sold frozen or in refrigerated cases. The high O_2 permeability of the film provides the necessary O_2 to maintain the red oymyoglobin color of the fresh sausage or red meat. The package provides an aerobic condition. With the frozen cooked patties that are sold refrigerated, there are some special problems of visible indicators or spoilage that must be addressed. In some cases, these frozen patties are prepackaged at a central location while in others the store buys the patties bulk and repacks them into consumer packages in overwrapped foam trays.

APPENDIX C

Examples for the Application of HACCP Principles
for the Production of Foods in Categories 1-2-3

The following example will provide further directions on how HACCP can be used to assure the production of safe foods.

Figures 1-3 illustrate the process flows for the three product categories under discussion.

Figure 1 outlines the steps in the production of a sous vide product, sliced cooked turkey breast with gravy, which has been vacuum sealed in a flexible plastic pouch and then given a final heat treatment prior to distribution. In this example, raw turkey breasts are trimmed, pumped with a solution containing sodium chloride and sodium phosphate, the meat is then placed into a tumbler. After tumbling, the meat is stuffed into a casing, placed onto racks, and moved to a cook oven where it is heated to at least the minimum internal temperature required by the USDA (i.e., 160°F.) After chilling the meat is sliced and placed into a pouch to which gravy is then added. The product is then vacuum sealed, heated, chilled, placed into cartons, and then moved to storage for subsequent distribution.

Model Process Flow for Categories 1-3

Figure 1. Example: Cooked, sliced turkey breast with gravy, vacuum packaged and then pasteurized

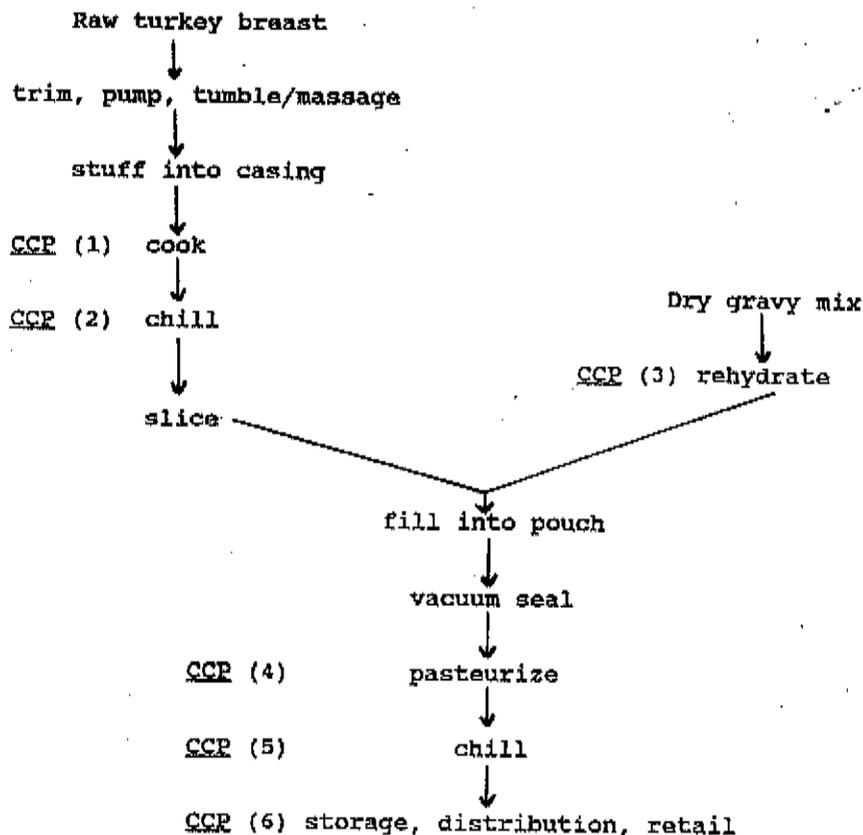


Figure 2. Example: Sliced turkey breast dinner packaged in a tray with a modified atmosphere (MAP)

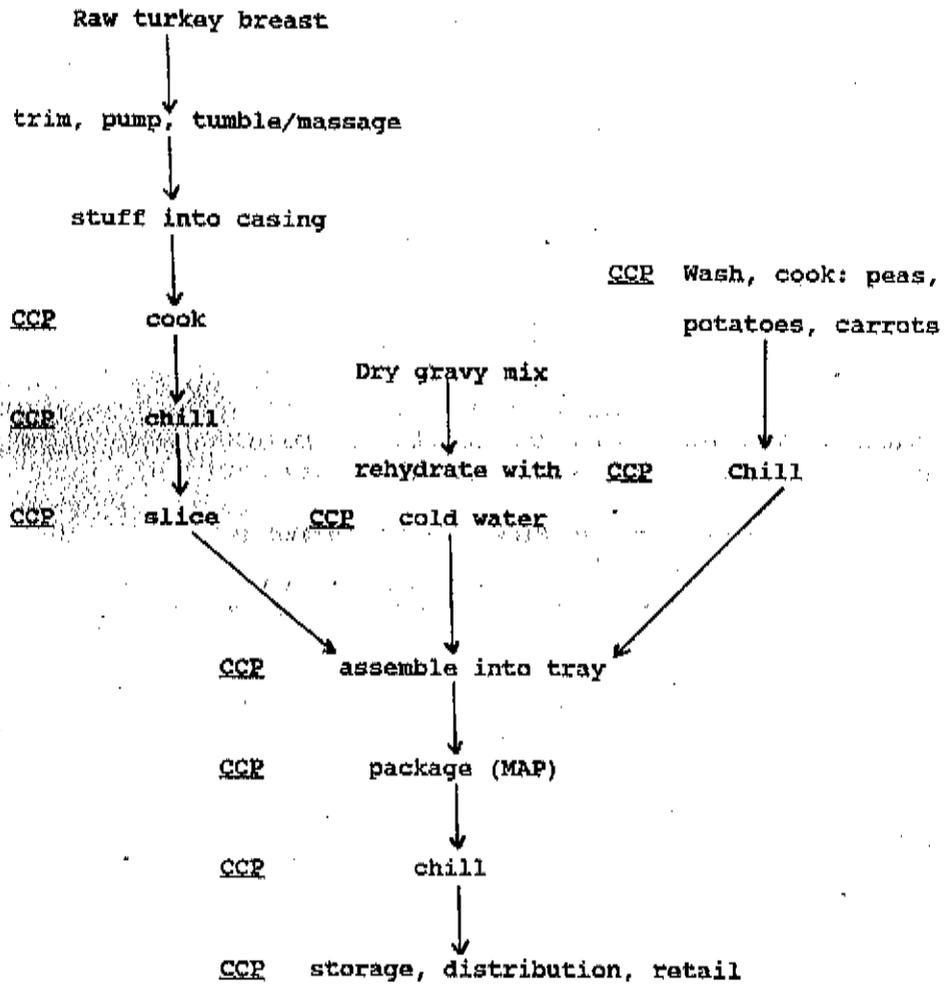
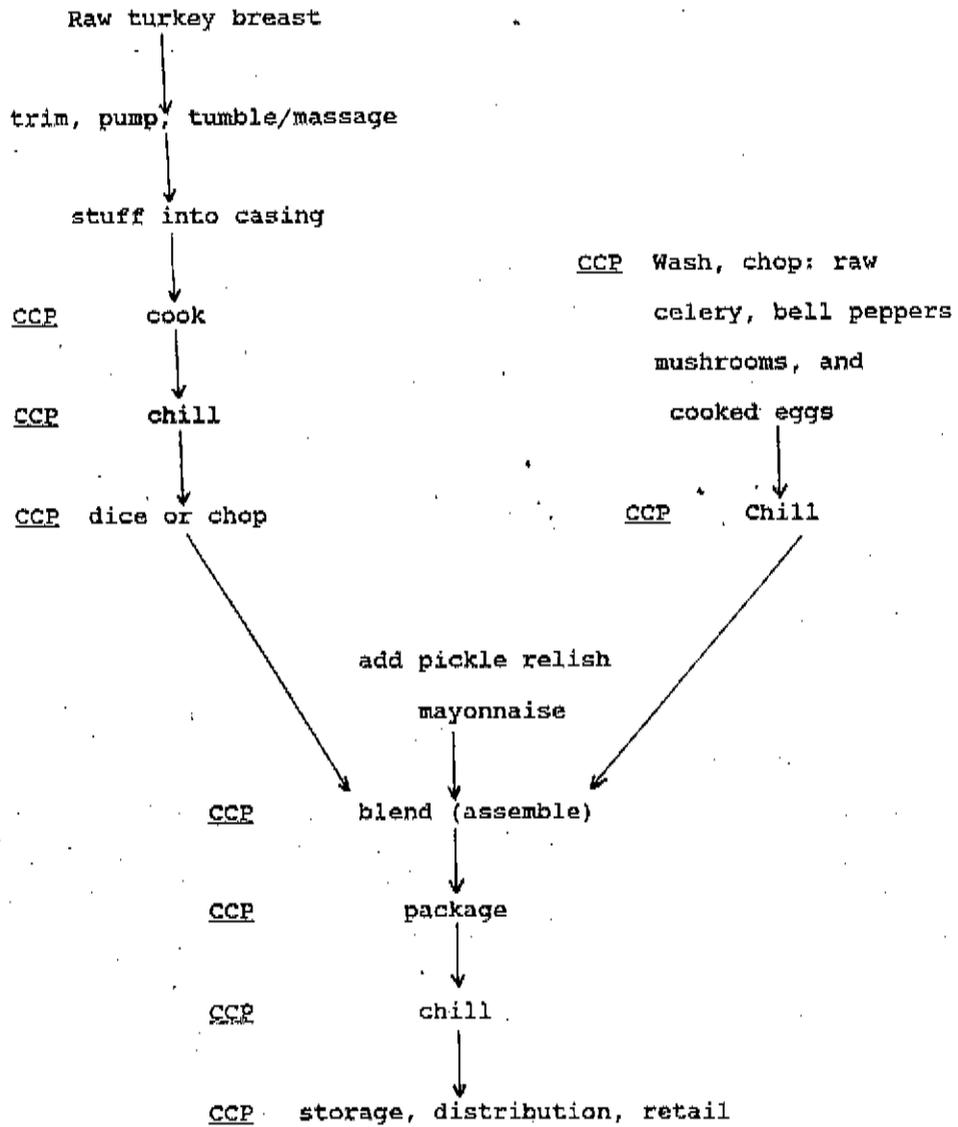


Figure 3. Example: Turkey salad



As outlined in this example, the process has six critical control points (CCPs): cooking, chilling, rehydrating, pasteurizing, chilling, and storing-distributing-displaying. Components of each of the CCPs are summarized in the following tables.

COOKING - CCP No. 1

<u>Conditions</u>	<u>Monitoring</u>	<u>Verification</u>
1) Water and product temperature. Cook to 160°F internal temperature	1) Temperature sensor	1) Check accuracy of temperature sensor
2) Uniform thickness	2) Visual check of casing size at time of stuffing	
3) Uniform heat distribution in tank	3) Observe that water is being agitated or circulated during heating	3) Periodic check of water tank by multiple temperature sensors

CHILLING - CCP No. 2

<u>Conditions</u>	<u>Monitoring</u>	<u>Verification</u>
1) Water and product temperature. Time to reach ≤40°F.	1) Clock, temperature sensor	1) Check accuracy of temperature sensor
2) Uniform chilling	2) Observe that water is being agitated or circulated during chilling	2) Periodic check of water tank by multiple temperature sensors

REHYDRATING - CCP No. 3

<u>Conditions</u>	<u>Monitoring</u>	<u>Verification</u>
1) Time for rehydration and chilling gravy to $\leq 40^{\circ}\text{F}$.	1) Clock, temperature sensor	1) Check accuracy of temperature sensor 2) Total count in subsequent lots of gravy produced throughout the day

PASTEURIZING - CCP No. 4

<u>Conditions</u>	<u>Monitoring</u>	<u>Verification</u>
1) Time and temperature of heating	1) Clock, temperature sensor, color change on ID tag	1) Check accuracy of temperature sensor
2) Avoid overlapping packages	2) Visual sensor	
3) No packages held for pasteurization on later day	3) Visual	

CHILLING - CCP No. 5

<u>Conditions</u>	<u>Monitoring</u>	<u>Verification</u>
1) Water and product temperature. Time to reach $\leq 40^{\circ}\text{F}$.	1) Clock, temperature sensor	1) Check accuracy of temperature sensor
2) Uniform chilling	2) Observe that water is being agitated or circulated during chilling	
3) Avoid overlapping packages	3) Visual	

STORING, DISTRIBUTING, DISPLAYING - CCP No. 6

<u>Conditions</u>	<u>Monitoring</u>	<u>Verification</u>
1) Temperature ≤40°F	1a) Temperature sensor	1a) Check accuracy
2) Safe shelf life	2a) Calendar and printed "Use By" dates	2a) Accelerated shelf life incubation test 2b) Rotation schedule

The conditions necessary to control each CCP are noted along with how the step in the process is to be monitored. Procedures for verifying control are also provided. A more detailed discussion of the six CCPs follows:

COOKING - CCP No. 1

In this example the stuffed turkey breast meat is placed onto racks for cooking in a tank of water.

Conditions--The required USDA minimum internal temperature of 160°F provides a substantial margin of safety for destroying nonsporeforming pathogens. The product is relatively large in diameter and requires a long period of time for heating and chilling at temperatures which are lethal to vegetative cells. To assure uniform compliance with meeting the product temperature requirement and assure safety, it is necessary to control the thickness of the product and the uniformity of the heat distribution within the cook tank.

Monitoring--The temperature of the water is monitored. The minimum internal temperature of the product is monitored by a temperature sensor placed at the center of a turkey roll. The temperature measurement can be either continuously measured and recorded or the product can be checked with a thermometer to assure compliance before the chilling process is begun. Water circulation or agitation to assure uniform heating can be monitored visually.

Verification--Temperature sensors should be periodically checked for accuracy. Heat distribution should be tested using multiple temperature sensors placed throughout the cook tank. The frequency of verification depends upon experience with the equipment.

CHILLING - CCP No. 2

After the product reaches 160°F, the hot water is drained and replaced with fresh water to begin the chilling process. After the temperature has been reduced to about 70°F the product is removed from the water and transferred to a cooler to complete the final chilling process. Chilling is essential to restrict the outgrowth of spores which may be present, as well as to reach an optimal temperature for proper slicing. The time required for chilling the product must be controlled.

The most critical phase is when the product temperature decreases from about 125°F to below 70°F. This is the temperature range in which the outgrowth of sporeformers is of greatest concern.

The use of tap water for chilling influences the initial phase of the chilling process. Depending upon the source of water, the geographical location of the plant, and the season of the year, the temperature of the tap water may vary from 40° to 85°F. The water should be agitated in the tank. Also, fresh water should be continuously added so there is a continuous overflow. Obviously, the water temperature will influence when the product is transferred to the cooler to complete the chilling process. Some other options which can be used to facilitate cooling include the addition of ice to the chill tank, using a recycled refrigerated brine solution or water, or blast chilling with air.

Conditions--The internal product temperature should pass through the temperature range of 125° to 70°F within 4 hours. Subsequent chilling to 40°F should occur within an additional 16 hours. The transfer from the chill tank to the holding cooler should occur in a timely manner to assure the chilling process is continuous and complete. The water in the tank should be agitated and continuously replaced with fresh water so there is an overflow. The holding cooler must be set for less than 40°F. The ambient air temperature may increase during the production day as warm product is placed into the cooler. However, the refrigeration capacity in the cooler must be adequate to assure complete chilling of the product within the specified time limit.

Monitoring--The temperature of the product must be monitored to assure the temperature requirements are met within the time specified. The water should be observed to confirm that it is being properly agitated and is overflowing. The holding cooler temperature must be checked.

Verification--The temperature sensors must be checked to verify their accuracy. The uniformity of the chilling process must be checked by testing the internal temperature of product in various locations within the tank.

REHYDRATING - CCP No. 3

The process for rehydrating the gravy for this example will involve adding a dry gravy mix to water in a tank with a mixer. When rehydration is complete, ice is added to chill the gravy to 40°F or below and obtain the correct final water-to-gravy ratio. This rehydration process would normally be of short duration and may involve multiple production lots during the day. The temperature of the water used for rehydration will influence the quantity of ice that must be added. The reason for chilling the gravy is to restrict microbial growth after rehydration. Also, the gravy equipment will be in use throughout the production day. The colder temperature will limit microbial growth which might occur in the equipment as subsequent lots of gravy are produced. The operation instructions will require that all unused gravy be discarded at the end of the production day.

Conditions--Upon completing the rehydration process the gravy must be at $\leq 40^{\circ}\text{F}$.

Verification--The accuracy of the thermometer must be checked. The possibility of microbial growth in the equipment and with sequential lots of gravy should be investigated. The fact that this does not occur or cause concern can be verified by testing each lot of gravy throughout the production day. The frequency with which such verification is needed will depend upon experience and the accumulated data with the specific process and equipment in this production plant.

PASTEURIZATION - CCP No. 4

After the turkey roll has been sliced, placed into a pouch, and the gravy added, the pouches are then vacuum sealed. Since this product has been sliced, thus causing contamination, the pasteurization process must be designed to destroy the contaminating flora in the product at the center of the package. If the product had been cut into chunks, contamination would have been on the surface as opposed to the center. The process for this example involves combining sliced turkey and gravy, both of which have temperatures of 40°F or below. The product is not subjected to conditions which result in product temperatures below a certain minimum temperature. For the purposes of this example, the minimum will be 32°F at the time of pasteurization. The pasteurization process will be based upon heating a packaged product from 32° to 40°F to a specified higher minimum internal temperature for pasteurization. This process must assure the destruction of nonsporeforming contaminants such as L. monocytogenes which might occur during chilling, slicing and filling the pouches. Furthermore, the rehydrated gravy will contain a mixed microbial flora. The gravy will be purchased with a microbiological specification for total plate count (2 days/35°C with SPC agar). The acceptable

level will reflect a dry gravy mix produced by a company using good manufacturing practices (GMP's). No other microbiological specifications will be required. Occasional incoming lots will be tested and the results shared with the supplier.

In this example, the sealed pouches are placed onto a rack which is lowered into a tank of hot water. After the required time, the rack is raised and transferred to another tank for rapid chilling. It is important that the pouches of product be properly distributed on the rack so that none of the pouches overlap. To facilitate this, the rack should be designed so each pouch fits into a depression in the rack. This will reduce the risk that the pouches will shift as the rack is moved into the tank for heating.

Additional requirements in this process are that sealed pouches of product will not be held over and pasteurized on a later day. This will avoid microbial growth in the product prior to pasteurization. Also, the thickness of the pouches will be controlled to assure uniform heating during pasteurization. The conditions of pasteurization are of greater concern than in the cooking of the turkey roll. This is because the pouches are smaller in size and the time requirement for heating will be much shorter. Particular care must be given to controlling a high temperature-short time process since there is less room for error.

In this example, the pasteurization process has been designed to achieve a minimum destruction of 10^4 L. monocytogenes per gram based upon a starting temperature of 32°F and in the thickest possible pouch with the film and vacuum sealing equipment that is used. Rather than monitoring time and temperature, the process should be designed to maintain a water temperature of $\geq 180^\circ\text{F}$. It has been thoroughly tested and verified that all pouches of product will have met the conditions for pasteurization when a center product temperature of 150°F has been reached. The maximum time for this to occur has been established under various possible conditions. In this example the conditions which must be met for the pasteurization process have been reduced to the initial product temperature ($\geq 32^\circ\text{F}$), water temperature ($\geq 180^\circ\text{F}$), and time from the moment the product is placed into the water tank until it is removed.

A requirement of the overall plant design has been to assure that the product will flow in one direction. The layout of the plant directs product flow from packaging to pasteurization to chilling and then to final boxing. As an additional precaution, each rack of product carries an identification tag. Each tag contains an indicator which changes color when heated to a

certain minimum temperature. This offers a visual check that the product on the rack has been through the pasteurization tank. Operating instructions specify that all damaged or otherwise unacceptable packages which have been through the pasteurizer will be destroyed and not be repackaged or reprocessed.

Conditions--The initial internal product temperature ($\geq 32^{\circ}\text{F}$), water temperature ($\geq 180^{\circ}\text{F}$), time of heating, and distribution of the pouches on the rack must be controlled to meet the pasteurization requirements. In addition, all product must either be pasteurized on the day of packaging or destroyed.

Monitoring--the time-temperature requirements are monitored with a clock and temperature sensors. The other requirements are monitored visually.

Verification--Timing and temperature sensing devices must be checked for accuracy.

CHILLING - CCP No. 5

This chilling procedure is similar to that in CCP No. 6 with one major difference--the smaller product size and more rapid chilling rate of the pouches. This procedure is physically separated from the previous steps in the process. The water used for chilling is chlorinated to minimize the risk of product contamination in the event a leaker pouch should occur and go undetected during labeling and boxing. The water is agitated to facilitate the chilling process.

Conditions--The temperature of the product must be monitored to assure a controlled, continuous rate of chilling to a final product temperature of $\leq 40^{\circ}\text{F}$. The water must contain a residual available chlorine level of 0.5-1.0 ppm.

Monitoring--The rate of chilling and the final product temperature are monitored. The chlorine level of the water is checked using a paper test strip for chlorine content.

Verification--The accuracy of the temperature sensor is checked. The accuracy of the paper test strip for available chlorine content can be checked using an on-site chemical assay.

STORING, DISTRIBUTING, DISPLAYING - CCP No. 6

After chilling the pouches are labeled, boxed, palletized, and then moved into storage for distribution. This particular product must be maintained at $\leq 40^{\circ}\text{F}$ throughout these processing steps and during distribution and display at the retail level because this product has not been formulated to provide a secondary barrier and relies upon refrigeration as the sole means to prevent the growth of sporeforming pathogens.

The product contains a label with a "Use By" date and instructions for proper refrigeration.

Conditions--Product temperature must be maintained at $\leq 40^{\circ}\text{F}$. The product must move through the distribution system in a timely manner. The product must be used within the "Use By" date.

Monitoring--The product temperature through distribution and display is checked with a temperature sensor. The TTIs are checked visually. The "Use By" date and movement of product are checked visually.

Verification--The accuracy of the temperature sensor and TTIs are checked.

APPENDIX D

Table 1. (1) Summary of D-Values and Regression Statistics for Survivor Curve of Listeria monocytogenes Scott A in Lean and Fatty Ground Beef

Temp. °F	Meat Type	Culture Media	Correlation Coefficient	Slope	Y-intercept Log CFU/g	D-value Min.
125	Lean	CBNA	-.9427	-0.7382	5.5354	81.3
125	Fatty	CBNA	-.9792	-0.8438	5.9994	71.1
135	Lean	CBNA	-.9667	-0.3852	8.2370	2.6
135	Fatty	CBNA	-.9197	-1.1735	5.6143	5.8
145	Lean	CBNA	-.8859	-1.7303	4.2014	0.6
145	Fatty	CBNA	-.6232	-0.8226	3.1168	1.2

¹ Table derived from: Fain, Alfred R., et. al., Lethality of Heat to Listeria monocytogenes Scott A D-value and Z-value Determinations in Ground Beef and Turkey, ABC Research 1989, Publication in review.

Table 2. (2) Recommended Minimum Processing Times at Specified Temperatures

Temperature °F	Time in Minutes	Temperature °F	Time in Minutes
125	244.	143	6.18
126	199.	144	5.04
127	162.	145	4.11
128	132.	146	3.35
129	109.	147	2.73
130	87.8	148	2.23
131	71.6	149	1.82
132	58.4	150	1.48
133	47.6	151	1.21
134	38.8	152	0.98
135	31.6	153	0.80
136	25.8	154	0.65
137	21.0	155	0.53
138	17.2	156	0.44
139	14.0	157	0.36
140	11.4	158	0.29
141	9.30	159	0.24
142	7.58	160	0.19

(2) Derived from values in Table 1, 4-D value calculated.

APPENDIX E

Guidelines for Listeria monocytogenes Thermal Inactivation Studies in Extended Shelf Life Pre-cooked Refrigerated Foods

There are many factors that must be considered in designing a Listeria monocytogenes thermal inactivation study to evaluate the microbiological safety of a refrigerated food with extended shelf life. Such factors include:

1. Types and number of strains of L. monocytogenes to use as an inoculum.
2. Methods for production, enumeration and standardization of inoculum.
3. Size of inoculum to be used.
4. Methods for inoculating different types of products.
5. Packaging of products.
6. Sample size and number of samples to test.
7. Heating of products.
8. Determination of D and Z values in the laboratory.
9. Enumeration and detection media.
10. Product composition.

The following procedures are suggested as guidelines for use in designing L. monocytogenes thermal inactivation studies. The procedures described may not be suitable for all types of refrigerated foods and modifications may be necessary to accommodate the type of food being evaluated. Such studies should be conducted and interpreted by an experienced food microbiologist.

1. Type and number of L. monocytogenes strains. At least five strains of L. monocytogenes should be used including representatives of serotypes 1 and 4b. Suggested strains include: Scott A, Type 4b, clinical; Brie 1, Type 4b, cheese; Murray B, Type 4b, clinical; LCDC 81-861, Type 4b, cole slaw; V7, Type 1, raw milk; and HOVJS, Type 1, hamburger.

Preferably, strains isolated from a particular food should be used to inoculate a similar food such as HOVJS being used to inoculate a meat product. Strains Scott A and V7 should be used as reference strains in the mixed strain inoculum in all studies.

2. Methods for Production, Enumeration, and Standardization of Inoculum. The organisms should have been stored since initial isolation or receipt in the laboratory by a method that minimizes or eliminates transfers (such as a frozen or lyophilized suspension).

The inoculum should be prepared by inoculating Tryptose Phosphate Broth and incubating for 24 to 26 hours at 30°C in a static condition to obtain about 1×10^9 cells/ml of stationary phase cells. Cultures should be inoculated the day prior to product inoculation with a minimum holding period prior to actual use. Each strain should be centrifuged, washed and resuspended in Phosphate Buffered Saline (PBS). Dilutions of each strain should be made to yield approximately equal numbers of each of the five strains. The five strains should be thoroughly mixed prior to being used as an inoculum.

3. Size of Inoculum. After the mixed working inoculum is prepared, the viable count of the mixture should be determined using Tryptose Phosphate Agar (TPA) or Tryptic Soy Agar with 0.6% Yeast Extract (TSAYE). The actual inoculum level in the food should be confirmed by sampling the inoculated food immediately after inoculation using either of the above media. Other media recommended by regulatory agencies may be used.

Each of the individual strains in the inoculum should contribute about 20 percent of the total intended inoculum that may vary from 1×10^3 per package of product to 1×10^8 per ml./gram of product (see section 7).

4. Methods for Inoculating Different Types of Products. Surface inoculation of solid foods to simulate post-heating contamination can be performed by dipping the food into the inoculum suspension for a standardized period. This procedure requires correction of the solution to provide the same a_w as the food. Some researchers prefer to inject a point inoculum through a septum on a barrier bag with vacuum or MAP atmosphere.

It is recommended that an inoculum size of no more than 1% of the product weight or volume be added to the product as the mixed Listeria inoculum to achieve the desired inoculum level.

Semi-solid foods that are subjected to post cooking treatment such as mixing, extruding, or molding can be mixed in a sterile Colworth "Stomacher[®]" bag. If the product is not manipulated after cooking, the inoculum can be surface smeared over the semi-solid food by using a sterile bent glass rod or a sterile swab.

Liquid products are most easily inoculated by adding the smallest volume ($\leq 1\%$) of inoculum that is practical and thoroughly mixing it into the food.

Assay of the inoculated products may have to include homogenization, rinse techniques, or specific site sampling depending upon specific product type and inoculation route.

5. Packaging of Product⁽¹⁾. Products that are to be packaged under special conditions such as vacuum or modified atmosphere packaging should use an inoculation and packaging scheme that duplicates the actual packaging conditions of the product. The atmospheres should be defined and analytically determined. Any post-packaging treatments that are to be conducted should be defined and well controlled.

The entire inoculation, packaging, and post-packaging handling process should be performed such that the normal course of changes of the package and atmosphere are not altered.

The inoculated product should be packaged as intended for retail sale using vacuum or modified atmospheres and suitable thermocouples inserted into the coldest heating spot of each product using a special double gasketed packing gland to seal the thermocouple assembly to the plastic barrier package. An accurate ($\pm 1^\circ\text{F}$) time/temperature data logger should be used to measure product and processing water temperatures. Zero time counts should be performed on inoculated packages.

6. Sample Sizes and Number of Samples to Test. The sample size used for each data point should be as large as practical to reduce variation around the data points. A minimum sample size of 25 grams should be used for analysis that is blended or homogenized using a Colworth Stomacher^R laboratory blender.

A minimum of three replicates, and preferably five of a given type of food, should be taken at zero time and each sampling interval. A minimum of duplicate heating runs should be performed.

1 Conventional plastic barrier packaging is defined as plastic resin film of PVDC (saran) or EVOH that has an oxygen transmission rate measured at 73°F (m^2 , 24 hours, one atmosphere) of between 5 to 100cc. Common oxygen transmission ranges for various types of films include:

Barrier - 5 to 20cc O_2 (as determined above)

High barrier - 1 to 5cc O_2

Very high barrier - $<1\text{cc } \text{O}_2$

7. Heating of Products. Traditional techniques for thermal death time studies should be used to verify the decimal reduction times decided as appropriate for the product. The Committee suggests a 4D reduction as the minimum process for meat and poultry products.

The product should be heated using the desired time/temperature relationship. Triplicate zero time and heated samples should be examined microbiologically using the procedures described in Section 8 to determine log reductions. A minimum of two such trials are recommended.

8. Determination of D and Z Values in the Laboratory. A single method is recommended for determining the effectiveness of Listeria control procedures. This method is outlined below:

This procedure involves the actual determination of D and Z values at specific temperatures in individual products. For this procedure, the product must be thoroughly mixed with an inoculum containing approximately 1×10^9 per ml. of the L. monocytogenes suspension. One gram portions can be added to each of the sterile thermal death time (TDT) tubes. The tubes are sealed with a flame, and placed in baskets for ease and speed of handling. Time/temperature data should be monitored with thermocouples for both product and the heating medium. The TDT tubes must be completely submerged during the heating process. Appropriate time intervals should be selected at 125°, 135°, and 145° since preliminary data for L. monocytogenes indicate: $D_{125^\circ\text{F}} = 90.1 - 96.2$ minutes, $D_{135^\circ\text{F}} = 2.60 - 6.63$ minutes, $D_{145^\circ\text{F}} = 0.58 - 1.22$ minutes, and Z value of 9.0 to 10.8°F.

Come up times should be recorded and zero time is indicated as the time when triplicate temperature monitoring tubes reach the test temperature. Triplicate product tubes should be removed at each time interval and immediately transferred to an ice bath until analyzed. After cooling, the TDT contents should be transferred to sterile 0.1% peptone diluent and thoroughly mixed. Appropriate dilutions should be prepared and surface plated on either TPA or LPM (See section 9). At least duplicate runs should be performed. D and Z values in minutes can be determined from the survivor curve as described in the Laboratory Manual for Food Canners and Processors, Volume 1., National Canners Association, (1968).

Literature and company data file searches can be conducted to list D values and Z values for L. monocytogenes in various major product classes so that data for integrated lethality may be established. As an alternative to inoculated pack studies, processors may use an integrated lethality procedure using an approved process authority.

Methods demonstrated to give comparable results should be considered.

9. Enumeration methods employed for the procedure in Section 8 should permit recovery of heat injured cells; therefore, the current acceptable methods recommended by the regulatory agency will be used. The Fraser-Sperber technique may be useful, but offers no advantage for food containing large numbers of enterococci.

Backup enrichment methods should be prepared to confirm that there are no surviving L. monocytogenes cells below the detection limit of less than 100 per gram when direct plating methods are used.

10. Product Composition. In addition to detecting or quantifying L. monocytogenes in product, duplicate uninoculated samples of the product at zero time should be assayed for moisture, fat, protein, salt content, pH, and a_w if a meat or poultry containing product. Product analyses should be designed to determine major product characteristics and may need to be modified if the product is chiefly vegetable or pasta, in nature. Depending on the type of product, other analyses (such as titratable acidity, nitrite content, or preservative level) also should be performed. If the product is packaged under modified atmosphere conditions, gas analysis should be performed at zero time.

Any change in product formulation will require re-determination of the heat resistance characteristics.



APPENDIX F

Guidelines for Clostridium botulinum Inoculation Studies to Evaluate the Potential Risk of "New Generation" Refrigerated Foods with Extended Shelf Life

Clostridium botulinum inoculation studies for this category of foods are done to identify the risk of botulinal toxin production in products: (1) held under refrigerated storage at the highest temperature used in approximately .5% of household or retail refrigeration units, and (2) held at a temperature that represents conditions if the product was mistakenly not refrigerated by the consumer. For the latter situation it is important to relate time of overt spoilage (unfit for human consumption) to time to botulinal toxin production. Additional reasons for doing C. botulinum inoculation studies are: (1) to verify that time/temperature integrators (TTI's) used to monitor temperature abuse of product will truly indicate temperature abuse before botulinal toxin formation could occur in a product, and (2) to evaluate if product modifications (such as adding preservatives or lowering pH or a_w) will prevent toxin formation.

Considering the extreme toxicity of botulinal toxin, it is imperative that C. botulinum inoculation studies be designed and conducted only by experts who understand the hazards of botulinal toxin and are familiar with proper safety precautions for handling C. botulinum.

Several points should be considered in designing a C. botulinum challenge study. Examples include:

1. Types and number of strains of C. botulinum to be used.
2. Methods for spore production, preparation, and enumeration.
3. Number of spores to be inoculated.
4. Methods for inoculating product with spores.
5. Packaging of product.
6. Time and temperature(s) of incubation of product.
7. Sample size, sampling times, number of samples to test.
8. Botulinal toxin testing procedure.
9. Types of product analyses at different stages of the study.

The following are suggested procedures to use for C. botulinum inoculation studies. These procedures are intended to serve only as guidelines; equivalent protocols are also acceptable. These procedures may not be suitable for all types of refrigerated foods; modifications of procedures may be necessary to accommodate the type of food being evaluated.

A. Types and Number of C. botulinum Strains

Proteolytic and nonproteolytic types of C. botulinum used in challenge studies should be tested separately. A mixture of a minimum of five strains each of type A and proteolytic type B is suggested for studies of proteolytic C. botulinum. Strains that may be used include: type A--56A, 62A, 69A, 77A, or 90A and proteolytic type B--53B, 113B, 213B, 13983B, or Lamanna-okra B. Strains 62A and 213B should be used in all studies. Additional strains such as isolates from refrigerated foods may also be used in combination with these strains. If practical, strains may be screened to select those that grow best in principal components of the product to be evaluated.

A mixture of a minimum of three strains each of nonproteolytic type B and E, and one strain of nonproteolytic type F is suggested for studies of nonproteolytic C. botulinum. Strains that may be used include: nonproteolytic type B--2B, 17B, 2129B, 17844B, or 25765B; type E--Beluga, Saratoga, Minnesota, Iwani or Alaska; and nonproteolytic type F--83, 187 or 3194. Strains 17B and Beluga should be used in all studies.

Each strain of both proteolytic and nonproteolytic C. botulinum used for inoculation studies periodically (yearly) should be assayed by the mouse bioassay for toxin production. Any culture producing less than 1000 MLD/ml should not be used; either a productive culture of the same strain should be obtained or a different strain should be used in lieu of the nonproductive culture.

B. Methods for Spore Production, Preparation, and Enumeration

Spore crops may be produced by a variety of methods. Examples include: (1) the use of many different sporulation broths that are selected on the basis of strain sporulation characteristics; (2) biphasic methods using different types of liquid media over different types of agar media; and (3) agar media (such as anaerobic egg yolk agar) held under anaerobic conditions. There appears to be no common approach to producing spore crops. Most investigators use an incubation temperature for proteolytic strains of 35°C and for nonproteolytic strains of 26° to 30°C. Time to sporulation depends on the cultural conditions and the strain of C. botulinum, and is determined by periodic

microscopic examination of the culture. If a defined protocol for producing spore crops is to be recommended, we need a better consensus among investigators in the field of the best procedure(s) for producing spores.

Spores during harvesting should be washed at least five times with sterile distilled water and appropriate centrifugation. Following washing, spores should be treated by sonication to destroy sporangia and vegetative cells and free the spores. The sonicated spores should be washed with sterile distilled water at least 10 more times using centrifugation and resuspension. The spore suspension in sterile distilled water or in 50% glycerol plus 0.25% Tween 80 in sterile distilled water should be stored in vials at -20°C or -15°C, respectively. When needed, a frozen spore suspension should be thawed by placing the vial in lukewarm (ca. 30°C) water for several minutes. Spore suspensions in glycerol - Tween 80 solution are not frozen.

Spores may be enumerated by a 5-tube most probable number (MPN) procedure. Dilutions of heat-shocked (80°C, 10 minutes for proteolytic strains or 60°C, 10 minutes for nonproteolytic strains) spores (or product) are inoculated into tubes of TPGY medium (trypticase 5%, peptone 0.5%, yeast extract 2%, dextrose 0.4%, and sodium thioglycollate 0.1%) and the TPGY tubes are incubated anaerobically in Gas-Pak jars at 35°C for 7 days for proteolytic strains and at 30°C for 7 days (with subsequent trypsinization if the mouse bioassay for toxin detection is used) for nonproteolytic strains. Pure spore suspensions can be enumerated by visually examining tubes for growth; however, for food samples which contain other organisms, the mouse test or an equivalent assay to confirm the presence of botulinal toxin must be done. The MPN procedure generally is preferred for enumerating spores in inoculated foods which may contain too few spores for detection by direct plating methods.

Alternatively, spore crops with sufficient numbers of spores can be enumerated by direct plating procedures. Heat-shocked spores are diluted and plated onto anaerobic egg yolk agar or an equivalent medium held at 35°C for 48-72 hours under anaerobic conditions for proteolytic strains or at 26° or 30°C for 48-72 hours under anaerobic conditions for nonproteolytic strains.

C. Number of Spores Inoculated

Spore mixtures to be used as inocula should contain an approximately equivalent number of spores of each strain of C. botulinum in the cocktail. Spore counts should be done on each strain before the spores are pooled into a cocktail. Spores should be diluted appropriately in sterile distilled water or in 50% glycerol - 0.25% Tween 80 and stored at -20°C or -15°C, respectively.

For foods that are fluid or that can be prepared with spores uniformly distributed throughout, a minimum inoculum level of 50 to 100 spores per gram is recommended. No more than 5000 spores per gram should be used.

For foods that require surface inoculation and in which spores cannot be uniformly distributed throughout, a minimum inoculum level of 100 to 1000 spores per square centimeter surface area is recommended.

The inoculum level may be adjusted for particular products depending on the spore load that may be expected under worst case conditions.

D. Methods of Inoculation

Spores should be heat shocked either immediately before inoculation (proteolytic types, 80°C, 10 minutes; nonproteolytic types, 60°C, 10 minutes) or as part of the process the food will receive after inoculation (e.g., process cheese may be heated at 82°C before packaging).

Methods for inoculating spores may vary depending on the product. When liquid may be applied without substantially disrupting the properties of the food, spore suspensions in sterile distilled water may be added to the product and mixed in for uniform distribution. Large solid products may be surface inoculated by dropwise (up to 0.1 ml per drop) addition of inoculum that is spread out in a thin layer using sterile utensils (e.g., sterile gloves or best glass rods).

For products that possess inhibitory properties attributed to water activity, salt content, or some other factor that may be affected by dilution if water is added, then the inoculum should be applied via a suitable dry, sterile carrier (such as sand) or in a homogenate of the particular food (adjusting the formulation of the food to compensate for the added water). For some products, a point inoculation technique may be used. Spores should be inoculated into the most permissive area of the food (such as meat chunks that may have a higher pH than surrounding sauce).

E. Packaging of Product

For products that are packaged under special conditions such as controlled or modified atmospheres, an inoculation scheme should be used which duplicates the condition of the product as it is normally packaged. Such products should be inoculated in a manner that does not affect the normal course of changes within the package relative to the gas mixture. Alternative packaging may be used provided conditions within the package approximate the conditions within commercially packaged product.

F. Time and Temperatures of Incubation of Product

The recommended conditions for inoculated pack studies with nonproteolytic C. botulinum are at 55°F for one and one-half times the product's shelf life or for up to the time when the product is overtly spoiled (unfit for human consumption). Studies with the proteolytic C. botulinum are recommended at 80.6°F (27°C) for up to the time when the product is overtly spoiled (unfit for human consumption) or for one-half the refrigerated shelf life if the product does not appear spoiled by that time. If the product contains multicomponents, then testing should terminate 1 day beyond the time the last component of the product is overtly spoiled (unfit for human consumption).

If TTI's are used as indicators of temperature abuse, time to toxicity studies should be done with nonproteolytic C. botulinum at least at 6°, 10°, and 20°C and with proteolytic C. botulinum at least at 20° and 27°C to verify that the TTI's will change before toxin can be produced.

G. Sample Size, Sampling Times, and Number of Samples to Test

Ideally, the entire sample should be homogenized or extracted for botulinal toxin testing. If samples are large (>300 g), a minimum sample size of 50 g is recommended.

Sampling times should be adjusted according to the expected shelf life of the product. Samples for botulinal toxin assay should be taken at "0"-time (day of inoculation) and at a minimum of four additional times, with at least three sampling times between halfway and the final testing time. Product incubated at 27°C should be tested at the time it becomes overtly spoiled.

The recommended minimum number of samples assayed for botulinal toxin at each sampling time is five. A minimum of three samples taken at "0"-time and at the final sampling time is recommended for C. botulinum spore enumeration. It is not necessary to continue sampling at times after the first toxic sample is detected.

H. Botulinal Toxin Testing Procedure

The mouse bioassay procedure as described in the U.S. Food and Drug Administration Bacteriological Analytical Manual (6th ed., 1984) is the recommend method for botulinal toxin testing. Only individuals properly immunized with botulinal toxoid should perform these tests. Samples inoculated with nonproteolytic C. botulinum spores should be tested first without trypsinization. If mice survive, then tests should be done on trypsinized samples. Preferably, toxin analysis should be done on the day

of sampling, but if this is not possible, samples should be homogenized or extracted in 0.05 M sodium phosphate-gel buffer (pH 6.2), sedimented by centrifugation (27,000 x g, 20 min, 4°C), and the supernatant fluids (at least 10 ml; adjusted to pH 6.2, if necessary) stored at -20°C.

An alternate procedure (such as an ELISA method) for the mouse bioassay test may be used providing the alternate method has been documented to be of equal or greater sensitivity than the mouse bioassay.

I. Product Analyses

In addition to botulinal toxin testing and C. botulinum spore enumeration, the product (duplicate samples) at "0"-time should be assayed for moisture, fat, pH, and aerobic plate count. Depending on the type of product, other analyses (such as protein, salt content, water activity, titratable acidity, nitrite content, sorbate content, psychrotroph count, spore count, lactic acid bacteria count, anaerobe count) also should be done. If the product is packaged under modified atmosphere conditions, gas analysis should be done at the initial sampling time. Visual appearance (including gas formation [puffiness of samples]) and odor of samples should be determined and recorded at each sampling time to indicated degree of spoilage.

8

Knowledge required by personnel and the public

- 8.1 Introduction
- 8.2 Producers
- 8.3 Processors and food service personnel
- 8.4 Transport and storage personnel
- 8.5 The public
- 8.6 Regulatory personnel
- 8.7 Persons who develop HACCP programmes

8.1 Introduction

The incidence of food-borne illness is high throughout the world, and where data are available it is readily demonstrable that the majority of incidents take place in food service establishments and homes (see Table 1.12). The principal factors that contribute to these incidents are shown in Table 1.11. As indicated in Chapter 1, losses due to microbial spoilage of foods are enormous. A portion of these losses takes place prior to harvest and slaughter. Further losses may occur at each step in the chain from producer to ultimate consumer. Accordingly it is important that those involved at all links in the food chain be knowledgeable as to the measures they can take to reduce the incidence and the magnitude of these losses.

Food-borne disease and spoilage result from negligence or ignorance or both. Problems develop when those who are involved in handling food do not possess the knowledge necessary to control microbiological hazards. It follows that a number of specific groups must be educated if the incidence of spoilage and disease is to be reduced. These groups include:

- (a) producers;
- (b) processors and food service personnel;
- (c) those involved in transportation and storage.

- (d) the public;
- (e) regulatory personnel;
- (f) persons who conduct HACCP evaluations.

The level of knowledge required by persons in these groups varies with the role they play in the overall process. The minimum information required by individuals in these groups is listed in Tables 8.1-8.6. The systematic application of this information is the cornerstone of the HACCP system.

8.2 Producers

Table 8.1 shows the information basic to controlling or minimizing microbial hazards at the producer level. It must begin with sound animal husbandry and horticultural practices. It requires a knowledge of the sources of microorganisms as these relate to animal diseases and to food spoilage. It requires an appreciation that pathogens can be carried by growing plants and animals, consequently leading to the harvested plant and slaughtered animal being potential sources of infection to man. The need for proper cleaning and temperature control is of prime importance. The type of knowledge required by fishermen is somewhat different from those in other agricultural businesses, as is shown in Table 8.1.

8.3 Processors and food service personnel

The food processing segment of the industry includes line operators, quality control (QC) personnel and management. Each of these subgroups requires qualitatively and quantitatively different knowledge to be effective in minimizing microbial hazards. The requirements are shown in Table 8.2.

Line operators are the personnel who are directly responsible for food processing, preparation and storage. They are concerned with a segment of a sequence of operations that leads from raw material to finished product. As indicated in Table 8.2, part A, these persons should have a knowledge of the microbiological hazards associated with that phase of the operation for which they are responsible. In some cases the microbiological implications may be broad, e.g. the hand-boning of cooked poultry, whereas in others they may be trivial or even absent (e.g. the check-weighing of finished packaged product units). Thus the extent of knowledge required will vary accordingly.

The QC personnel have much wider technical responsibility than

Table 8.1 Basic knowledge required by those producing food

A. *General*

All food producers should know:

- That microorganisms are the prime cause of food spoilage and food-borne disease
- The primary sources of organisms causing spoilage and disease
- The role of contamination in contributing disease-causing organisms to foods
- The influence of temperature on the microbiological quality and safety of the foods

B. *Animal foods*

Producers of animal foods should also know:

- The principles of animal husbandry
- The role of feedstuffs in animal disease
- That hazardous contaminants, e.g. aflatoxins and salmonella, can pass through to the final product
- That the animal is a major source of contamination of milk and that appropriate milking practices can minimize contamination
- The need for cleanliness of milking facilities, viz. milking machines, pipes and tanks
- The risks and benefits of egg cleaning procedures
- The influence of temperature and humidity on the quality of stored eggs

C. *Plant foods*

Producers of plant foods should also know:

- The basic principles of good agricultural or horticultural practices
- The indications of spoilage at the time of harvest
- The means to minimize contamination by spoilage organisms during harvesting
- The appropriate handling techniques to minimize damage

D. *Marine foods*

Producers of marine foods should also know:

- That marine animals harvested from polluted waters are likely to be contaminated with enteric pathogens
 - The need for cleanliness of implements and storage facilities utilized in the capture, storage and, where applicable, processing of marine animals
 - That evisceration will influence the keeping quality of fish
 - That spoiled fish should not be further processed because of the risk of scombroid poisoning
-

Table 8.2 Basic knowledge required by food industry personnel**A. Line operators**

Line operators should know:

- The major sources of microorganisms in the product for which they are responsible
- The role of microbes in disease and food spoilage
- Why good personal hygiene is required
- The importance of reporting illness, lesions and cuts to supervisory personnel
- The nature of the control required at their point in the process
- The proper procedures and frequency for cleaning equipment for which they are responsible
- The procedures necessary to report deviations from control specifications
- The characteristics of normal and abnormal product at their given step in the process (e.g. colour, texture, package integrity, odour)
- The importance of maintaining proper records
- How to monitor CCP of operations within their responsibility

B. Quality control personnel

QC personnel should know:

- The sources of microbes, their importance in disease and spoilage, and how they can be controlled
- How to perform and interpret all chemical, physical and microbiological analyses relevant to their operation
- Why these are relevant to the operation
- The objectives of the HACCP system and in particular the importance of monitoring to determine whether a process is under control
- The prescribed action to be taken when monitoring results indicate the process is going out of control and the procedure for reporting this to the person in authority to determine the nature of action required
- How to investigate the most likely causes of process deviations, and, if the solution is not readily apparent, the procedure for obtaining additional help
- How to maintain and transmit pertinent QC records

C. Management

Management should know:

- That the HACCP programme focuses on those points that are critical to the operation
- That the microbiological and economic consequences of a process being out of control can be enormous
- That it is through monitoring of CCPs that it can be determined whether a process is under control
- Where the responsibility and knowledge level of the line operators, QC personnel and technical experts begin and end

- The value of showing the results of a HACCP monitoring programme to legal and regulatory authorities
 - The sources of microbes, their importance in disease and spoilage and the benefits of good personal hygiene of line workers
 - That it is its responsibility to ensure that line workers and QC personnel are brought to a knowledge level commensurate with the needs of their jobs
-

most line workers. Therefore they must have the same basic knowledge of the sources of microbes and their importance in disease and spoilage not only for a particular operation but also for the overall manufacturing or preparation process. In addition they must be conversant with the techniques required to monitor CCPs, their interpretation, the recommendations emanating therefrom and proper maintenance of the QC records.

To management falls the responsibility for understanding the benefits of HACCP, its implementation and coordination. It is not expected that their level of technical knowledge will exceed that of the line workers, with respect to sources of microorganisms and their importance in disease and spoilage, but that their appreciation of this mandates that an overall control programme must be established. Management should appreciate the value of the HACCP programme not only in internal control, but also in its relationship with regulatory agencies with whom it should not hesitate to share the results of the monitoring integral to HACCP.

8.4 Transport and storage personnel

Those involved in transporting and storing foods have an equal responsibility to acquire knowledge of how microbiological hazards can be minimized (Table 8.3). As with personnel in other segments of the

Table 8.3 Basic knowledge required by those involved in warehousing (storage and transporting foods)

Those involved in warehousing should know:

- That contaminated foods can cause illness and that microbes spoil foods
 - The practices necessary for the safe transport of the products with which they are concerned
 - That vehicles must be cleaned and the means for achieving this task
 - The influence of temperature on product quality and microbial growth
 - The importance of controlling insects and rodents
-

Table 8.4 Basic knowledge required by the public

The public should know:

- The cause and effect relationship of individual actions on food safety and spoilage
 - Practical measures to ensure the safety of the foods they prepare, process or store
 - Proper processing and home preservation methods (e.g. home canning of foods, fermentation) and the consequences of using improper procedures
 - That improper food holding practices, such as leaving foods in ovens at low temperatures or at room temperatures or placing large containers of unchilled foods in refrigerators, will allow bacteria to multiply to high numbers
 - The heating procedures necessary to kill vegetative forms of pathogens in raw foods of animal origin and left-over chilled foods
 - That raw foods (e.g. meat, poultry, fish, shell eggs) carry pathogens when they enter kitchens
 - That by handling raw foods, microbes can pass to hands and then to other foods
 - That clothes, sponges and brushes used to clean food preparation surfaces can transfer microbes from raw foods to equipment and surfaces that will be used for cooked foods
 - That cooked foods should not pass over the same surfaces or through equipment that have been in contact with raw foods unless those surfaces have been properly cleaned
-

industry, the understanding that microbes cause both disease and spoilage is paramount. Knowing the potential sources of microbes (e.g. raw ingredients, persons who load and unload the carrier, animals and products previously hauled, vermin, unclean vehicles, bins) and understanding the beneficial effects of temperature control and proper cleaning and disinfection are essential to maintaining control of the operation.

8.5 The public

As noted above, the number of food-related disease incidents could be significantly reduced if the public were better informed about proper handling of food. The core elements of the knowledge that all persons should have are shown in Table 8.4. The most fundamental concept is that raw food materials harbour microbes that will spoil it in time unless it is frozen or processed (cooked) before the spoilage occurs. They must be aware that certain raw foods (primarily those of animal origin) are likely to be contaminated with disease-producing micro-organisms. They must be aware of the measures for control of pathogens in raw foods, in particular those of animal origin. As noted