

A Microbiological Decision Tree Approach for
Performing a Hazard Analysis and its Relationship
to Microbiological Risk Analysis

by

Edward Jeffery Rhodehamel

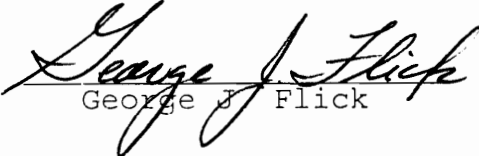
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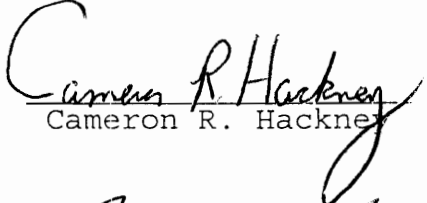
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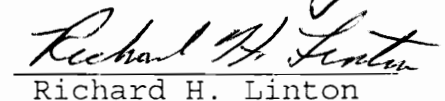
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Edward Jeffery Rhodehamel
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(ABSTRACT)

The annual incidence of microbiological food borne disease in the United States ranges between 6.5 million to 33 million cases with as high as 9,000 deaths. There is a developing consensus that the Hazard Analysis and Critical Control Point (HACCP) concept is the most effective and rational means of assuring food safety from harvest to consumption. The first step in the application of the HACCP concept involves conducting a hazard analysis. It is essential that this procedure is performed correctly, because the subsequent plan and procedures developed to control the identified hazards are based on this critical first step. Recently the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and Codex Alimentarius have published information on HACCP principles and application, but have not provided a comprehensive method for conducting a hazard analysis. Guidance on hazard analysis issues such as the determination of

significant hazards for inclusion in a HACCP plan, the probability of occurrence (risk), and hazard severity is lacking. Practical guidance for conducting a hazard analysis and applying Principle #1 was developed. A decision tree approach is proposed that provides a logical framework for deciding what hazards are to be included in the HACCP plan and thus controlled in the food process. Additionally, guidance on what considerations and information are required at each level of the decision tree is provided. These decision trees and accompanying information provide a practical and uniform basis for applying Principle #1 and determining which hazards should be addressed in a HACCP plan. The use of risk assessment as a part of risk analysis is also gaining increasing popularity as a means to prioritize food safety issues and policy. Some have proposed the incorporation of risk assessment within the HACCP concept. The relationship of risk analysis to hazard analysis and justification for keeping the two procedures separate is discussed. The methods used in risk assessment and HACCP are at times similar, but should not be considered the same. Risk assessment and HACCP are two separate functions with two separate scopes, and the incorporation of risk assessment into hazard analysis at this time is counterproductive and should be discouraged.

DEDICATION

This dissertation is dedicated to the three most important women in my life, my wife Kimberly, my daughter Sarah, and my mother Rosemary.

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I. INTRODUCTION

Microbiological food borne disease is a significant threat to public health and carries with it substantial economic costs. Archer and Kvenberg (1985) and Todd (1989) estimated that the incidence of food borne illness ranges from 12.6 to 81 million cases per year with a cost of 1.9 to 8.4 billion dollars. A report by the Council for Agricultural Science and Technology (CAST) indicated that the consensus of expert task force members was that the annual microbiological food borne disease burden of the United States likely ranged from 6.5 million to 33 million cases with as high as 9,000 deaths (CAST, 1994).

The Hazard Analysis and Critical Control Point (HACCP) concept involves a systematic preventive approach to be used in food production as a means to ensure food safety. The United States National Advisory Committee on Microbiological Criteria for Foods (NACMCF) has endorsed HACCP as an effective and rational means of assuring food safety from harvest to consumption. Preventing problems from occurring is the paramount goal underlying any HACCP system. Changing food industry practices, changing dietary choices of the American people, and globalization of food supplies will bring new challenges to providing safe food from such well known pathogens as *Clostridium botulinum* and

Salmonella spp. to emerging pathogens such as *Escherichia coli* O157:H7 (DHHS/CDC, 1994). HACCP programs address these food safety problems by ensuring the production of safe wholesome foods through proactive and preventive measures.

A. History and Significance of HACCP

The hazard analysis critical control point (HACCP) concept had its origins in food production and research done for the space program (Bauman, 1992). The basics were developed by a team of scientists from the Pillsbury Company with the cooperation and participation of the National Aeronautics and Space Agency (NASA), the Natick Laboratories of the U.S. Army and the U.S. Air Force Space Laboratory Project Group.

Food produced for space flight required that there be as close to 100% assurance of safety as possible. Using the existing quality control techniques, it was quickly determined that there was no way to assure there would not be a problem. In addition, the amount of testing needed for any particular batch of food was extremely high. The number of samples needed was actual prohibitive, and would leave only a small portion available for the space flights. The zero defects program utilized by NASA was designed for hardware. The type of testing used for hardware was non-

destructive and involved techniques such as x-ray and ultrasound. These techniques were not suitable for food.

After extensive evaluation, it was concluded that the only way to ensure food safety would be to develop a preventive system they called HACCP. This system would require control over raw materials, processing, environment, personnel, storage, and distribution. It was concluded that if this control could be established, along with appropriate record keeping, that food produced for the space program would have a high degree of assurance that the food was safe. Bauman (1990, 1992) noted that it was the type and degree of record keeping that provided a clue of how to approach this new system.

HACCP was developed to be a preventive system that when properly applied, controlled any area or point in the food system that could introduce or contribute to a hazard in the food. There was no guidance at the time on how to perform a hazard analysis, so the team looked at other production areas where safety was a concern. They found a system of analysis called "modes of failure" that was developed by the U.S. Army Natick Research, Development, and Engineering Center which was used for medical supplies. Thus, hazard analysis came to involve the systematic analysis of the entire process to identify where hazards

are introduced naturally, or what could go wrong and contribute to a hazard in the food. The HACCP system was introduced publicly at the 1971 National Conference on Food Protection (DHEW, 1972).

The 1971 National Conference on Food Protection was convened because there was a perceived need for reevaluating the current food protection measures and improving these programs by introducing new administrative and operational techniques. It was hoped that the recommendations from the conference would form a national plan of action for improving the microbiological quality of the nation's food supply (DHEW, 1972).

Eliminating all outside sources of contamination especially from raw materials is often proposed as a cure for the microbiological problems of the food industry. The report of the Proceedings of the 1971 Conference on Food Protection indicated this was unrealistic and that food processors will have to continue to contend with actual and potential microbiological contamination on raw materials as well as from the environment.

One of the recommendations of the conference was that, under the leadership of the NAS/NRC, a consensus be sought from government agencies, academia and industry to define tolerance levels for microorganisms or their toxins in

specific foods. Zero tolerances were considered unreasonable because they have no rational or statistical basis. The most that be assured with any measurable confidence is a probability that the unwanted organisms occur in the food at or below some specified level.

The conference adopted what was then called the critical control point (CCP) concept. The idea behind this concept was that every food processing operation susceptible to unwanted microbiological contamination must be checked or controlled at one or more of the steps in the overall process. These critical control points were locations or points in a food processing operation where microbiological contamination was controlled or prevented. These CCPs were the most vulnerable or critical steps and it was considered more efficient to concentrate attention and resources on them. The conference workshop recommended that the CCP concept be evaluated as quickly as possible, and further developed by both food processors and regulatory agencies as a means of achieving a degree of food safety that will provide maximum consumer protection. It also recommended that once the validity of the method has been established, its application should be encouraged and facilitated through the publication of flow sheets that serve to indicate the physical location of the CCPs.

The conference concluded that finished product testing did not fit the ideal definition of a CCP. The testing of finished food products to evaluate the effectiveness of the total program of preventing contaminations will work when there is massive contamination. Finished product testing would not be able to provide reasonable assurance when low level or sporadic contamination existed.

The conference was asked to provide a complete system of classification of food processes that would provide the contamination hazards inherent in certain types of classes of processes and would assist others in preventing similar failures and potential health hazards. The workshop attendees, agreed that such a system would be useful, but that such a system did not currently exist and may not be feasible. They concluded that there are so many different types of processing operations and many are so complex and novel that it would not be feasible to attempt a complete classification at that time. Over twenty years later these observations are still true since food sources, methods of production, processing, packaging, and distribution have become more diverse and complex. The microbiological hazards that we need to be concerned with have also increased in number and complexity. The consumer and consumption patterns and habits are increasingly dynamic.

Attempts to provide a complete classification today would most certainly be dated before publication and may be detrimental by providing a false sense of security to individuals unfamiliar with the dynamic nature of food safety.

The introduction of HACCP led to excitement among food safety professionals as they realized the advantages of this approach. The concept was quickly incorporated into the low-acid canned food and acidified food regulations (DHEW/FDA, 1973). However, after the initial success of these regulations, the implementation of HACCP systems into daily operations has been largely limited to individual large companies (Buchanan, 1990). There was some international interest in the use of HACCP in the early 1980's (WHO/ICMSF, 1982, Simonsen et al., 1987). The WHO/ICMSF report described a HACCP system as consisting of basically three principles: (a) an analysis of hazards and assessments of the severity; (b) identification of CCP; and (c) monitoring of these points and taking whatever corrective action is necessary.

In 1985 the HACCP concept was again seriously considered for broad application in the food industry when the NRC/NAS Subcommittee on Microbiological Criteria for Foods and Food Ingredients recommended that a preventive

system (HACCP) was essential to control microbiological hazards (NRC/NAS, 1985). Specifically, they stated:

"Because the application of the HACCP system provides for the most specific and critical approach to the control of microbiological hazards presented by foods, use of this system should be required of industry. Accordingly, this subcommittee believes that government agencies responsible for control of microbiological hazards in foods should promulgate appropriate regulations that would require industry to utilize the HACCP system in their food protection programs."

They concluded that end-product testing was not adequate to prevent food borne disease. Recent reports support that many in the scientific community believe that this conclusion is still valid today (DHHS/FDA, 1994a, 1994b, Van Schothorst and Jongeneel, 1994). Van Schothorst and Jongeneel (1994) stated that HACCP looks at the whole line to identify the points where problems can occur and be prevented or minimized, and monitors the control measures. Originally, food technologists viewed food processing as a series of discrete steps or operations. Quality control was organized around each operation and end-product testing was used to determine whether the whole line was operating

correctly. End-product testing has also been used as a means to control the safety of products. However, end-product testing as a means to ensure food safety has several serious limitations. First, the contaminant must be distributed homogeneously in the product to permit any statistical interpretation of the results. Since this is seldom the case, it becomes impossible to guarantee that a particular contaminant is absent. Second, even if the contaminant is distributed homogeneously, it is often difficult to analyze a sufficient number of samples to obtain statistically significant results. Third, most microbiological analyses are time consuming and do not provide real-time control of the operation. Fourth, end-product testing is not preventive by design and does not address the root causes of food safety problems. End-product testing is reactive and only detects defects after the fact.

The NRC/NAS Subcommittee also recommended that a National Advisory Committee on Microbiological Criteria for Foods (NACMCF) be established. Since the publication of the NRC/NAS report there has been considerable renewed interest in the HACCP concept.

In 1986 Congress requested that the National Oceanic and Atmospheric Administration (NOAA) design "a program of

certification and surveillance to improve the inspection of fish and seafood consistent with the Hazard Analysis Critical Control Point system" (U.S. Congress, 1986, Adams et al., 1992). The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) was established in 1987 based on the recommendation in the NRC/NAS report (NRC/NAS, 1985). It was recommended that the NACMCF "address (a) the selection of foods and food ingredients on the basis of need for microbiological criteria that could effectively supplement and be incorporated in food protection programs of federal, state, and municipal food regulatory agencies, and (b) the development of criteria for each food for which it was determined that microbiological criteria would serve a useful purpose." The NACMCF serves the United States Department of Agriculture (USDA), Food and Drug Administration (FDA), National Marine Fisheries Service (NMFS), and the Office of the Surgeon General (U.S. Army) and is made up of 25 respected scientists in the food safety and human health disciplines. One of the first assignments for the committee was to draft a guide setting forth the principles of HACCP systems. The NACMCF has espoused HACCP as an effective and rational approach to ensure food safety, and described the seven basic principles of a HACCP system

(NACMCF, 1989).

Since the NACMCF made their recommendations, HACCP has been re-emerging in the 1990's as the primary approach to food safety (Buchanan, 1990). The NACMCF refined the HACCP concept by developing definitions of terminology and adding to the principles of HACCP appropriate descriptions of what each principle involves (Bauman, 1992). The NACMCF document was intended to provide a guide for implementing a uniform system of food safety through the use of the principles and definitions. The use of HACCP as described by NACMCF would provide a high level of assurance that food was safe and facilitate international trade through a universally accepted food safety system. The International Commission on Microbiological Specifications in Foods (ICMSF) has also endorsed the HACCP concept (ICMSF, 1988). The ICMSF described HACCP with slightly different definitions and introduced the concept of two different types of critical control points (CCP1 and CCP2). A CCP1 was a location, practice, procedure, or process that would assure the control of a hazard, and a CCP2 was a location, practice, procedure, or process that would minimize the hazard, but cannot assure the control of a hazard.

The Codex Alimentarius Commission's Committee on Food Hygiene recognized the importance and the advantages of the

HACCP concept as an effective means for producing safe food, and established a HACCP Working Group in 1991. This working group consisted of approximately 27 respected scientists in food safety from 10 different countries that met in June 1991 at Chipping Campden, UK. The NACMCF had just released or adopted a set of HACCP recommendations (NACMCF, 1989) and this document was used by the Codex HACCP Working Group as the frame of reference to begin their work. The HACCP Working Group was given three objectives: (a) define HACCP; (b) provide guidelines for its use or application; and (c) suggest strategies for incorporating HACCP into the Codex Codes of Practice. The document produced by this working group was titled "Draft Principles and Application of the Hazard Analysis Critical Control Point (HACCP) System" (Codex, 1991). One of the objectives of the Codex HACCP Working Group was to define HACCP. The NACMCF document had quite an extensive list of definitions, but the Codex group decided to take a different approach. The first draft of the document (Codex, 1991) contained no definitions, because when a term needed to be defined the definition was used within the context of the document. This document was subsequently revised and the second Codex document (Codex, 1993) contained six definitions, compared to 24 in the NACMCF

document. The Codex document defined HACCP as: "A system which identifies specific hazards and preventative measures for their control." The definition for hazard was different from that of the NACMCF. Codex defines hazard: "The potential to cause harm. Hazards can be biological, chemical, physical." The NACMCF definition of hazard is: "A biological, chemical, or physical property that may cause a food to be unsafe for consumption." The critical limit definition is also different between the two documents with Codex defining a critical limit as: " a value which separates acceptability from unacceptability." The NACMCF defines critical limit as: "A criterion that must be met for each preventive measure associated with a CCP". All other definitions are very similar (i.e., critical control point is identical).

The Codex Working Group, in agreement with the NACMCF, also arrived at seven General Principles for applying the HACCP system. Overall, there are slight differences in wording on some of the principles, however, the intent and content are very similar. There are also differences in the order of the principles involving record keeping and verification (Principles 6 and 7 are reversed in the two documents). The Codex working group felt that verification (Principle 6) must be done, and then a record (Principle 7)

created to show a verification was performed. The NACMCF felt you must first establish recordkeeping procedures (Principle 6) as part of the system, and then verify (Principle 7) the system is effective. The argument can be circular, and what is most important is that both are accomplished. The change in principle sequence is not significant to prevent a consensus begin reached that the HACCP as described by the Codex Working Group and the NACMCF are essentially the same.

The heart of the Codex document is the application of the Principles. The Codex Working Group provided for the first time a logic sequence for applying the principles. In addition, the Codex document also provided for the first item a decision tree for CCP determination (Codex, 1991). The NACMCF reconvened a HACCP Working group in July 1991. The primary purpose was to review the Committee's November 1989 HACCP document comparing it with the draft report prepared by a HACCP Working Group of the Codex Committee on Food Hygiene. Based upon its review, the NACMCF (1992) determined to expand upon its initial report by emphasizing the concept of prevention, incorporating a decision tree intended to facilitate the identification of CCPs, and providing a more detailed explanation of the application of HACCP principles. The NACMCF again endorsed HACCP as an

effective and rational means of assuring food safety from harvest to consumption. The NACMCF also revised the Codex CCP decision tree, and in turn, Codex subsequently revised their document and incorporated the NACMCF's revision (Codex, 1993). There has been a continual effort to refine and strengthen the HACCP concept with both working group documents building on each other.

The World Health Organization (WHO) believes that HACCP offers a rational approach to the control of microbiological hazards in foods by avoiding the many weaknesses inherent in the inspectional approach and circumventing the shortcomings of reliance on microbiological testing (Bryant, 1992). WHO has also recognized the importance of training in the successful implementation of HACCP systems and provide more specific guidance in the training of HACCP applications to food processing (WHO, 1993).

The International Life Sciences Institute (ILSI) and ILSI Europe have published a concise monograph that provides the benefits of HACCP and a simple "how-to" guide (ILSI, 1993). The guide provides some slightly different definitions and a different approach for determining CCPs. The decision tree for CCP determination has separate questions for raw materials and processing stages (ILSI,

1993).

There is beginning to be a universal acceptance among the international food industry, scientific, and regulatory communities that HACCP provides the most effective and rational means to ensure food safety (Rhodehamel, 1992b). HACCP has either been proposed or recommended as the preferred system for: food manufacturing in general (AC, 1993; Bryant, 1992; Codex, 1993; ILSI, 1993; Moy et al., 1994; Microbiology and Food Safety Committee of the National Food Processors Association, 1993a; NACMCF, 1992); meat, and poultry products (Hathaway and Bullians, 1992; Tompkin, 1986, 1990, 1994; USDA/FSIS, 1994b, 1994c, 1994d, 1994e); drinking water supply (Havelaar, 1994); dairy products (ABI/NCI, 1990; Van Schothorst and Kliess, 1994); chilled or refrigerated foods (Baird-Parker, 1994; Brackett, 1993; Bryan, 1990a; CFA, 1990; Daniels, 1991; Microbiology and Food Safety Committee of the National Food Processors Association, 1993b; Refrigerated Foods and Microbiological Criteria Committee of the National Food Processors Association, 1988); chocolate products (Cordier, 1994); retail food industry (Bryan, 1990b; DHHS/PHS/FDA, 1993; Educational Foundation, 1993; Reimer, 1994; Synder, 1991); airline catering (Beumer et al., 1994); domestic kitchens/consumers (Beard, 1991; Bryan, 1992; Griffith and

Worsfold, 1994); seafood (NACMCF, 1991; NMFS, 1987; Spencer, 1992); sous vide products (Betts and Gaze, 1995; Rhodehamel, 1992b; Smith et al., 1990); product distribution (Kalish, 1991); and as previously mentioned, low-acid canned food and acidified food (DHEW/FDA, 1973).

Based on the recommendations of international and scientific organizations, several regulatory agencies are promulgating regulations that would require the food industry to utilize the HACCP system in their food production programs. Both Canada and the European Union (EU) have implemented or are in the process of implementing mandatory HACCP-based seafood inspection systems (Council of the European Communities, 1991, Spencer, 1992). In addition to the EU, and Canada, Iceland, Australia, and many other fishing nations have moved to a mandatory HACCP approach (DHHS/FDA, 1994a). On July 22, 1991, the European Communities Council Directive 91/493 was issued to set out the conditions for the production and placing on the EU market fish and fishery products (Council of the European Communities, 1991). This Directive requires, as of January 1, 1993, that both member States and third countries take all necessary measures so that, at all stages of the production of fishery products, persons responsible, must carry out their own checks based on the following

principles: (a) identification of critical control points in their establishments on the basis of the manufacturing processes used; (b) establishment and implementation of methods for monitoring and checking such critical control points; and (c) keeping a written record so that they can be submitted to the competent authority. While the directive provides some flexibility in terms of equivalence, it is clear that the EC is looking for implementation of a mandatory HACCP system (DHHS/FDA, 1994a). The Council of Europe also passed a directive (EEC directive 93/43) on June 14, 1993 concerning food product hygiene that required all food companies in the European Union (EU) to have in place an effective HACCP system by December 14, 1995 (Council of the European Communities, 1993).

The Canadian Department of Fisheries and Oceans has recently completed implementation of a mandatory Quality Management Program (QMP) for the fish processing industry that is HACCP-based (Spencer, 1992). Discussions with Canada under the terms of section 708 of the U.S./Canada Free Trade Agreement (FTA) to harmonize or make equivalent the two nation's respective inspection systems and standards have made it clear that a mandatory HACCP-based inspection system will significantly facilitate the process

(Reagan, 1988). Adoption of an equivalent system would not only achieve the objectives of the FTA, but potentially would save resources currently devoted to monitoring shipments between the two countries. Agriculture Canada announced its Food Safety Enhancement Program (FSEP) in 1993 to encourage the adoption of HACCP principles in all agri-food establishments with full implementation scheduled for September 1996 (AC, 1993).

The multilateral round of trade negotiations under the General Agreement on Tariffs and Trade (GATT) resulted in further focus on HACCP as efforts where significant efforts were taken to harmonize or make equivalent country inspection systems and requirements. The draft text on sanitary and phytosanitary measures acknowledged the desire of the contracting parties, including the United States, to support "the use of harmonized sanitary and phytosanitary measures between contracting parties, on the basis of international standards, guidelines, and recommendations developed by the relevant international organizations including the Codex Alimentarius Commission" (GATT Secretariat, 1991). This effort toward harmonization, coupled with the current recommendations of the Codex Committee on Food Hygiene encouraging the international use of the HACCP system (Codex, 1993), will drive the adoption

and implementation of HACCP systems by the food industry and regulatory agencies. Either the failure to implement HACCP by food industries or the failure of a country's regulatory agencies to adopt a mandatory HACCP-based inspection system may ultimately undermine an industry's and/or country's ability to successfully export its products, with considerable economic consequences (DHHS/FDA, 1994a).

Both of the regulatory agencies that share the principal responsibility for ensuring the safety of food in the United States are promulgating regulations that would require the food industry to utilize the HACCP system in their food production programs. The Food and Drug Administration (FDA) published in the Federal Register a proposal to adopt regulations to ensure the safe processing and importing of fish and fishery products (DHHS/FDA, 1994a). The purpose of the proposed regulations was to establish mandatory preventive controls, based on a system known as HACCP, to ensure the safety of seafood products sold commercially in the United States and exported abroad. FDA proposed that all domestic and foreign processors and importers adopt HACCP controls to prevent the occurrence of hazards that could affect the safety of these seafood products for consumers. These procedures would include the

monitoring of selected processes in accordance with HACCP principles. FDA proposed these regulations because a system of preventive controls is the most effective and efficient way to ensure that these products are safe. Later in the same year, the FDA also published in the Federal Register an advanced notice of proposed rulemaking (ANPR) announcing that the agency is considering the proposal of regulations that would establish requirements for a comprehensive food safety assurance system for both domestically produced and imported foods (DHHS/FDA, 1994b). In the notice, FDA stated that it had tentatively concluded that such a system should be based upon the principles of HACCP. FDA requested comments on a number of specific issues, as well as on all aspects of such a food safety system. In the same Federal Register issue, the FDA also published a notice of invitation to individual food companies to participate in a voluntary HACCP Pilot Program (DHHS/FDA, 1994c).

The U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) published in the Federal Register (February 3, 1995) proposed requirements for all FSIS-inspected meat and poultry establishments that are designed to reduce the occurrence and numbers of pathogenic microorganisms in meat and poultry

establishments and products and to lessen the incidence of food borne illness associated with the consumption of those products (USDA/FSIS, 1995). The FSIS proposed to: (1) clarify the responsibility of establishment management to ensure compliance with sanitation requirements; (2) require at least one antimicrobial treatment during the slaughter process prior to chilling of the carcass; (3) establish enforceable requirements for prompt chilling of carcasses and parts; (4) establish interim targets for pathogen reduction and mandate daily microbial testing in slaughter establishments to determine whether targets are being met or medial measures are necessary; and (5) require that all meat and poultry establishments develop, adopt, and implement a system of preventive controls, known as HACCP, to improve the safety of their products. FSIS also announced its intent to initiate rulemaking jointly with the FDA to establish Federal standards for the safe handling of food during transportation, distribution, and storage of food products prior to delivery to retail stores, as well as further efforts to encourage adoption and enforcement by States of consistent, science-based standards to ensure food safety at the retail level. These proposals and initiatives were part of a comprehensive strategy to improve the safety of meat and poultry products

when they are delivered to the consumer.

The significance of HACCP will continue to unfold and expand as the regulatory and the international communities move rapidly toward the consensus that HACCP is the most effective and rational means for producing safe food, and that HACCP be required to facilitate both international and domestic trade.

B. Seven Principles of HACCP

The NACMCF suggested that HACCP is the most effective and rational approach to ensure food safety. The NACMCF further refined the HACCP concept and developed seven widely accepted HACCP principles and explained the process in greater detail (NACMCF, 1992). The Codex Alimentarius Commission also recognizes the seven general principles for applying the HACCP system and there is general agreement in the international and scientific communities that HACCP consists of seven basic principles although some terminology and definitions differ slightly. The seven widely accepted HACCP principles described by the NACMCF are as follows:

B.1. Principle No. 1: Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards occur and describe the preventive measures.

The first step in the establishment of a HACCP system for a food process is the identification of the hazards

associated with the product. NACMCF recommended that a HACCP team next conduct a hazard analysis and identify the steps in the process where hazards of potential significance can occur. A hazard is defined as a biological, chemical or physical property that may cause a food to be unsafe for consumption. For inclusion in the list, the hazards must be of such a nature that their prevention, elimination or reduction to acceptable levels is essential to the production of a safe food. Hazards which are of a low risk and not likely to occur would not require further consideration.

NACMCF (NACMCF, 1992) recommended that during the hazard analysis, the potential significance of each hazard should be assessed by considering its risk and severity. Risk is an estimate of the likely occurrence of a hazard. The estimate of risk is usually based upon a combination of experience, epidemiological data, and information in the technical literature. Severity is the seriousness of a hazard.

The HACCP team has the initial responsibility to decide which hazards are significant and must be addressed in the HACCP plan. The NACMCF (NACMCF, 1992) admitted that this decision can be debatable. There may be differences of opinion, even among experts, as to the risk of a hazard.

The HACCP team must rely upon the opinion of the experts who assist in the development of the HACCP plan. They recommended that the hazard analysis must consider factors which may be beyond the immediate control of the processor. For example, product distribution may be beyond the immediate control of the processor, but information on how the food will be distributed could influence how the food will be processed.

During the hazard analysis, safety concerns must be differentiated from quality concerns. The team must then consider what preventive measures, if any, exist which can be applied for each hazard. Preventive measures are physical, chemical, or other factors that can be used to control an identified health hazard. More than one preventive measure may be required to control a specific hazard, and more than one hazard may be controlled by a specified preventive measure (NACMCF, 1992).

The hazard analysis and identification of associated preventive measures accomplishes three purposes. First, those hazards of significance and associated preventive measures are identified. Second, the analysis can be used to modify a process or product to further ensure or improve safety. Third, the hazard analysis provides a basis for determining Critical Control Points (CCPs) in Principle 2.

The hazard analysis procedure recommended by NACMCF (NACMCF, 1992) differed from the Committee's original HACCP document (NACMCF, 1990). However, NACMCF stated that this did not negate the validity of HACCP plans based on the earlier method of hazard analysis. The procedures outlined in their revised document were recommended for future use. The hazard analysis should question the effect of a variety of factors upon the safety of the food. The new hazard analysis consisted of asking a series of questions which were appropriate to the specific food process and facility. The NACMCF felt it was not possible to provide a list of all the questions which may be pertinent to a specific food or process in their document. They provided examples of questions that may be considered during the hazard analysis in an Appendix A in the revised document (NACMCF, 1992). Upon completion of the hazard analysis, the significant hazards associated with each step in the flow diagram should be listed along with any preventive measures to control the hazards.

B.2. Principle No. 2: Identify the Critical Control Points (CCPs) in the process.

NACMCF (NACMCF, 1992) defined a critical control point (CCP) as a point, step or procedure at which control can be applied and a food safety hazard can be prevented,

eliminated, or reduced to acceptable levels. All significant hazards identified by the HACCP team during the hazard analysis must be addressed.

The information developed during the hazard analysis should enable the HACCP team to identify which steps in the process are CCPs. NACMCF (NACMCF, 1992) provided a CCP decision tree to facilitate the identification of each CCP. All hazards which reasonably could be expected to occur should be considered. Critical control points are located at any point where hazards need to be either prevented, eliminated, or reduced to acceptable levels. They gave examples of CCPs that could include, but were not limited to: cooking, chilling, specific sanitation procedures, product formulation control, prevention of cross contamination, and certain aspects of employee and environmental hygiene.

B.3. Principle No. 3: Establish critical limits for preventive measures associated with each identified CCP.

The NACMCF (NACMCF, 1992) defined a critical limit as a criterion that must be met for each preventive measure associated with a CCP. Each CCP can have one or more preventive measures that must be properly controlled to assure prevention, elimination or reduction of hazards to acceptable levels. NACMCF (NACMCF, 1992) described

critical limits as boundaries of safety for each CCP. Critical limits may be set for preventive measures such as time, temperature, physical dimensions, moisture level, water activity, pH, titratable acidity, salt concentration, available chlorine, viscosity, or preservatives. Critical limits may be derived from sources such as regulatory standards and guidelines, literature surveys, experimental studies, and experts.

B.4. Principle No. 4: Establish CCP monitoring requirements. Establish procedures for using the results of monitoring to adjust the process and maintain control.

Monitoring is a planned sequence of observations or measurements to determine whether a CCP is under control and produce an accurate record for future verification procedures. NACMCF (NACMCF, 1992) identified three main purposes for monitoring as those that: (a) track the system's operation so that a trend toward a loss of control can be recognized, and corrective action can be taken to bring the process back into control before a deviation occurs; (b) indicate when loss of control and a deviation has actually occurred, and corrective action must be taken; and (c) provide written documentation for use in verification of the HACCP plan.

The NACMCF (NACMCF, 1992) pointed out that ideally,

monitoring should be at the 100% level (i.e., continuous monitoring), with continuous monitoring possible through many types of physical and chemical methods. For example, temperature and time for a scheduled thermal process can be recorded continuously on temperature-recording charts. Continuous monitoring is always preferred when feasible. When it is not possible to monitor a critical limit on a continuous basis, NACMCF (NACMCF, 1992) suggested that monitoring intervals must be frequent enough to permit the manufacturer and regulatory agencies to determine whether the hazard is under control. They suggested that statistically designed data collection or sampling systems would lend themselves to this purpose. They emphasized that when using statistical process control, it is important to recognize that critical limits must not be exceeded. For example, when a pH of 4.6 or less is required for product safety, the maximum pH of the product may be set at a target that is below pH 4.6 to compensate for variation. Finally, they recommended that most monitoring procedures for CCPs should be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Microbiological testing is seldom effective for monitoring CCPs due to their time-consuming nature. Therefore, physical and

chemical measurements are preferred because they may be done rapidly and can indicate the conditions of microbiological control in the process.

B.5. Principle No. 5: Establish corrective action to be taken when monitoring indicates that there is a deviation from an established critical limit.

While the HACCP system is designed to identify potential health hazards and to establish strategies to prevent their occurrence, perfection is rarely, if ever, achievable. Thus, NACMCF (NACMCF, 1992) stated that there must be a corrective action plan in place to: (a) determine the disposition of non-compliance product; (b) fix or correct the cause of non-compliance to ensure that the CCP is brought under control; and (c) maintain records of the corrective actions. Because of the variations in CCPs for different foods and the diversity of possible deviations, specific corrective action plans must be developed for each CCP.

B.6. Principle No. 6: Establish effective recordkeeping procedures that document the HACCP system.

This principle, as described by the NACMCF (NACMCF, 1992), requires the preparation and maintenance of a written HACCP plan that lists the following:

- (a) The HACCP team and assigned responsibilities.

- (b) Description of the product and its intended use.
- (c) Flow diagram for the entire process indicating CCPs.
- (d) Hazards associated with each CCP and preventive measures.
- (e) Critical limits.
- (f) Monitoring system.
- (g) Corrective action plans for deviations from critical limits.
- (f) Recordkeeping procedures.
- (g) Procedures for verification of HACCP system.

Secondly, this principle requires the maintenance of records generated during the operation of the plan. The NACMCF (NACMCF, 1992) provided examples of HACCP record produced during the operation of the Plan in an Appendix D in the revised document. It is the record-keeping associated with HACCP procedures that makes the system work, both from the standpoint of the HACCP operator (industry) and the regulator (DHHS/FDA, 1994a). The requirement to record events at critical control points on a regular basis ensures that preventive monitoring is occurring in a systematic way.

B.7. Principle No. 7: Establish procedures for verification that the HACCP system is working correctly.

The NACMCF followed the recommendation of the NRC/NAS (1985) that part of the successful implementation of HACCP systems will rely on instituting proper verification procedures. The NACMCF stated that there are four processes involved in verification. These processes involve: (a) verifying that the critical limits are adequate to control the hazards; (b) ensuring that the HACCP plan is working properly, (e.g., that it is being followed, and that appropriate risk management decisions and product dispositions are made when process deviations occur); (c) ensuring that there is documented, periodic revalidation of the plan to confirm that it is still relevant to raw materials as well as to conditions and processes in the plant; and (d) the government's regulatory responsibility and actions to verify that the establishment's HACCP system is functioning satisfactorily.

II. HAZARD ANALYSIS

HACCP is a systematic approach to control hazards used in food production as a means to ensure food safety. The NACMCF (1992) recommended that a hazard analysis should identify the steps in the process of food production from growing to consumption where hazards of potential significance can occur and the preventive measures used to control them. Numerous other groups and organizations have provided limited guidance on performing a hazard analysis. However, there is no explicit procedure on how to perform the hazard analysis, the most important step in HACCP.

A hazard is defined by the NACMCF as a biological, chemical, or physical property that may cause a food to be unsafe for consumption. Thus, by definition one must be concerned with three classes of hazards; biological, chemical, and physical. The first hazard category, biological can be further divided into three types: bacterial, viral, and parasitic (protozoa and worms). Many HACCP programs are designed specifically around the bacterial hazards.

The information and discussions contained in this dissertation will be limited to hazards associated with food borne pathogenic bacteria. A comprehensive treatment that includes viral, parasitic, chemical, and physical

hazards is beyond the scope of this text. It is anticipated that the guidance and the structure for performing a hazard analysis provided within this manuscript can be adapted to these other hazard categories.

Food borne pathogenic bacterial hazards can result either in food borne infections or intoxications. A food borne infection is caused by ingesting a sufficient number of pathogenic bacteria to cause infection, and the reaction of tissues to their presence, or to their multiplication or elaboration of toxins. A food borne intoxication is caused by the ingestion of preformed toxins produced and excreted by certain bacteria when they multiply in foods (Bryan 1979). The requirements for a food borne pathogenic bacterial hazard are when a microorganism or its toxin causes the food to be unsafe for consumption. There are several conditions that must exist for there to be a significant hazard in a food. The hazard must be present in the food (i.e., pathogen and/or its toxin must be present): (a) for some toxins or microorganisms with a very low infective dose, its present in a food is a hazard; and (b) for other hazards, they either must be present in high numbers to cause illness or grow and produce toxins. The food must be capable of supporting growth or toxin production for those hazards that require growth. In

addition, the food must remain under conditions of supporting growth or toxin production long enough for a hazard to occur (e.g., temperature, gaseous environment, a_w , pH, salt). Finally, enough of the food must be consumed with the hazard to exceed the threshold of susceptibility of the consumer.

When developing a HACCP program, the food grower, processor, or food handler should have three basic aims with regard to food borne pathogenic bacteria: (1) destroy, eliminate, or reduce the hazard; (2) prevent contamination and/or recontamination of food; and (3) prevent the multiplication of microbiological hazards or the formation of toxin. Preventive measures should be taken to achieve these goals. The critical control points, in a HACCP system are based on these three basic preventive measures (Rhodehamel, 1992a).

Bacteria can be destroyed or eliminated by such processes as thermal processing, freezing, and/or drying (Rhodehamel, 1992a). After the microorganism has been eliminated, measures to prevent recontamination should be taken. Finally, if the hazard cannot be totally eliminated from the food, microbial growth and toxin production must be inhibited. Growth can be inhibited through the intrinsic characteristics of the food, such as pH and water

activity (a_w), or by the addition of salt or other preservatives. Conditions under which the food is packaged (aerobic or anaerobic) and storage temperatures (refrigeration or freezing) can also be used to inhibit growth.

Information on the specific limiting growth parameters, heat resistance, growth inhibitors, or particular resistance to chemical disinfectants for these and other food borne bacterial pathogens is available in various excellent references on food borne pathogenic bacteria (Cliver, 1990; Doyle 1989; FDA, 1992; Hui et al., 1994; ICMSF, 1980; Jay, 1992; Riemann and Bryan, 1979; Shapton and Shapton, 1991). Many food commodities have a unique microbiology and group of associated pathogens. Processors of specific foods (e.g., seafood) should consult reference materials in those areas (e.g., Ward and Hackney, 1991).

A. Current Definitions and Procedures for Conducting a Hazard Analysis

The HACCP concept continues to evolve as evidenced by the increased number of scientific studies, articles, reviews, and guidance documents that have been published, particularly in the last ten years. There were a number of areas of debate within the scientific, academic and

regularity communities during the evolution. One of these areas involved in the early debates concerned the number of HACCP principles from the original three (WHO 1982) to the seven principles accepted today (NACMCF, 1992). Although there are now seven widely recognized principles of HACCP, an occasional opinion is given that there be at least one more principle added, training. Another area of debate or confusion involved the determination of critical control points (CCP). Guidance in this area has been proposed with a CCP decision tree (Codex, 1991; NACMCF, 1992). Although the addition of the decision tree was intended to facilitate this determination, many have difficulty with its application. Another area that often leads to debate or confusion is the first step, the hazard analysis. The hazard analysis is particularly important since it is the foundation upon which the remaining principles rest.

Numerous guidance documents have been published that instruct the reader to conduct a hazard analysis (Bauman, 1990; CFDR, 1992; Codex, 1991, 1993; FPI, 1993; IAMFES, 1991; ICMSF, 1988; ISLI, 1993; Mortimore and Wallace, 1994; NACMCF, 1989, 1992; Notermans et al., 1994; Pierson and Corlett, 1992; WHO, 1992, 1993). However, most do not give specific instructions, or direct the reader to make decisions on significant hazard, likelihood of occurrence,

or hazard severity without explanations of the terms, significance, likelihood, or severity. The following description are summaries on how some of the more recent and major guidance documents have explained or instructed the reader on hazard analysis.

A.1. Howard Bauman

Howard Bauman, one of the team members generally credited as originating the HACCP concept (1990), states that the hazard analysis portion of HACCP is the identification of sensitive ingredients, sensitive areas in the processing of food, or ingredients, and people control from which one can identify the critical points that must be monitored to assure safety of the product. To perform or develop the hazard analysis portion within a HACCP system, he felt that each ingredient used was to be analyzed at each stage of the process as it moved through the food chain in order to determine what might happen to it and what hazards may be present when it arrived at the plant. The manufacturing process was also analyzed to determine which areas might be a safety hazard. This included contamination from human, chemical, and atmospheric sources. The finished product was also analyzed from the consumer standpoint to determine what safety concerns were associated with the product if it were

to be abused. These recommendations gave only broad issues to be considered, but little practical advice.

A.2. International Commission on Microbiological Specifications for Foods (ICMSF)

The ICMSF published their guidance on HACCP in 1988. The HACCP system was described as comprising of six sequential steps (no record keeping step). They described the first step (the hazard analysis) as the identification of hazards and assessment of severity of these hazards and their risks. They defined hazard as the unacceptable contamination, unacceptable growth and/or unacceptable survival by microorganisms of concern to safety or spoilage, and/or the unacceptable production or persistence in foods of products of microbial metabolism. Severity was defined as the seriousness (magnitude) of the hazard, and risk as an estimate of the likely occurrence of a hazard. Thus, the ICMSF guidance limited HACCP to solely microbiological safety and spoilage concerns. Hazard analysis was described as an evaluation of the total process to: (1) identify potentially hazardous raw material; (2) identify potential sources of contamination in the process; (3) determine the potential for microorganisms to survive or multiply during the process; and (4) assess risks and severity of hazards identified.

The identification of hazards relies primarily on epidemiological evidence that a hazard exists in a given food. In the absence of epidemiological evidence, technical information is needed to reach a decision with respect to the existence of a hazard. The ICMSF guidance recommended that, at a minimum, the microbiologist should consider the three broad areas relating to possible hazards: (1) product formulation; (2) intended process; and (3) conditions of intended distribution and use. Based on the information obtained in the analysis, the microbiologist gives a preliminary assessment of the hazards involved.

The hazard analysis then continues with the assessment of the hazard. ICMSF states that the analysis of hazards must be quantitative to be meaningful, and that this requires an assessment of severity and risk. However, the discussion that follows uses only qualitative terms such as high or low severity and high or low risk. Their guidance on how to use severity and risk is unclear since the examples given do not indicate when a hazard should not be considered. The example given for a hazard scenario of low severity and high risk involved a spoilage (quality) issue in pasteurized milk. ICMSF recommended that a hazard analysis should be applied to all points in production to

ultimate use by the consumer. Their final advice was that "considerable technical expertise" was required to address all the facets of a hazard analysis including the quantitative aspects.

A.3. World Health Organization (WHO)

The World Health Organization (Bryant, 1992) guidance on HACCP describes the components of the system and identification of terms. The hazard analysis is described as the identification of hazards and assessment of the severity of these hazards and their risks, associated with the growth, harvesting, processing, manufacture, distribution, marketing, preparation and/or use of a raw material or food ingredient. The hazard analysis consisted of an evaluation of all procedures concerned with the production, distribution and use of raw materials and food products to: (1) identify the potentially hazardous raw materials and foods that may contain poisonous substances, pathogens, or large numbers of food spoilage microorganisms, and/or that can support microbial growth; (2) identify the potential sources and specific points of contamination; (3) determine the probability that microorganisms will survive or multiply during production, processing, distribution, storage and preparation for consumption; and (4) assess the risks and severity of the

hazards identified. Hazard was defined as the unacceptable contamination, growth, or survival in food or microorganisms that may affect food safety or lead to spoilage, and/or the unacceptable production or persistence in foods of products of microbial metabolism (e.g., toxins and enzymes). Severity was defined as the magnitude of the hazard, or the seriousness of the possible consequences, and risk as an estimate of the probability of a hazard occurring.

The guidance states that technical expertise is required to assess hazards and their severity, and to predict risks. Little information on identifying hazards is provided other than that epidemiological data help to identify potential hazards. The document states that contributory factors to food borne disease outbreaks have been found to be remarkably similar when evaluating the international data. Generally, the data show that outbreaks are the result of contamination, microbial survival, or microbial growth. Thus, the document recommends that during the hazard analysis of a process, each phase or step should be evaluated to determine, whether any of these three situations have occurred, are occurring, or are likely to occur. This is the basic guidance given on how one assesses the risks involved with

identified hazards. The document recommends that, based on epidemiological data, certain situations have occurred in the past that continue to cause food borne disease outbreaks, and thus, these situations can be considered likely to occur. Although the WHO document recommends that a hazard analysis consists of three separate functions (i.e., identification of hazards, assessing their severity and assessing their risks), no guidance is given on how to assess hazard severity or why and how severity should be used within HACCP systems. In addition, quality issues such as spoilage are included in this guidance. Currently, there is general acceptance that HACCP should address safety issues only.

Recent WHO documents (WHO, 1993) concerning the training considerations for HACCP implementation have limited HACCP to safety hazards only. The recommendations in this document state that the HACCP team should list all the biological, chemical, and/or physical hazards that may be reasonably expected to occur at each step, including acquisition and storage of ingredients. A hazard is defined in this document as the unacceptable contamination of a biological, chemical, or physical nature, and/or survival or multiplication of microorganisms of concern for food safety, and/or unacceptable production or persistence

in foods of toxins or other undesirable products of microbial metabolism. The team should also describe and consider what control measures exist which can be applied for each identified hazard. WHO recommends that regulatory agencies should confirm that the HACCP team has considered all hazards which can reasonably be expected to occur. They should also ensure the HACCP team has access to information regarding emerging hazards and new risks known by the regulatory agencies (e.g., recently recognized pathogens, recent food borne disease outbreaks and hazard occurrences). Although the document's basic recommendations on what a hazard analysis should involve is closer to what is generally accepted in the scientific community, no instructions or guidance on identifying hazards or on how to make a determination of reasonably expected to occur is provided.

A.4. Campden Food and Drink Research Association

The CFDR's Technical Manual No. 38 (CFDRA, 1992) provides guidance on how to apply HACCP. The CFDRA recommends that before a HACCP Team is selected, the terms of reference should be clearly stated. Issues such as whether the HACCP Team will consider microbiological, chemical, or physical hazards (or any combination of these) and whether quality aspects are to be addressed. Most

importantly, the terms of reference should clearly state whether the product is to be safe at point of consumption, or at the point of manufacture with clear storage and proper use instructions included. Their recommendations for a HACCP Team performing a hazard analysis involve listing all the hazards that may be reasonably expected to occur at each process step, together with the measures that can be used to control such hazards. They provide additional guidance suggesting the HACCP Team should also consider the way the food production process is managed and what could realistically occur that may not be covered by the flow diagram (e.g., process delays, temporary storage). Although the document's basic recommendation on how to do a hazard analysis seems straightforward, no instructions or guidance on identifying hazards or on how to make a determination of reasonably expected to occur is provided.

A.5. International Association of Milk, Food, and Environmental Sanitarians (IAMFES)

IAMFES (1991) guidance for performing a hazard analysis involves identifying all hazards, assessing their severity, and accurately predicting risks. They state that there are hazards associated with the ingredients used, the operations to which they are subjected, and the storage and handling of the product. The techniques described for

performing a hazard analysis are elaborate and involve interviewing responsible persons, observing operations, reviewing recipes/formulae for hazards, evaluating operations for hazards, measure time/temperature exposures of foods, measure pH, measure water activity (aw), collect food samples, test samples for pathogens/indicator organisms, conduct experimental studies (inoculated pack, microbial challenge and new product testing), analyze measurements, draw flow diagram, predict ways foods will be handled after they leave control of processor, assessing severity and risks of hazards, and discontinuing or modifying the process if necessary. Many of these functions are part of the "preliminary steps" for conducting a hazard analysis that are part of the currently recognized or accepted principles of HACCP.

IAMFES guidance suggests that each hazard be assigned a severity value [e.g., life threatening (LI), severe or chronic (SI), and moderate or mild (MI) illnesses]. The reason or end result of the severity assignment is unclear and does not effect critical control point determinations.

Finally, IAMFES guidance recommends examining hazards relative to the likelihood of its occurrence [high (H), moderate (M), low (L), negligible (N), or variable (V)]. Those hazards likely to occur frequently are given a high

risk. No other guidance is given on how to assign risk to identified hazards. However, IAMFES does make the recommendation that a CCP is called for, if there is a high or moderate risk of a disease outcome. Thus, even though guidance is not given in the hazard analysis section, IAMFES is recommending that hazards with a low or negligible risk need not be controlled by CCPs.

A.6. National Advisory Committee on Microbiological Criteria for Foods / Pierson and Corlett

The NACMCF published its first set of recommendations on HACCP in 1989 that included as Principle 1, the assessment of hazards associated with the growing, harvesting, raw materials and ingredients, processing, manufacturing, distribution, marketing, preparation, and consumption of the food (NACMCF, 1989). They recommended a two-step procedure for hazard assessment that consisted of ranking a food according to six hazard characteristics, followed by the assignment of risk category which is based upon the ranking. The risk categories were to be used for recognizing the hazard risk for ingredients and how they must be treated or processed to reduce the risk for the entire food production and distribution sequence (NACMCF, 1989; Pierson and Corlett, 1992).

The description of hazard assessment in the NACMCF

report raised several concerns within academia and the food industry (FPI, 1993, Van Schothorst, 1992). Some felt that, since there were differences in interpretation of the general hazard characteristics, the final assignment of risk categories could be somewhat subjective. More importantly, while the hazard assessment was intended to provide a systematic assessment of risks, there was no connection or link with Principle 2 (Determination of Critical Control Points) and the risk category assigned to a food or ingredient. Based on these observations the NACMCF Subcommittee reconvened to review the Committee's November 1989 HACCP document and compare it to a draft report prepared by a HACCP Working Group of the Codex Alimentarius Committee on Food Hygiene.

A.7. Codex Alimentarius Commission, Committee on Food Hygiene

The Codex Alimentarius Commission's Committee on Food Hygiene established a HACCP Working Group to provide guidance on the principles and application of HACCP (Codex, 1993). The document does not use the term hazard analysis for Principle 1, but rather recommends that one should "List all hazards associated with each step and consider any preventive measures to control hazards". The document recommends that all hazards that may be reasonably likely

to occur at each step should be listed. The hazards must be of a nature that their elimination or reduction to acceptable levels is essential to the production of safe food. Then the preventive measures should be considered and described for each hazard. The HACCP Working Group provided one of the first documents that eliminated severity from consideration during the hazard analysis. Discussions within the group concluded a hazard, by definition, causes the food to be unsafe for consumption. Even an identified hazard of minor severity causes the food to be unsafe for consumption, and thus must be controlled. If the severity of a hazard was so minor as to not make the food unsafe, then it would not be a hazard, and need not be included in the hazard analysis. Thus, no distinction between hazards of low severity (e.g., mild, limited gastroenteritis) or high severity (e.g., life-threatening botulism) is made at the hazards analysis step. Both hazards should have preventive measures associated with their control. Although the document provided the best guidance at the time for applying HACCP, the hazard analysis section contained little advice on how to perform that principle.

**A.8. National Advisory Committee on Microbiological
Criteria for Foods (Revised Recommendations)**

The revised NACMCF document (NACMCF, 1992) recommended that principle one should read: "Principle 1: Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards occur and describe the preventive measures." The NACMCF recommended that a HACCP team should conduct the hazard analysis and identify the steps in the process where hazards of potential significance can occur. For inclusion in the list, the hazards must be of such a nature that their prevention, elimination or reduction to acceptable levels is essential to the production of a safe food. Hazards which are of a low risk and not likely to occur would not require further consideration. The terms used in their recommendation are somewhat confusing. Since risk is the likelihood of occurrence the recommendation appears redundant. It is unclear if the intent was to describe a situation where if a hazard is of low severity and not likely to occur it need not be considered. The HACCP team was to have the initial responsibility to decide which hazards are significant and must be addressed in the HACCP plan. They admitted that even experts can have differences of opinion as to the risk of a hazard. The hazard analysis should question the effect of a variety of factors upon the safety of the food, and must also consider factors which may be beyond the immediate control of the

processor. The new hazard analysis consisted of asking a series of questions which were appropriate to the specific food process and facility. Although it was not possible to provide a list of all the questions which may be pertinent to a specific food or process in their document, they (NACMCF, 1992) did provide examples of questions that may be considered during the hazard analysis in an Appendix A in the revised document (attached as Appendix A in this document).

The NACMCF went on to recommend that during the hazard analysis, the potential significance of each hazard should be assessed by considering its risk and severity. Risk was defined as an estimate of the likely occurrence of a hazard, and is usually based upon a combination of experience, epidemiological data, and information in the technical literature. The severity was defined as the seriousness of a hazard. Finally, NACMCF stated that the team must then consider what preventive measures, if any, exist which can be applied for each hazard. Preventive measures were described as physical, chemical, or other factors that can be used to control an identified health hazard. They noted that more than one preventive measure may be required to control a specific hazard, and more than one hazard may be controlled by a specified preventive

measure.

The NACMCF stated that the revised procedures for performing a hazard analysis accomplished three purposes: (1) identification of significant hazards and associated preventive measures; (2) the analysis could be used to modify a process or product to further ensure or improve safety; and (3) the revised analysis now provided the basis for determining critical control points (CCPs) in Principle 2 which was lacking in their original document.

A.9. Food Processors Institute

The Food Processors Institute (FPI) is the educational arm of the National Food Processors Association (NFPA). The recommendations for how to perform a hazard analysis in the FPI guidance document mirror those of the NACMCF in their 1992 document (FPI, 1993). It recommends a listing of the potential hazards along with preventive measures, and then assessing the risks associated with those hazards. Hazards are eliminated (from the list) if they represent low risks and are not likely to occur. Again, there is a mixing of terms in the last statement, and should probably state that hazards are eliminated (from the list) if they are not likely to occur. The document also states that the decision to list a specific hazard may be debatable since the risk associated with the hazard may be uncertain. The

document recommends the opinion of an expert microbiologist is helpful and should be obtained when conducting the hazard analysis.

A.10. International Life Sciences Institute (ILSI)

The ILSI concluded, after reviewing available publications, that there was no simple guidance on how to conduct a hazard analysis. Their published guide, "A Simple Guide to Understanding and Applying the Hazard Analysis and Critical Control Point System" defined the first principle of HACCP as "Identification of hazards and assessment of their severity and risk (hazard analysis)" (ILSI, 1993). Later in the same text, hazard analysis is described as the procedure used to identify potential hazards and to estimate the severity of a hazard and the likelihood (risk) that it will occur. The document states that an additional purpose of the hazard analysis is to determine whether a control point is critical.

ILSI's guidance begins with how to perform a HACCP study. It begins with "Activity 1: Identification of the Hazards (hazard analysis)". ISLI recommends that a multidisciplinary team is essential to ensure that informed unbiased assessments will be made and that each team member should be trained in HACCP and have working knowledge of the process/product under study. The identification of

hazards begins with determining the scope of the study by including the types of microorganisms, chemicals, and foreign materials that must be defined. The products characteristics and its expected use by the consumer in terms of known hazards are examined. The important areas to consider are product formulation, processing, packaging, storage/handling, target groups (final consumer), and consumer practices. All these factors must be taken in account to determine the risk and severity of potential hazards. The next task the team should do is to produce a flow diagram. They recommended that the flow diagram include the data needed for microbiological hazard analysis, including information on the likelihood of contamination with microorganisms and their toxins, and their potential for survival and growth. Although ILSI's guidance give areas and characteristics considered when doing a hazard analysis, no guidance on actually how to do a hazard analysis is provided. They recommended that severity of the hazard should be considered or defined, but failed to provide guidance on how that should be incorporated into the hazard analysis. Also, they provided unique guidance on what information a flow diagram should contain (i.e., likelihood of contamination and potential for growth and survival). Finally, no guidance is given

concerning preventive measures and whether they are involved in a hazard analysis.

A.11. Mortimore and Wallace

In their book, *HACCP: A Practical Approach*, Mortimore and Wallace (1994) described a process where at each stage in the Process Flow Diagram all hazards should be identified and listed that could conceivably occur. They suggest this could be done through a structured brainstorming process. The authors suggest hazards should be identified and their causes also listed. Once identified through the brainstorming session, the HACCP Team should analyze the hazards and reject only those that they are confident do not exist as a hazard. Mortimore and Wallace warn that "Caution must be employed when ruling out potential hazards from a process. You must be absolutely sure there is no risk, and that they are never likely to occur." The authors go on to state that HACCP requires control of any hazard which can reasonably be expected to occur. They do not provide guidance on the difference between never likely and reasonably likely.

The authors took the same approach concerning the hazard severity as the Codex working group and recommended that severity of the hazard should not influence the decision to include or exclude the hazard from the hazard

analysis. The HACCP Team then determines the significance of each identified hazard by making a judgement as to the risk of the hazard. Risk was defined as the likelihood that the hazard will happen. An identified hazard only needs to be considered if it can reasonably be expected to occur. Those hazards that are not reasonably likely to occur should not be included in the HACCP Plan. The authors caution that there is no generally agreed upon definition for reasonably likely to occur, however they recommend one should consider the epidemiological, technical, and scientific literature, and use common sense. They recommended the following questions should be considered: (1) has the hazard ever been associated with the raw material or process under consideration; (2) has the hazard caused a food borne illness in the food product under consideration; (3) could processing or storage conditions permit recontamination or introduction of the hazard; and (4) could the consumer mishandling the product permit a hazard to occur? Finally, they suggested taking a conservative approach by including a hazard when unsure or in doubt.

The authors' guidance states that a hazard analysis should identify all significant hazards along with preventive measures. Preventive measures could be

identified at the same time during the identification of hazards, or only after the significant hazards have been determined. They recommended that when a HACCP approach is used during new product development, the identification of potential preventive measures along with hazards may permit additional safety measures to be built into the food and/or process. This advice on hazard analysis falls into a similar pattern of suggesting that experts be consulted to list significant hazards, and then determine which are reasonably likely to occur.

A.12. Notermans, Zwietering, and Mead

Notermans et al., (1994) described the first step in HACCP as identifying the hazards associated with a particular food product. A list of all those bacteria known to cause food borne disease in humans should be created. Following an evaluation of raw materials, the production process, contamination, or recontamination after processing, food borne pathogens are either added or deleted from the list. In a sense, the authors were trying to provide a means for determining which hazards are reasonably likely to occur. Food borne pathogenic bacteria could be deleted from the list only when they are "totally absent from raw materials" or "never caused food borne disorders in the past with identical or related food

products".

The authors do not mention what the end result of the exercise is or whether the purpose is to eliminate all food borne pathogenic bacteria from the list. In addition, after going through their hazard analysis, the authors fail to state whether the remaining food borne pathogenic bacteria are the only hazards that need to be addressed in HACCP Principle 2. They do not provide a link to the second principle of establishing CCPs nor is there any attempt during the process to identify preventive measures. Many food borne pathogenic bacteria could be deleted from the list after asking their question #2 (Does the process eliminate the microorganism completely?), but no attempt is made to identify which point(s) in the process would be responsible (preventive measure). In addition, a scenario exists where an individual could go on to HACCP Principle #2 with no hazards remaining on the list. This would make it difficult to identify CCPs at points where significant hazards are reasonably likely to occur. Although this approach is not without merit, it does not provide a practical means of achieving what is generally recognized (Codex, 1993; NACMCF, 1992) as the requirements of a hazard analysis.

B. Hazard Analysis Guidance

The review of the current literature on hazard analysis reveals generally three common areas within the guidance. They involve identification of significant hazards, assessing their severity, and assessing their risk (likelihood of occurrence). The following guidance is the author's best attempt for describing a practical approach for performing a hazard analysis. This guidance will identify the significant food borne pathogenic bacteria and some general preventive measures, provide information on when the hazards can be reasonably likely to occur or be associated with raw materials and process operations (steps), and provide a decision tree approach that will walk an individual through the thought process needed to perform a hazard analysis. The end result will be that all significant hazards that are reasonably likely to occur and the preventive measures will be identified, and provide the basis for determining CCP in Principle 2. Several HACCP guidance documents have recommended that the severity of identified hazards should be assessed. Several attempts at ranking food borne pathogenic bacteria have been proposed (IAMFES, 1991; ICMSF, 1986; Rhodehamel, 1992a). Examples are presented in Tables 1 and 2. These classifications, although somewhat different and debatable, are not useful when performing a hazard analysis. The guidance provided

TABLE 1. Food borne Pathogenic Bacteria Grouped on the Basis of Severity^a

I. Severe Hazards

Clostridium botulinum types A, B, E, and F
Shigella dysenteriae
Salmonella typhi; *paratyphi* A, B
Brucella abortis; *B. suis*
Vibrio cholerae O1
Vibrio vulnificus

II. Moderate Hazards: Potentially Extensive Spread^b

Listeria monocytogenes
Salmonella spp.
Shigella spp.
Enterovirulent *Escherichia coli* (EEC)^c
Streptococcus pyogenes

III. Moderate Hazards: Limited Spread

Bacillus cereus
Campylobacter jejuni
Clostridium perfringens
Staphylococcus aureus
Staphylococcus intermedius
Vibrio cholerae, non-O1
Vibrio parahaemolyticus
Yersinia enterocolitica

^aAdapted from (ICMSF, 1986; Rhodehamel, 1992a).

^bAlthough classified as moderate hazards, complications and sequelae may be severe in certain susceptible populations.

^cEnterovirulent group includes the enteroinvasive (EIEC), enteropathogenic (EPEC), enterotoxigenic (ETEC), and enterohemorrhagic or verotoxigenic *E. coli* (EHEC).

TABLE 2. Food borne Pathogenic Bacteria Grouped on the Basis of Severity (Adapted from IAMFES, 1991)

I. Life-threatening Illness (LI)

Clostridium botulinum types A, B, E, and F
Listeria monocytogenes (in susceptible individuals)
Salmonella typhi
Vibrio cholerae O1
Vibrio vulnificus

II. Severe or chronic Illnesses (SI)

Brucella
Campylobacter
Enterovirulent *Escherichia coli* (EEC)^a
Salmonella spp.
Shigella spp.
Streptococcus Type A
Vibrio parahaemolyticus
Yersinia enterocolitica

III. Moderate Illnesses (MI)

Bacillus spp.
Clostridium perfringens
Listeria monocytogenes (in healthy individuals)
Staphylococcus aureus

^aEnterovirulent group includes the enteroinvasive (EIEC), enteropathogenic (EPEC), enterotoxigenic (ETEC), and enterohemorrhagic or verotoxigenic *E. coli* (EHEC).

in this dissertation, in agreement with the Codex HACCP Working Group document, does not incorporate the assignment of severity to hazards. As stated previously, a hazard by definition causes a food to be unsafe for consumption. Food borne bacteria that do not cause the food to be unsafe are not a hazard. The assignment of hazard severity does not influence hazard identification or whether a preventive measure should control the hazard. All hazards must be controlled by an identified preventive measure. The author does concede that hazard severity may have a role within a HACCP system. Hazard severity may influence such things as critical limits and the frequency and extent of verification procedures.

Baird-Parker (1995) reported that severity should be considered when determining the level of safety in food. He did not provide guidance on how severity should be considered within a hazard analysis. He stated that the food industry will always aim to achieve a level of safety that is much higher for a life-threatening disease such as *C. botulinum* than that for a mild food borne illness-causing organism such as *C. perfringens*. Thus, he concluded that an exposure level to *C. botulinum* contamination of <1 can in 10^{12} was acceptable, whereas for non life-threatening or spoilage organisms an exposure

level of <1 can in 10^4 was acceptable.

For those individuals who wish to consider the severity within their HACCP system (e.g., establishing more conservative critical limits for hazards of greater severity) the ranking of hazards during the hazard analysis would make sense. However, it is not a necessary function of a hazard analysis and the absence of severity ranking from a hazard analysis would not negate its findings.

B.1. NACMCF Guidance

The NACMCF states that there are two main considerations involved in performing a hazard analysis. These involve determining which significant hazards are reasonably likely to occur and listing the preventive measures (NACMCF, 1992). The NACMCF recommends the information from the hazard analysis be placed in a table that lists the operation (step), the identified hazard, and preventive measure. The following decision tree approach will be based on the NACMCF recommendations on hazard analysis. It will provide the guidance and the structure for performing a hazard analysis and may be adapted to other hazard categories.

The NACMCF provided examples of questions to consider in a hazard analysis in Appendix A to their 1992 document (attached as Appendix A to this document). Although the

document recommended that "the hazard analysis should question the effect of a variety of factors upon the safety of the food", it did not provide guidance on how the answers to the questions should be used. In other words, what does a "yes" imply, or does a "no" mean with regard to hazards. For example, one of the questions asks whether potable water is used in formulating or handling the food. Whatever the answer to that question is, there is no connection or link to what is done in the hazard analysis. For example, one can answer no to this question and then stop and go on to the next question. Experts in microbiology, who are the ones suggesting that this question be asked, already know that if nonpotable water is used then there are some hazards that are reasonably likely to occur. However, that may not be obvious to everyone without expert microbiological knowledge. The Appendix A questions provide excellent guidance on what general factors need to be considered in the twelve areas identified. The Appendix can be used in conjunction with the decision trees proposed in this document because it highlights most of the areas that need to be considered before one can answer a decision tree question as either yes or no. Examples of this are provided in Appendix A section "Intrinsic Factors". These questions highlight the

areas that should be considered when asking either, the Raw Material/Ingredient Decision Tree questions relative to whether the food product would permit growth, or when asking the Operation/Step Decision Tree questions on an operation (step) like "Formulation". Finally, the Appendix A addresses the general factors (i.e., sections on facility design, equipment design, sanitation, and employee health, hygiene, and education) that should be considered when establishing prerequisite programs.

B.2. Food borne Pathogenic Bacteria Hazard Guidance

The following guidance gives the reader the practical information needed to make food borne pathogenic bacteria hazard analysis determinations. Before this information is reviewed, some general understanding of food borne pathogenic bacteria and the hazards they represent is needed. The guidance on food borne pathogenic bacteria is divided into three areas. The first section identifies significant hazards (bacterial food borne pathogens), the illness characteristics, foods associated, and suggested preventive measures for their control. The second section contains a list of food categories and the bacterial food borne pathogens that are reasonably likely to occur (or are associated with the food) in each category. Finally, the third section contains a list of food processing related

hazards. These are hazards that are reasonably likely to occur if the food processing operation (or step) is not controlled. These sections were developed using the information contained in the following references (AC, 1994; APHA, 1992; Cliver, 1990; Doyle, 1989; FDA, 1992; FDA, 1994; Hui et al., 1994; IAMFES, 1991; ICMSF, 1978; ICMSF, 1986; Jay, 1992; NRC/NAS, 1991; Rhodehamel, 1992a; Reimann and Bryan, 1979; Shapton and Shapton, 1991; Ward and Hackney, 1991). The information contained in these references and my personal experiences permit the conclusion that the identified hazards in the first section are reasonably likely to occur or be associated with either the foods in section two or the food processes identified in section three. This information was obtained through scientific studies, epidemiological investigations and the personal experiences of the author. A more comprehensive list of all hazards (biological, chemical, and physical) and diseases transmitted by food was provided by Bryan (1984).

It should be noted that, as always, the development of a HACCP system is specific to the food process at a specific location. The information contained in the following section is intended to provide practical guidance with the hazard analysis. An evaluation on-site of the

actual food process is still necessary to determine whether any hazards not identified in this guidance may be reasonably likely to occur in each unique food and food processing operation.

B.3. Food borne Pathogenic Bacteria

This section provides a brief description on most of the significant food borne pathogenic bacteria. Extensive information exists in the scientific literature and the reader is referred to the following resources for more comprehensive information on these organisms (APHA, 1992; Cliver, 1990; Doyle, 1989; FDA, 1992; FDA, 1994; Hui et al., 1994; ICMSF, 1978; ICMSF, 1986; Jay, 1992; NRC/NAS, 1991; Rhodehamel, 1992a; Reimann and Bryan, 1979; Shapton and Shapton, 1991; Ward and Hackney, 1991). These pathogens should be considered hazards within the content of a HACCP system because they can cause a food to be unsafe for consumption. The following summaries provide information on the organism, the illness or illnesses caused, the food associated (either by being associated with raw materials, reported in the scientific literature, or the results of reported food borne illness), and suggested preventive measures.

B.3.a. Aeromonas hydrophila

Aeromonas hydrophila is a species of bacterium that is

present in all freshwater environments and in brackish water. Some strains of *A. hydrophila* are capable of causing illness in fish and amphibians as well as in humans who may acquire infections through open wounds or by ingestion of a sufficient number of the organisms in food or water. Little is known about other *Aeromonas* spp., but they are similarly aquatic microorganisms and some have been implicated in human disease.

B.3.a1 *Illness Associated*

A. hydrophila may cause gastroenteritis in healthy individuals or septicemia in individuals with impaired immune systems or various malignancies. At present, there is controversy as to whether *A. hydrophila* is a cause of human gastroenteritis. The infectious dose of this organism is unknown, but divers who have ingested small amounts of water have become ill, and *A. hydrophila* has been isolated from their stools. However, volunteer human feeding studies, even with large number of cells (e.g., 10^{11} organisms), have failed to elicit human illness. Its presence in the stools of individuals with diarrhea, in the absence of other known enteric pathogens, suggests that it has some role in disease.

Two distinct types of gastroenteritis have been associated with *A. hydrophila*. One type is characterized

by a cholera-like illness with a watery (rice and water) diarrhea. The other type is a dysenteric illness characterized by loose stools containing blood and mucus. A general infection in which the organisms spread throughout the body has been observed in individuals with underlying illness (septicemia).

B.3.a2. Foods Associated

A. hydrophila has frequently been found in fish and other seafood (shrimp, scallops, crabs, and oysters). It has also been found in market samples of red meats (beef, pork, lamb) and poultry. Since *A. hydrophila* can be isolated from numerous sources, it is presumed that not all strains are pathogenic. Most cases of *A. hydrophila* associated gastroenteritis have been sporadic, rather than associated with large outbreaks. *A. hydrophila* has been epidemiologically linked to raw oysters, however, there has not been a confirmed outbreak to this date.

B.3.a3. Preventive Measures

One preventive measure would involve preventing food contamination via contaminated water. Shellfish should only be harvested from approved waters even though *A. hydrophila* are not restricted to polluted waters. Harvesting only from approved waters will make it less likely that shellfish will be heavily contaminated with *A.*

hydrophila. Other preventive measures would involve: (1) ensuring food is thoroughly cooked before consumption; (2) once the organism is eliminated, prevent cross-contamination (recontamination) by: (a) ensuring food handlers practice proper hygiene; (b) cleaning and sanitizing the utensils, equipment, and the environment; and (c) separating raw and cooked product.

B.3.b. Bacillus cereus

Bacillus cereus is a Gram-positive, facultatively aerobic sporeforming rod-shaped bacterium. *Bacillus* species are widely distributed because the spores, which are resistant to extreme conditions (e.g., drying, heating, cold), permit the organism to survive through adverse conditions and exist in a variety of natural habitats. *B. cereus* spores are associated with a wide variety of raw food materials because of their environmental ubiquity. *B. cereus* is commonly found in soil, cereals (particularly rice), starches, herbs, spices, and other dried foodstuffs.

B.3.b1. Illness Associated

B. cereus food poisoning is the general description, although two recognized types of illness are caused by two distinct metabolites. The diarrheal type of illness is caused by a large molecular weight protein, while the vomiting (emetic) type of illness is believed to be caused

by a low molecular weight, heat-stable peptide.

The diarrheal type food poisoning is characterized by the onset of watery diarrhea, abdominal cramps, and pain occurs between 4 and 16 hours after consumption of contaminated food. Nausea may accompany diarrhea, but vomiting rarely occurs. Symptoms persist between 12 and 24 hours in most instances. The symptoms of *B. cereus* diarrheal type food poisoning are similar to those caused by *Clostridium perfringens* food poisoning.

The emetic type of food poisoning is characterized by nausea and vomiting within 0.5 to 6 h after consumption of contaminated foods. Occasionally, abdominal cramps and/or diarrhea may also occur. Duration of symptoms is generally less than 24 hours. The symptoms of *B. cereus* emetic type of food poisoning are similar to those caused by *Staphylococcus aureus* food borne intoxication. The presence of large numbers of *B. cereus* (greater than 10^5 or 10^6 organisms/g) in a food is indicative of active growth and proliferation of the organism and is consistent with a potential hazard to health.

B.3.b2. Foods Associated

A wide variety of foods including meats, milk, raw vegetables, and fish have been associated with the diarrheal type food poisoning. The emetic (vomiting-type)

outbreaks have almost exclusively been associated with boiled or fried rice dishes; however, other starchy foods such as mashed potatoes, pasta and cheese products have also been implicated. Food mixtures such as sauces, puddings, soups, casseroles, pastries, and salads have also been frequently incriminated in food poisoning outbreaks.

B.3.b3. Preventive Measures

Since the spores of *B. cereus* are so widespread it would be impractical to eliminate spore contamination of foods. Preventive measures should limit *B. cereus* growth in the food. Spores will survive cooking temperatures at or below 100°C (212°F) so efforts must be made to: (1) keep the food hot (>60°C or >140°F); or (2) sufficient rapid chilling (<5°C or <41°F in less than a total of six hours) to prevent growth, followed by thoroughly reheating foods (71-100°C or 160-212°F) before consumption.

B.3.c. Campylobacter jejuni

Campylobacter jejuni is a Gram-negative slender, curved, and motile rod. It is a microaerophilic organism, which means it has a requirement for reduced levels of oxygen. Because of its microaerophilic characteristics the organism requires 3 to 5% oxygen and 2 to 10% carbon dioxide for optimal growth conditions. The organism is commonly carrier in the intestinal tracts of warm-blooded

animals, and a wide variety of wild and domestic animals are reservoirs. Recent surveys have shown that *C. jejuni* is the leading cause of bacterial diarrheal illness in the United States. Animal derived foods are believed to be the principal vehicle for transmission of *Campylobacter* enteritis (campylobacteriosis). Aerotolerant *Campylobacter* spp. have been recently classified into the new genus *Arcobacter*, and are recognized as human pathogens.

B.3.c1. Illness Associated

Campylobacteriosis is the name of the illness caused by *C. jejuni*. It is also often known as campylobacter enteritis or gastroenteritis. *C. jejuni* infection causes diarrhea, which may be watery or sticky and can contain blood. Other symptoms often present are fever, abdominal pain, nausea, malaise, headache, muscle pain, and vomiting. The illness can occur between 1 and 10 days, but usually occurs between 2 and 5 days after ingestion of the contaminated food or water. Illness generally lasts from 7 to 10 days, but relapses are not uncommon (about 25% of cases). The infective dose of *C. jejuni* is considered to be small. Human feeding studies suggest that about 400-500 bacteria may cause illness in some individuals, while in others, greater numbers are required. Complications are relatively rare, but infections have been associated with

reactive arthritis, hemolytic uremic syndrome, and infections of nearly any organ can occur after septicemia.

B.3.c2. Foods Associated

C. jejuni frequently contaminates raw chicken. Surveys show that 20 to 100% of retail chickens are contaminated. Raw milk is also a source of infections. The bacteria are often carried by healthy cattle, chickens, swine, sheep, goats, turkeys, ducks, cats, dogs birds, and by flies on farms. Some studies indicate that *C. jejuni* may be associated with fresh mushrooms. Outbreaks have been associated with raw milk, and eating undercooked chicken, processed turkey, raw clams, eggs, and raw hamburger. One outbreak was linked to eating cake which may have been contaminated by a food handler. It is sometimes present in non-chlorinated water sources such as streams and ponds, and several waterborne outbreaks have occurred.

B.3.c3. Preventive Measures

C. jejuni is relatively fragile, and sensitive to environmental stresses (e.g., 21% oxygen, drying, heating, disinfectants, acidic conditions). Preventive measures include: (1) properly cooking meats of animal origin (especially chicken), pasteurizing milk, and chlorinating drinking water; and (2) once the organism is eliminated

from the product, prevent cross-contamination (recontamination) by: (a) ensuring food handlers practice proper hygiene; (b) cleaning and sanitizing the utensils, equipment, and the environment; (c) separate raw and cooked product by having separate utensils and equipment; (d) physically separate raw product and cooked product areas in the facility; and (3) providing proper temperature control throughout the process to limit growth.

B.3.d. Clostridium botulinum

Clostridium botulinum is an anaerobic, Gram-positive, spore-forming rod that produces a potent neurotoxin. The spores are heat-resistant and can survive in foods that are incorrectly or minimally processed. Seven types (A, B, C, D, E, F and G) of botulism are recognized, based on the antigenic specificity of the toxin produced by each strain. Types A, B, E and F cause human botulism. The organism and its spores are widely distributed in nature. They occur in both cultivated and forest soils, bottom sediments of streams, lakes, and coastal waters, and in the intestinal tracts of fish and mammals, and in the gills and viscera of crabs and other shellfish.

Food borne botulism (as distinct from wound botulism and infant botulism) is a severe type of food poisoning caused by the ingestion of foods containing the potent

neurotoxin formed during growth of the organism. The toxin is heat labile and as a general rule-of-thumb can be destroyed if boiled for 10 minutes or longer. The incidence of the disease is low, but the disease is of considerable concern because of its severity and high mortality rate if not treated immediately and properly.

B.3.d1. Illness Associated

Four types of botulism are recognized: food borne, infant, wound, and a form of botulism whose classification is as yet undetermined. Certain foods have been reported as sources of spores in cases of infant botulism and the undetermined category; wound botulism is not related to foods.

Food borne botulism is the name of the disease (food borne intoxication) caused by the consumption of foods containing the neurotoxin produced by *C. botulinum*. The infective dose of toxin that can cause illness is considered to be a very small amount (a few nanograms).

Infant botulism, first recognized in 1976, affects infants under 12 months of age. This type of botulism is thought to be caused by the ingestion of *C. botulinum* spores which colonize and produce toxin in the intestinal tract of infants (toxicoinfectious botulism). Honey is the only implicated food source for *C. botulinum* spores.

Onset of symptoms in food borne botulism is usually 18 to 36 hours after ingestion of the food containing the toxin, although cases have varied from 4 hours to 8 days. Early signs of intoxication consist of marked lassitude, weakness and vertigo, usually followed by double vision and progressive difficulty in speaking and swallowing. Difficulty in breathing, weakness of other muscles, abdominal distention, and constipation may also be common symptoms. Botulinum toxin causes flaccid paralysis by blocking motor nerve terminals at the myoneural junction. The flaccid paralysis progresses symmetrically downward, usually starting with the eyes and face, to the throat, chest and extremities. When the diaphragm and chest muscles become fully involved, respiration is inhibited and death from asphyxia results.

Clinical symptoms of infant botulism consist of constipation that occurs after a period of normal development. This is followed by poor feeding, lethargy, weakness, pooled oral secretions, and wail or altered cry. Loss of head control is striking. Recommended treatment is primarily supportive care.

B.3.d2. Foods Associated

The types of foods involved in botulism vary according to food preservation and eating habits in different

regions. Most foods associated with botulism come from environments where it is likely the spores will be found. Any food that is conducive to outgrowth and toxin production, that when processed allows spore survival, and is not subsequently heated before consumption can be associated with botulism. Almost any type of food that is not very acidic (pH above 4.6) can support growth and toxin production by *C. botulinum*. Botulinal toxin has been demonstrated in a considerable variety of foods, such as canned corn, peppers, green beans, soups, beets, asparagus, mushrooms, ripe olives, spinach, tuna fish, chicken, chicken livers, liver pate, luncheon meats, ham, sausage, stuffed eggplant, lobster, and smoked and salted fish. Most of the 10 to 30 outbreaks that are reported annually in the United States are associated with inadequately processed, home-canned foods, but occasionally commercially produced foods have been involved in outbreaks. Sausages, meat products, canned vegetables and seafood products have been the most frequent vehicles for human botulism.

B.3.d3. Preventive Measures

The spores survive most thermal processes except those specifically designed to eliminate them (e.g., 12D thermal processing of low-acid canned foods). If such a process is not used, one must assume that spores are present in the

food. If the food is to be packaged in an anaerobic or reduced oxygen atmosphere, measures to inhibit *C. botulinum* growth and toxin production are necessary. *C. botulinum* growth can be controlled by one or a combination of the following conditions: pH <4.6; $a_w \leq 0.94$; 5-10% salt concentration; nitrite and salt combinations (e.g., cured meats); other preservatives; temperature control (freezing/refrigeration), and biocontrol (e.g., inoculation of product with lactic acid bacteria). Sole reliance on refrigeration to ensure safety is inappropriate. Botulinum toxin produced is one of the most potent substances known but is relatively heat labile (destroyed by boiling for 10 minutes). Reliance on final cooking by the consumer to destroy the toxin is extremely inappropriate. Thus, preventive measures involve the following: (1) ensuring an adequate thermal process, designed to eliminate the organism from the food product, is delivered; (2) once the spores are eliminated, prevent cross-contamination (recontamination) by: (a) ensuring container integrity; (b) ensuring food handlers practice proper hygiene; (c) cleaning and sanitizing the utensils, equipment, and the environment; (d) separate raw and cooked product; (3) if spores are assumed present in final product, especially if packaged in an anaerobic or reduced oxygen atmosphere, then

C. botulinum growth and toxin production must be inhibited by any of the previously mentioned methods; and (4) providing proper temperature control to inhibit growth and toxin production.

B.3.e. Clostridium perfringens

Clostridium perfringens type A is an anaerobic, Gram-positive, sporeforming rod. It is widely distributed in soils and the environment and frequently occurs in the intestines of humans and many domestic and feral animals. Spores of the organism persist in soil, sediments, and areas subject to human or animal fecal pollution.

B.3.e1. Illness Associated

Perfringens food poisoning is the term used to describe the common food borne illness caused by *C. perfringens*. This common form of perfringens poisoning is characterized by intense abdominal cramps and diarrhea which begin between 6 and 24 hours after consumption of foods containing large numbers of *C. perfringens* bacteria. The illness generally lasts between 12 and 24 hours, but less severe symptoms may persist in some individuals for 1 or 2 weeks. A few deaths have been reported as a result of dehydration and other complications. The symptoms are caused by ingestion of large numbers (greater than 10^8) vegetative cells (food infection). Toxin production is

associated with sporulation in the digestive tract.

B.3.e2. Foods Associated

Meats, meat products, and gravy are the foods most frequently implicated in perfringens food poisoning. Spores of *C. perfringens* are commonly present on the surfaces of animal derived protein foods (beef, poultry, and turkey), and in ingredients such as dried spices or gravy mixes. In most instances, the actual cause of poisoning by *C. perfringens* is temperature abuse of prepared foods. Institutional feeding (such as school cafeterias, hospitals, nursing homes, prisons, etc.) where large quantities of food are prepared several hours before serving is the most common circumstance in which perfringens poisoning occurs. Improper cool down and storage of prepared foods permits small numbers of the organisms that can be present after cooking to multiply to food poisoning levels.

B.3.e3. Preventive Measures

Since the spores of *C. perfringens* are so widespread it would be impractical to eliminate spore contamination of foods. Preparation of food a day or more before consuming and adequate hot holding and reheating of previously cooked and chilled foods are the most frequent contributing factors causing perfringens food poisonings. Preventive

measures should limit *C. perfringens* growth in the food. Spores will survive cooking so efforts must be made to: (1) keep the food hot (>60°C or >140°F); or (2) foods such as gravies, broths, sauces (with or without meat), and large pieces of meat should have sufficient rapid chilling (<5°C or <41°F in less than a total of six hours) to prevent growth, followed by thoroughly reheating foods (71-100°C or 160-212°F) before consumption will prevent nearly all *perfringens* food poisonings.

B.3.f. Enterohemorrhagic Escherichia coli O157:H7 (EHEC)

Escherichia coli are Gram-negative, rod-shaped bacteria belonging the family *Enterobacteriaceae*. *E. coli* is a normal inhabitant of the intestines of all animals, including humans. When aerobic culture methods are used, *E. coli* is the dominant species found in feces. Normally *E. coli* serves a useful function in the body by suppressing the growth of harmful bacterial species and by synthesizing appreciable amounts of vitamins. A minority of *E. coli* strains are capable of causing human illness by several different mechanisms. Currently, there are four recognized classes of enterovirulent *E. coli* (collectively referred to as the EEC group) that cause gastroenteritis in humans. Among these is the enterohemorrhagic (EHEC) strain designated *E. coli* O157:H7. Other enterohemorrhagic

strains exist (e.g., O111:NM, O111:H-, O48:H21, and O104:H21) and can be referred to as either verotoxigenic strains or more recently, Shiga toxin-producing *E. coli* (STEC) (Acheson and Keusch, 1996). *E. coli* serotype O157:H7 is a rare variety of *E. coli* that produces large quantities of one or more related, potent toxins that cause severe damage to the lining of the intestine. These toxins [verotoxin (VT), shiga-like toxin] are closely related or identical to the toxin produced by *Shigella dysenteriae*.

B.3.f1. Illness Associated

Hemorrhagic colitis is the name of the acute disease caused by *E. coli* O157:H7. The illness is characterized by severe cramping (abdominal pain) and diarrhea which is initially watery, but becomes grossly bloody (frank or pure blood in stools). Fever is either low-grade or absent and occasionally vomiting occurs. The onset of symptoms is generally between 3 and 4 days. The illness is usually self-limited and lasts an average of 4 days, but can last between 2 to 9 days. Some individuals exhibit watery diarrhea only. The infective dose is unknown, but outbreak data, and information on the organism's ability to be passed person-to-person in the day-care setting or nursing homes, the infective dose may be very low (10 organisms). Severe complications of the disease involve, particularly

with the very young (up to 15% of those with hemorrhagic colitis), the development of hemolytic uremic syndrome (HUS). HUS is characterized by renal failure and hemolytic anemia, and can lead to permanent loss of kidney function. In the elderly, complications involving HUS, plus fever and neurologic symptoms, constitutes thrombotic thrombocytopenic purpura (TTP). The mortality rate from TTP can be as high as 50% in the elderly.

B.3.f2. Foods Associated

Undercooked or raw hamburger (ground beef) has been implicated in nearly all documented outbreaks and in other sporadic cases. Raw milk was the vehicle in a school outbreak in Canada. These are the only two confirmed foods associated with disease, but other meats may contain *E. coli* O157:H7. The organism has been isolated from several types of meat (beef, pork, chicken, turkey, and lamb). Dairy cattle appear to be a natural reservoir of *E. coli* O157:H7.

B.3.f3. Preventive Measures

The major contributing factors causing hemorrhagic colitis food borne outbreaks inadequate cooking, using contaminated raw ingredients, and cross-contamination. Preventive measures involve the following: (1) eliminate the presence on raw materials or limit the amount

introduced; (2) a bacteriocidal process (e.g., thermal process) designed to eliminate the organism from the food product (e.g., thoroughly cooking foods of animal origin and pasteurizing milk); (3) once the organism is eliminated or reduced to acceptable levels, prevent cross-contamination (recontamination) by: (a) ensuring food handlers practice proper hygiene; (b) cleaning and sanitizing the utensils, equipment, and the environment; (c) separate raw and cooked product by having separate utensils and equipment; (d) physically separate raw product and cooked product areas in the facility; and (4) providing proper temperature control throughout the process to limit growth.

B.3.g. Enteroinvasive Escherichia coli or (EIEC)

Escherichia coli are Gram-negative, rod-shaped bacteria belonging the family *Enterobacteriaceae*. *E. coli* is a normal inhabitant of the intestines of all animals, including humans. When aerobic culture methods are used, *E. coli* is the dominant species found in feces. Normally *E. coli* serves a useful function in the body by suppressing the growth of harmful bacterial species and by synthesizing appreciable amounts of vitamins. A minority of *E. coli* strains are capable of causing human illness by several different mechanisms. Currently, there are four recognized

classes of enterovirulent *E. coli* (collectively referred to as the EEC group) that cause gastroenteritis in humans. Among these are the enteroinvasive (EIEC) strains.

B.3.g1. Illness Associated

Enteroinvasive *E. coli* (EIEC) may produce a mild form of dysentery, often mistaken for dysentery caused by *Shigella* species. The EIEC strains responsible for this syndrome are closely related to *Shigella* spp. The illness is characterized by the appearance of blood and mucus in the stools of infected individuals. The onset of symptoms occurs within 8 to 24 hours following the ingestion of contaminated food. The illness is characterized by abdominal cramps, diarrhea, vomiting, fever, chills, and a generalized malaise. Dysentery caused by this organism is generally self-limiting with no known complications, except in pediatric cases, where hemolytic uremic syndrome (HUS) may result. The infective dose of EIEC is thought to be high (10^8 organisms), although reduced gastric function can lower the number of organisms required.

B.3.g2. Foods Associated

It is unknown what foods may harbor these pathogenic enteroinvasive (EIEC) strains, but any fecal contamination of food from an ill individual, either directly or via contaminated water, could cause disease in others.

Outbreaks have been associated with salmon, poultry, hamburger meat, unpasteurized milk, Camembert cheese, and potato salad.

B.3.g3. Preventive Measures

Preventive measures involve preventing contamination via the fecal-oral route either directly or via contaminated water. Thus, use of potable or boiled water would be an effective preventive measure. Preventive measures include: (1) properly cooking meats of animal origin; (2) pasteurizing milk; (3) use of safe and suitable water source; and (4) once the organism is eliminated from the product, prevent cross-contamination (recontamination) by: (a) ensuring food handlers practice proper hygiene (e.g., proper hand washing after defecation before handling food, utensils, or equipment); (b) cleaning and sanitizing the utensils, equipment, and the environment; (c) separate raw and cooked product by having separate utensils and equipment; and (d) physically separate raw product and cooked product areas in the facility.

B.3.h. Enteropathogenic Escherichia coli (EPEC)

Escherichia coli are Gram-negative, rod-shaped bacteria belonging the family *Enterobacteriaceae*. *E. coli* are present in the normal gut flora of humans, bovines, swine, and other mammals. Currently, there are four

recognized classes of enterovirulent *E. coli* (collectively referred to as the EEC group) that cause gastroenteritis in humans. Among these are the enteropathogenic (EPEC) strains. EPEC are described as *E. coli* belonging to serogroups epidemiologically implicated as pathogens, but whose virulence mechanism is unrelated to the excretion of typical *E. coli* enterotoxins. Since food borne outbreaks are sporadic, the source(s) and prevalence of EPEC are not clearly understood. Humans, bovines, and swine can be infected, but the proportion of pathogenic to nonpathogenic strains is unknown.

B.3.h1. Illness Associated

Infantile diarrhea is the name of the disease usually associated with EPEC. EPEC causes either a watery or bloody diarrhea. Diarrhea is often accompanied with fever, vomiting, or abdominal pain. The illness occurs between 17 and 72 hours after ingestion and can last from 6 hours to 3 days. EPEC are highly infectious for infants and the infective dose is presumably very low. In the few documented cases of adult diseases, the dose is presumably similar to other pathogens that require colonization (greater than 10^6 total dose). Volunteer studies in adults showed the infective dose was 10^8 organisms, however, infants are susceptible to lower inocula.

B.3.h2. Foods Associated

Common foods implicated in EPEC outbreaks are raw beef chicken, previously cooked pork, and contaminated meat pie, although any food exposed to fecal contamination can be strongly associated with the illness. The drinking of unchlorinated well water was also implicated as the cause of an EPEC outbreak.

B.3.h3. Preventive Measures

Countries with poor sanitation practices have the most frequent outbreaks. EPEC outbreaks most often affect infants, especially those that are bottle fed, suggesting that contaminated water is often used to rehydrate infant formula in underdeveloped countries. Thus, use of potable or boiled water to rehydrate infant formula would be an effective preventive measure. Other preventive measures involve preventing contamination via the fecal-oral route either directly or via contaminated water. Thus, use of potable or boiled water would be an effective preventive measure. Preventive measures include: (1) properly cooking meats of animal origin; (2) pasteurizing milk; (3) use of safe and suitable water source; and (4) once the organism is eliminated from the product, prevent cross-contamination (recontamination) by: (a) ensuring food handlers practice proper hygiene (e.g., proper hand washing after defecation

before handling food, utensils, or equipment); (b) cleaning and sanitizing the utensils, equipment, and the environment; (c) separate raw and cooked product by having separate utensils and equipment; and (d) physically separate raw product and cooked product areas in the facility.

B.3.i. Enterotoxigenic Escherichia coli (ETEC)

Escherichia coli are Gram-negative, rod-shaped bacteria belonging the family *Enterobacteriaceae*. *E. coli* is a normal inhabitant of the intestines of all animals, including humans. When aerobic culture methods are used, *E. coli* is the dominant species found in feces. Normally *E. coli* serves a useful function in the body by suppressing the growth of harmful bacterial species and by synthesizing appreciable amounts of vitamins. A minority of *E. coli* strains are capable of causing human illness by several different mechanisms. Currently, there are four recognized classes of enterovirulent *E. coli* (collectively referred to as the EEC group) that cause gastroenteritis in humans. Among these are the enterotoxigenic (ETEC) strains. They comprise a relatively small proportion of the species and have been etiologically associated with diarrheal illness of all age groups from diverse global locations. The organism frequently causes diarrhea in infants in less

developed countries and in visitors there from industrialized countries.

B.3.i1. Illness Associated

Gastroenteritis is the name of the illness caused by ETEC, although travelers' diarrhea is a frequently used common name. The most frequent clinical syndrome of infection includes watery diarrhea, abdominal cramps, low-grade fever, nausea and malaise. The disease is usually self-limiting. The infective dose is believed to be a relatively large dose with the ingestion of 10^8 to 10^9 ETEC probably necessary to establish colonization of the small intestine. Once colonized, these organisms proliferate and produce toxins which induce fluid secretion (watery diarrhea). Onset of symptoms can occur within 24 hours if a high infective dose is ingested. Infants may require fewer organisms for infection to be established.

B.3.i2. Foods Associated

ETEC is not considered a serious food borne disease hazard in countries having high sanitary standards and practices. Contamination of water with human sewage may lead to contamination of foods. Infected food handlers may also contaminate foods. These organisms are infrequently isolated from dairy products such as semi-soft cheeses. Water and some foods (French Brie cheese and salads with

raw vegetables) have been involved in ETEC outbreaks.

B.3.i3. Preventive Measures

Preventive measures involve preventing contamination via the fecal-oral route either directly or via contaminated water. Thus, use of potable or boiled water would be an effective preventive measure. Other preventive measures include: (1) properly cooking meats of animal origin; (2) pasteurizing milk; (3) use of safe and suitable water source; and (4) once the organism is eliminated from the product, prevent cross-contamination (recontamination) by: (a) ensuring food handlers practice proper hygiene (e.g., proper hand washing after defecation before handling food, utensils, or equipment); (b) cleaning and sanitizing the utensils, equipment, and the environment; (c) separate raw and cooked product by having separate utensils and equipment; and (d) physically separate raw product and cooked product areas in the facility.

B.3.j. Listeria monocytogenes

Listeria monocytogenes is a motile, Gram-positive rod-shaped bacterium with a widespread distribution in nature. It has been found in at least 42 mammalian species, both domestic and feral, as well as at least 22 species of birds, ticks, flies, insect larvae, snails, frogs, fish, and shellfish. It can be isolated from soil, silage, and

other environmental sources. *L. monocytogenes* is quite hardy and resists the deleterious effects of freezing, drying, and heat remarkably well for a bacterium that does not form spores. Some studies suggest that 1-10% of humans may be intestinal carriers of *L. monocytogenes*.

B.3.j1. Illness Associated

The disease, listeriosis, is clinically defined when *L. monocytogenes* is isolated from blood, cerebrospinal fluid, or an otherwise normally sterile site. The manifestations of listeriosis include septicemia, meningitis, encephalitis, and intrauterine or cervical infections in pregnant women, which may result in spontaneous abortion or stillbirth. The onset of these symptoms is usually preceded by influenza-like symptoms including persistent fever. The onset time to serious forms of listeriosis is unknown but may range from a few days to three weeks. The onset time to gastrointestinal symptoms is unknown but is probably greater than 12 hours. When meningitis, septicemia, and perinatal/neonatal infections occur, the overall mortality may be as high 70%, 50%, and greater than 80% respectively. The infective dose of *L. monocytogenes* is unknown, but is believed to vary with the strain and susceptibility of the victim. From cases contracted through raw or supposedly pasteurized

milk, it appears that in susceptible persons, fewer than 1,000 total organisms may cause disease. All forms of listeriosis are more likely to occur in certain susceptible populations that include pregnant women/fetus, immunocompromised individuals (individuals with AIDS or on corticosteroid, anticancer drug, transplant rejection, or graft suppression therapy) cancer patients, the elderly, and less frequently reported are diabetic, cirrhotic, asthmatic, and ulcerative colitis patients. Some information suggests that normal, healthy people are at risk (antacids or cimetidine may predispose). A listeriosis outbreak in Switzerland involving cheese suggested that healthy uncompromised individuals could develop the disease, particularly if the foodstuff was heavily contaminated with the organism.

B.3.j2. Foods Associated

L. monocytogenes has been associated with such foods as raw milk, supposedly pasteurized fluid milk, cheeses (particularly soft-ripened varieties), ice cream, ice milk, chocolate milk, raw vegetables, fermented raw-meat sausages, raw and cooked poultry, raw meats (all types), and raw and smoked fish. Its ability to grow at temperatures as low as 1°C permits multiplication in refrigerated foods. Outbreaks have been associated with

raw milk, coleslaw, supposedly pasteurized fluid milk, soft-ripened and surfaced-ripened cheeses, and jellied pork tongue.

B.3.j3. Preventive Measures

Since *L. monocytogenes* has such a widespread distribution in nature, it is likely the organism will either be associated with numerous raw ingredients or can gain access to the food processing facility's environment. Any deviation and/or failure in a process that is design to eliminate this pathogen (e.g., thermal processing, or fermentation) provides an opportunity for the pathogen to persist in the product. Any process or operation that provides an opportunity for environmental or human contamination can be associated with *L. monocytogenes* ending up in the final product. Preventive measures involve the following: (1) eliminate the entrance of this bacterium into a facility or limit the amount introduced; (2) a listericidal process (e.g., cooking/thermal process) designed to eliminate the organism from the food product, such as (a) properly cooking meats of animal origin or (b) pasteurizing milk;; (3) once the organism is eliminated or reduced to acceptable levels, prevent cross-contamination (recontamination) by: (a) ensuring food handlers practice proper hygiene; (b) cleaning and sanitizing the utensils,

equipment, and the environment; (c) minimizing airborne contamination by paying attention to the flow of air within a facility; (d) separate raw and cooked product by having separate utensils and equipment; (e) physically separate raw product and cooked product areas in the facility; and (4) providing proper temperature control throughout the process to limit growth.

B.3.k. Plesiomonas shigelloides

Plesiomonas shigelloides is a Gram-negative, rod-shaped bacterium which has been isolated from freshwater, freshwater fish, and shellfish and from many types of animals including cattle, goats, swine, cats, dogs, monkeys, vultures, snakes, and toads. The ingested *P. shigelloides* organism does not always cause illness in the host animal but may reside temporarily as a transient, noninfectious member of the intestinal flora. It has been isolated from the stools of patients with diarrhea, but is also sometimes isolated from healthy individuals. It cannot yet be considered a definite cause of human disease, although its association with human diarrhea and the virulence factors it demonstrates make it a prime candidate.

B.3.k1. Illness Associated

P. shigelloides gastroenteritis is usually a mild

self-limiting disease with fever, chills, abdominal pain, nausea, diarrhea, or vomiting. *P. shigelloides* infection may cause diarrhea that lasts 1 to 7 days in healthy adults. Onset of symptoms may begin 24 to 48 hours after consumption of contaminated food or water. Symptoms may include diarrhea that is watery, non-mucoid, and non-bloody. In severe cases, diarrhea may be greenish-yellow, foamy, and blood tinged. Occasionally there may be high fever, chills, and protracted dysenteric symptoms in infants and children under 15 years of age. The infectious dose is believed to be quite high, at least greater than one million organisms.

B.3.k2. Foods Associated

Most human *P. shigelloides* infections are suspected to be waterborne. The organism may be present in unsanitary water which has been used as drinking water, recreational water, or water used to rinse foods that are consumed without cooking or heating. Most *P. shigelloides* infections occur in the summer months and correlate with environmental contamination of freshwater (rivers, streams, ponds, etc.). The usual route of transmission of the organism in sporadic or epidemic cases is by ingestion of contaminated water or raw shellfish. Foods that have been implicated in outbreaks of *P. shigelloides* gastroenteritis

include salted fish, crabs, and oysters.

B.3.k3. Preventive Measures

Preventive measures would involve: (1) ensuring food is thoroughly cooked before consumption; (2) once the organism is eliminated, prevent cross-contamination (recontamination) by: (a) ensuring food handlers practice proper hygiene; (b) cleaning and sanitizing the utensils, equipment, and the environment; and (c) separating raw and cooked product.

B.3.1. Salmonella spp.

Salmonella is a Gram-negative, nonsporeforming, rod-shaped, motile bacterium (nonmotile exceptions *S. gallinarum* and *S. pullorum*). The natural habitat is the intestinal tract of domestic and wild animals and humans. There is a widespread occurrence in animals, especially in poultry and swine. Environmental sources of the organism are numerous and include water, soil, insects, factory surfaces, kitchen surfaces, animal feces, raw meats, raw poultry, and raw seafoods.

B.3.1.1. Illness Associated

It is estimated that between 2 to 4 million cases of salmonellosis occur in the U.S. annually. The disease is caused by penetration and passage of *Salmonella* organisms from gut lumen into epithelium of small intestine where

inflammation occurs; there is evidence that an enterotoxin may be produced. Onset of acute symptoms can occur between 6 and 72 hours but usually is between 12 and 36 hours. Symptoms include nausea, vomiting, abdominal pain, diarrhea, fever, chills, and headache. These symptoms may last for 1 to 4 days or may be prolonged, again depending on host factors, ingested dose, and strain characteristics. There are reports of chronic sequelae that involve arthritic symptoms that may follow 3-4 weeks after onset of acute symptoms. *S. typhi* and the paratyphoid bacteria are normally septicemic and produce typhoid or typhoid-like fever in humans. The infective dose can be as few as 15-20 cells and depends upon the age and health of host, and strain differences among the members of the genus.

B.3.12. Foods Associated

One must assume that all animals are carriers of *Salmonella* and thus all foods of animal origin can be contaminated. Foods associated with *Salmonella* include raw meats (beef, ground beef, poultry, pork) eggs, milk, ice cream and other dairy products, fish, shrimp, frog legs, yeast, coconut, sauces and salad dressing, cake mixes, cream-filled desserts and toppings, dried gelatin, peanut butter, cocoa, and chocolate. Food producers and consumers should be aware that raw eggs, like other raw foods of

animal origin, may cause *Salmonella* infections. Based on this, consumers should avoid eating raw eggs and foods containing raw eggs. Raw eggs should be handled and stored in the same manner as other raw foods of animal origin. Recipes calling for raw eggs (e.g., home-made ice cream and mayonnaise, Caesar salad, Hollandaise sauce) should be considered potentially hazardous if they are not heated sufficiently to kill *Salmonella*. Raw eggs ought not be considered "health foods," particularly for the hospitalized, the elderly, the immunocompromised, and perhaps pregnant women.

B.3.13. Preventive Measures

Commercially produced mayonnaise and sauces are safe when they are prepared with pasteurized eggs and are adequately acidified to prevent the growth of *S. enteritidis*. Whenever possible, pasteurized, liquid eggs should be substituted for raw eggs, especially if they are destined for high risk individuals. The four major contributing factors causing *Salmonella* food borne outbreaks involve temperature abuse, inadequate cooking, using contaminated raw ingredients, and cross-contamination. Preventive measures involve the following: (1) eliminate the entrance of this bacterium into a facility or limit the amount introduced; (2) use of safe

and suitable water source; (3) a bactericidal process (e.g., cooking/thermal process) designed to eliminate the organism from the food product, such as (a) properly cooking meats of animal origin or (b) pasteurizing milk; (4) once the organism is eliminated from the product, prevent cross-contamination (recontamination) by: (a) ensuring food handlers practice proper hygiene; (b) cleaning and sanitizing the utensils, equipment, and the environment; (c) minimizing airborne contamination by paying attention to the flow of air within a facility; (d) separate raw and cooked product by having separate utensils and equipment; (e) physically separate raw product and cooked product areas in the facility; and (5) providing proper temperature control throughout the process to limit growth.

B.3.m. Shigella spp.

Shigella are Gram-negative, nonmotile, nonsporeforming rod-shaped bacteria. The illness caused by *Shigella* (shigellosis) accounts for less than 10% of the reported outbreaks of food borne illness in this country. *Shigella* rarely occurs in animals. It is principally a disease of humans and other primates such as monkeys and chimpanzees.

B.3.m1. Illness Associated

The illness caused by *Shigella* spp. is called

shigellosis (bacillary dysentery). The symptoms include diarrhea (mild to fulminating), abdominal pain, cramps, fever, chills, vomiting, tenesmus, toxemia, and blood, pus, or mucus in stools. The time to onset of symptoms ranges from 1 to 7 days, but usually less than 4 days. The illness usually lasts a few days, but can persist for up to 2 weeks. The infective dose is believed to be as few as 10 cells depending on age and condition of host. The *Shigella* spp. are highly infectious agents that are transmitted by the fecal-oral route. Reiter's disease, reactive arthritis, and hemolytic uremic syndrome (HUS) are possible sequelae of shigellosis. Infants, the elderly, and the infirm are susceptible to the severest symptoms of disease, but all humans are susceptible to some degree. Shigellosis is a common among individuals with acquired immune deficiency syndrome (AIDS) and AIDS-related complex.

B.3.m2. Foods Associated

Salads (potato, tuna, shrimp, macaroni, and chicken), lettuce and other raw vegetables, raw oysters, watermelon, spaghetti, beans, apple cider, milk and dairy products, cream puffs, hamburger, shrimp, and poultry. Fecal contamination of these foods is usually through handling of the food by asymptomatic person or person with a mild disease (fecal-oral route). The organism is frequently

found in water polluted with human feces. Fecally contaminated water and unsanitary handling by food handlers are the most common causes of contamination. Although all *Shigella* spp. have been implicated in food borne outbreaks at some time, *S. sonnei* is clearly the leading cause of shigellosis from food.

B.3.m3. Preventive Measures

The major contributing factors causing *Shigella* food borne outbreaks involve poor personal hygiene practiced by food handlers and temperature abuse for contaminated foods. Preventive measures involve the following: (1) ensuring food handlers practice proper hygiene (e.g., proper hand washing after defecation before handling food, utensils, or equipment); (2) separate raw and cooked product by having separate utensils and equipment; (3) physically separate raw product and cooked product areas in the facility; and (4) providing proper temperature control throughout the process to limit growth.

B.3.n. Staphylococcus aureus

S. aureus is a Gram-positive, spherical bacterium (coccus) which on microscopic examination appears in pairs, short chains, or bunched, grape-like clusters. Some strains are capable of producing a highly heat-stable protein toxin (staph enterotoxin) that causes illness in

humans. Staphylococcal food poisoning is one of the most common types of food borne disease. *S. aureus* can grow in a wide variety of foods and food ingredients. It is salt tolerant and can grow within a pH range of 5.2 to 9.0, a temperature range of 10°C (50°F) to 45°C (113°F), and at a_w levels as low as 0.86. Growth is necessary for enterotoxin production and production is minimal or nonexistent at the boundaries of growth. *S. aureus* is facultatively anaerobic, however, enterotoxin production occurs primarily under aerobic growth conditions. Reports show that *S. aureus* production of enterotoxin under anaerobic conditions is variable.

B.3.n1. Illness Associated

Staphylococcal food poisoning (food intoxication) is the name of the condition caused by the enterotoxins produced by some strains of *S. aureus*. Ingestion of the organism is not required to cause disease. Staphylococcal food poisoning results from ingesting staph enterotoxin produced in food in which *S. aureus* has grown to large numbers. The onset of symptoms in staphylococcal food poisoning is usually rapid, lasts for a short duration, and with an uneventful recovery. Severity of the illness depends on individual susceptibility to the toxin, the amount of contaminated food eaten, the amount of toxin in

the food ingested, and the general health of the victim. The most common symptoms are nausea, vomiting, retching, abdominal cramping, and diarrhea. Some individuals may not always demonstrate all the symptoms associated with the illness. In more severe cases, headache, muscle cramping, prostration, and transient changes in blood pressure and pulse rate may occur. Recovery generally takes two days, however, it is not unusual for complete recovery to take three days and sometimes longer in severe cases. The infective dose of less than 1.0 microgram of toxin in contaminated food will produce symptoms of staphylococcal intoxication. This toxin level is reached when *S. aureus* populations exceed 10^5 per gram.

B.3.n2. Foods Associated

Staphylococci organisms can be found in air, dust, sewage, water, milk, and food or on food equipment, environmental surfaces, humans, and animals. Humans and animals are the primary reservoirs. Staphylococci are present in the nasal passages, throats, and on the hair and skin of 50 percent or more of healthy individuals. Although food handlers are usually the main source of food contamination in food poisoning outbreaks, animal products (e.g., meat and milk), equipment, and environmental surfaces can also be sources of contamination with S.

aureus.

Foods frequently incriminated in staphylococcal food poisoning include meat and meat products; poultry and egg products; salads such as egg, tuna, shrimp, chicken, potato, and macaroni; bakery products such as custard and cream-filled pastries, cream pies, and chocolate eclairs; sandwich fillings; and milk and dairy products.

There are two major ways that foods can become involved in staphylococcal food poisoning. One is when unprepared or raw food capable of supporting the growth of *S. aureus* is either temperature abused before cooking or an inadequate and/or insufficient fermentation, brining, drying, or other bacteriocidal process occurs. Cooking these foods will eliminate the organism, but the highly heat-stable enterotoxin will not be destroyed and cause illness. There is evidence that the enterotoxins may not be completely inactivated at retort temperatures (121°C or 250°F). The other is when any food capable of supporting the growth of *S. aureus* that, after cooking, fermentation, brining, or drying, requires handling (slicing, mixing, making sandwiches) and is subsequently temperature abused after preparation, can be involved in staphylococcal food poisoning.

B.3.n3. Preventive Measures

The major contributing factors causing staphylococcal food poisoning involve temperature abuse before processing, inadequate fermentation, brining or drying, and cross-contamination during handling in combination with temperature abuse. Preventive measures should provide for proper handling of raw materials, steps to destroy, eliminate, or reduce the hazard, and measures to prevent recontamination. If organisms can reasonably be expected in the final product, conditions to inhibit growth and toxin production should be controlled. Preventive measures involve the following: (1) providing proper temperature control before processing (cooking, fermenting, brining, or drying) to limit growth; (2) ensuring that an adequate bacteriocidal process, designed to eliminate the organism from the food product, is delivered; (3) prevention of cross-contamination (recontamination) once the organism is eliminated or reduced to acceptable levels by: (a) ensuring food handlers practice proper hygiene (food handlers wash hands frequently or do not handle food if they have open sores, cuts, or lesions); (b) cleaning and sanitizing the utensils, equipment (e.g., slicers, mixers), and the environment; (c) separate raw and cooked product by having separate utensils and equipment; (d) physically separate raw product and cooked product areas in the facility; and

(4) providing proper temperature control after handling or preparation to limit *S. aureus* growth.

B.3.o. Streptococcus spp.

The genus *Streptococcus* is comprised of Gram-positive, microaerophilic cocci (round), which are not motile and occur in chains or pairs. The genus is defined by a combination of antigenic, hemolytic, and physiological characteristics into Groups A, B, C, D, F, and G. Groups A and D can be transmitted to humans via food.

Group A: one species with 40 antigenic types (*S. pyogenes*).

Group D: five species (*S. faecalis*, *S. faecium*, *S. durans*, *S. avium*, and *S. bovis*).

B.3.o1. Illness Associated

Group A Streptococci cause septic sore throat and scarlet fever as well as other pyogenic and septicemic infections. The illness is characterized by sore and red throat, pain on swallowing, tonsillitis, high fever, headache, nausea, vomiting, malaise, rhinorrhea, and occasionally a rash occurs. The onset of symptoms occurs between 1 and 3 days. The infectious dose is probably low (less than 1,000 organisms).

Group D Streptococci may produce a clinical syndrome similar to staphylococcal intoxication. The illness is

characterized by diarrhea, abdominal cramps, nausea, vomiting, fever, chills, and dizziness. The onset of symptoms occurs between 2 and 36 hours following ingestion of suspect food. The infectious dose is probably high (greater than 10^7 organisms).

B.3.o2. Foods Associated

Group A: Food sources include milk, ice cream, eggs, steamed lobster, ground ham, potato salad, egg salad, custard, rice pudding, and shrimp salad. In almost all cases, the foodstuffs were allowed to stand at room temperature for several hours between preparation and consumption. Entrance into the food is the result of poor hygiene, ill food handlers, or the use of unpasteurized milk. Outbreaks of septic sore throat and scarlet fever were numerous before the advent of milk pasteurization. Recently, salad bars have been suggested as possible sources of infection. Most current outbreaks have involved complex foods (i.e., salads) which were infected by a food handler with septic sore throat.

Group D: Food sources include sausage, evaporated milk, cheese, meat croquettes, meat pie, pudding, raw milk, and pasteurized milk. Entrance into the food chain is due to underprocessing and/or poor and unsanitary food preparation. Outbreaks are not common and are usually the

result of preparing, storing, or handling food in an unsanitary manner.

B.3.o3. Preventive Measures

Preventive measures include: (1) properly cooking raw ingredients; (2) pasteurizing milk; (3) once the organism is eliminated from the product, prevent cross-contamination (recontamination) by: (a) ensuring ill food handlers are not involved in preparing food; (b) ensuring food handlers practice proper hygiene; (c) separate raw and cooked product by having separate utensils and equipment; (d) physically separate raw product and cooked product areas in the facility; and (4) providing proper temperature control throughout the process to limit growth.

B.3.p. Vibrio cholerae Serogroup O1

Vibrio cholerae Serogroup O1 is responsible for Asiatic or epidemic cholera. The organism is widely distributed in the marine environment and resides in the intestinal tract of humans. No major outbreaks of this disease have occurred in the United States since 1911. However, sporadic cases occurred between 1973 and 1991, suggesting the possible reintroduction of the organism into the U.S. marine and estuarine environment. The cases between 1973 and 1991 were associated with the consumption of raw shellfish or of shellfish either improperly cooked

or recontaminated after proper cooking. Environmental studies have demonstrated that strains of this organism may be found in the temperate estuarine and marine coastal areas surrounding the United States.

B.3.p1. Illness Associated

Cholera is the name of the infection caused by *V. cholerae*. Symptoms of Asiatic cholera may vary from a mild, watery diarrhea to an acute diarrhea, with characteristic profuse watery diarrhea or "rice water stools". The onset of the illness is generally sudden, with incubation periods varying from 6 hours to 5 days. Abdominal cramps, nausea, vomiting, dehydration, and shock; after severe fluid and electrolyte loss, death may occur. Individuals infected with cholera require rehydration either intravenously or orally. The illness is generally self-limiting, death can occur from dehydration and loss of essential electrolytes. Medical treatment to prevent dehydration prevents these complications. The infective dose has been demonstrated by human volunteer feeding studies utilizing healthy individuals to be approximately between 10^6 and 10^8 organisms. Antacid consumption markedly lowers the infective dose.

B.3.p2. Foods Associated

Cholera is generally a disease spread by poor

sanitation, resulting in contaminated water supplies. Any food that comes in contact with these contaminated water supplies could be associated with this illness. Outbreaks have been associated with the consumption of raw shellfish (mussels, crabs, shrimp, oysters, and clams), or shellfish either improperly cooked or recontaminated after proper cooking. Sporadic cases occur when shellfish harvested from fecally polluted coastal waters are consumed raw. Cholera may also be transmitted by shellfish harvested from nonpolluted waters since *V. cholerae* O1 can be a part of the natural flora of these waters.

In 1991 outbreaks of cholera in Peru quickly grew to epidemic proportions and spread to other South American and Central American countries, including Mexico. Since that time, 24 cases of cholera have been reported in the United States. The U.S. cases were brought into the country by travelers returning from South America, or were associated with smuggled, temperature-abused, crustaceans.

B.3.p3. Preventive Measures

Preventive measures involve preventing contamination via the fecal-oral route either directly or via contaminated water. Thus, use of potable or boiled water would be an effective preventive measure. Shellfish should only be harvested from approved waters even though cholera

may also be transmitted by shellfish harvested from nonpolluted waters. Harvesting only from approved waters will make it less likely that shellfish will be heavily contaminated with *V. cholerae* O1. Other contributing factors causing cholera outbreaks involve inadequate cooking and/or cross-contamination. Preventive measures would involve: (1) a bacteriocidal process (e.g., thermal process) designed to eliminate the organism from the food product; (2) once the organism is eliminated, prevent cross-contamination (recontamination) by: (a) ensuring food handlers practice proper hygiene; (b) cleaning and sanitizing the utensils, equipment, and the environment; (c) separate raw and cooked product by having separate utensils and equipment; (d) physically separate raw product and cooked product areas in the facility.

B.3.q. Vibrio cholerae Serogroup Non-O1

Vibrio cholerae Serogroup Non-O1 infects only humans and other primates. It is related to *V. cholerae* Serogroup O1, the organism that causes Asiatic or epidemic cholera, but causes a disease less severe than cholera. Both pathogenic and nonpathogenic strains of the organism are normal inhabitants of marine and estuarine environments of the United States.

B.3.q1. Illness Associated

Non-O1 *V. cholerae* gastroenteritis is the name associated with this illness. Diarrhea, abdominal cramps, and fever are the predominant symptoms associated with this illness, with vomiting and nausea occurring less frequently. Diarrhea may, in some cases, be quite severe, lasting up to 6 to 7 days. Diarrhea will usually occur within 48 hours following ingestion of the organism. The infective dose is believed to require that large numbers (more than one million) of the organism must be ingested to cause illness.

B.3.q2. Foods Associated

Shellfish harvested from U.S. coastal waters frequently contain *V. cholerae* non-O1. Consumption of raw (raw oysters), improperly cooked, or cooked and recontaminated shellfish may lead to infection.

B.3.q3. Preventive Measures

Preventive measures involve preventing contamination via the fecal-oral route either directly or via contaminated water. Thus, use of potable or boiled water would be an effective preventive measure. Shellfish should only be harvested from approved waters since harvesting from approved waters will make it less likely that shellfish will be heavily contaminated with *V. cholerae* non-O1. Other contributing factors causing non-O1 *V.*

cholerae gastroenteritis outbreaks involve inadequate cooking and/or cross-contamination. Preventive measures would involve: (1) a bacteriocidal process (e.g., thermal process) designed to eliminate the organism from the food product; (2) once the organism is eliminated, prevent cross-contamination (recontamination) by: (a) ensuring food handlers practice proper hygiene; (b) cleaning and sanitizing the utensils, equipment, and the environment; (c) separate raw and cooked product by having separate utensils and equipment; (d) physically separate raw product and cooked product areas in the facility.

B.3.r. Vibrio parahaemolyticus

Vibrio parahaemolyticus is part of the natural flora in estuarine and marine environments of the United States. It is an obligate halophile (i.e., requires NaCl for growth). Both pathogenic and non-pathogenic forms of the organism can be isolated from marine and estuarine environments and from fish and shellfish dwelling in these environments. It is the leading cause of food borne disease in Japan and has caused outbreaks in the United States.

Several other marine vibrios have been implicated in human disease. Some may cause wound or ear infections, and others, gastroenteritis. There is little evidence that

certain of these organisms cause gastroenteritis. However, several have been isolated from the stools of diarrhea patients in which no other pathogens could be isolated. Methods for recovery of these organisms from foods are similar to those used for recovery of *V. parahaemolyticus*. The other marine vibrios species implicated in human disease include:

<i>Vibrio alginolyticus</i>	<i>Vibrio furnissii</i>
<i>Vibrio carchariae</i>	<i>Vibrio hollisae</i>
<i>Vibrio cincinnatiensis</i>	<i>Vibrio fluvialis</i>
<i>Vibrio damsela</i>	<i>Vibrio mimicus</i>
<i>Vibrio metschnikovii</i>	

B.3.r1. Illness Associated

V. parahaemolyticus-associated gastroenteritis is the name of the infection caused by this organism. Diarrhea, abdominal cramps, nausea, vomiting, headache, fever, and chills may be associated with infections caused by this organism. The illness is usually mild or moderate, although some cases may require hospitalization. The incubation period is between 4 and 96 hours and the disease lasts generally 3 days. The infective dose is believed to require that large numbers (more than one million) of the organism must be ingested to cause illness.

B.3.r2. Foods Associated

Infections with this organism have been associated with the consumption of raw, improperly cooked, or cooked and recontaminated seafood (fish, shrimp, crab, and other shellfish). Improper refrigeration of seafoods contaminated with this organism will allow its proliferation, which increases the possibility of infection.

B.3.r3. Preventive Measures

Preventive measures would involve: (1) ensuring food is thoroughly cooked before consumption; (2) once the organism is eliminated, prevent cross-contamination (recontamination) by: (a) ensuring food handlers practice proper hygiene; (b) cleaning and sanitizing the utensils, equipment, and the environment; and (c) separating raw and cooked product; and (4) providing proper temperature control throughout the process to limit growth.

B.3.s. Vibrio vulnificus

Vibrio vulnificus is a halophile (i.e., requires NaCl for growth). It has been isolated from a wide range of environmental sources, including water, sediment, plankton, and shellfish (oysters, clams, and crabs) and a variety of locations, including the Gulf of Mexico, the Atlantic Coast as far north as Cape Cod, and the entire U.S. West Coast. Cases of illness have also been associated with brackish

lakes in New Mexico and Oklahoma. It infects only humans and other primates.

B.3.s1. Illness Associated

This organism causes wound infections, gastroenteritis, or a syndrome known as "primary septicemia". Wound infections result either from contaminating an open wound with sea water harboring the organism, or by lacerating part of the body on coral, fish, etc., followed by contamination with the organism. The ingestion of *V. vulnificus* by healthy individuals can result in gastroenteritis. In these individuals, gastroenteritis usually occurs within 16 hours of ingesting the organism. The "primary septicemia" form of the disease follows consumption of raw seafood containing the organism by individuals with underlying chronic disease such as diabetes, cirrhosis, leukemia, lung carcinoma, acquired immune deficiency syndrome (AIDS), AIDS-related complex (ARC), or asthma requiring the use of steroids. The mortality rate for susceptible individuals with this form of the disease is over 50%. In these individuals, the microorganism enters the blood stream, resulting in septic shock, distinctive bulbous skin lesions, rapidly followed by death. The infective dose for gastrointestinal symptoms in healthy individuals is unknown, but for predisposed

persons, septicemia can presumably occur with doses of less than 100 total organisms.

B.3.s2. Foods Associated

This organism has been isolated from oysters, clams, and crabs. Consumption of these products raw, or products inadvertently recontaminated may result in illness.

B.3.s3. Preventive Measures

Susceptible individuals should be strongly advised not to consume raw or inadequately cooked seafood. Other preventive measures would involve: (1) ensuring food is thoroughly cooked before consumption; (2) once the organism is eliminated, prevent cross-contamination (recontamination) by: (a) ensuring food handlers practice proper hygiene; (b) cleaning and sanitizing the utensils, equipment, and the environment; and (c) separating raw and cooked product; and (3) providing proper temperature control throughout the process to limit growth.

B.3.t. Yersinia enterocolitica

Y. enterocolitica, a small rod-shaped, Gram-negative, facultative anaerobic bacterium, is often isolated from clinical specimens such as wounds, feces, sputum and mesenteric lymph nodes. However, it is not part of the normal human flora.

B.3.t1. Illness Associated

Yersiniosis is frequently characterized by such symptoms as gastroenteritis with diarrhea and vomiting; however, fever and severe abdominal pain are the classic symptoms. *Yersinia* infections mimic appendicitis, but the bacteria may also cause infections of other sites such as wounds, joints and the urinary tract. The onset of illness is usually between 1 and 2 days and lasts between 1 and 3 days. The infective dose is unknown.

B.3.t2. Foods Associated

Y. enterocolitica has been isolated from meats (pork, beef, lamb), oysters, shrimp, crabs, fish, tofu, ice cream, milk, and raw milk. Swine appear to be a major source of pathogenic strains. This organism can also be found in the soil, water (ponds and lakes), and in animals such as pigs, birds, beavers, cats, dogs, and squirrels, which provides additional opportunities for it to enter our food supply. Most isolates have been found not to be pathogenic. Outbreaks have been associated with chocolate milk that had been prepared by adding the chocolate after pasteurization and mixing with a paddle, tofu that had been packaged in untreated spring water, and pasteurized milk that may have had post-processing contamination.

B.3.t3. Preventive Measures

Preventive measures include: (1) properly cooking

foods of animal origin; (2) pasteurizing milk; (3) use of safe and suitable water source; (4) prevention of cross-contamination (recontamination) once the organism is eliminated from the product by: (a) use of potable water in food production; (a) ensuring food handlers practice proper hygiene; (b) cleaning and sanitizing the utensils, equipment, and the environment; (c) separation raw and cooked product; and (5) providing proper temperature control throughout the process to limit growth.

B.3.u. Miscellaneous enterics, Gram-negative genera including: Klebsiella, Enterobacter, Hafnia, Proteus, Citrobacter, Aerobacter, Providencia, Serratia

These rod-shaped enteric (intestinal) bacteria have been suspected of causing acute and chronic gastrointestinal disease. The organisms may be recovered from natural environments such as forests and freshwater as well as from farm produce (vegetables) where they reside as normal microflora. They may be recovered from the stools of healthy individuals with no disease symptoms. The relative proportion of pathogenic to nonpathogenic strains is unknown.

B.3.u1. Illness Associated

Gastroenteritis is name of the disease occasionally and sporadically caused by these genera. Acute

gastroenteritis is characterized by two or more of the symptoms of vomiting, nausea, fever, chills, abdominal pain, and watery (dehydrating) diarrhea occurring between 12 and 24 hours after ingestion of contaminated food or water. Chronic diarrheal disease is characterized by the dysenteric symptoms of foul-smelling, mucus-containing, diarrheic stools with flatulence and abdominal distention. The chronic disease may continue for months. The infectious dose is unknown. Both the acute and chronic forms of the disease are suspected to result from the elaboration of enterotoxins.

B.3.u2. Foods Associated

These bacteria have been recovered from dairy products, raw shellfish, and fresh raw vegetables. The organisms can occur in soils used for crop production and shellfish harvesting waters. No major common-source outbreak has been reported. *Citrobacter freundii* was suspected by CDC of causing an outbreak of diarrheal disease in Washington, DC. Imported Camembert cheese was incriminated.

B.3.u3. Preventive Measures

Preventive measures for this group of bacteria should be similar to those employed for other enteric pathogens such as *Salmonella*. The four major contributing factors

causing *Salmonella* food borne outbreaks involve temperature abuse, inadequate cooking, using contaminated raw ingredients, and cross-contamination. Preventive measures involve the following: (1) eliminate the entrance of this bacterium into a facility or limit the amount introduced; (2) use of safe and suitable water source; (3) a bacteriocidal process (e.g., cooking/thermal process) designed to eliminate the organism from the food product, such as (a) properly cooking meats of animal origin or (b) pasteurizing milk; (4) once the organism is eliminated from the product, prevent cross-contamination (recontamination) by: (a) ensuring food handlers practice proper hygiene; (b) cleaning and sanitizing the utensils, equipment, and the environment; (c) minimizing airborne contamination by paying attention to the flow of air within a facility; (d) separate raw and cooked product by having separate utensils and equipment; (e) physically separate raw product and cooked product areas in the facility; and (5) providing proper temperature control throughout the process to limit growth.

B.4. Reasonably Likely To Occur

When conducting a hazard analysis all hazards should be addressed. However, a HACCP system only needs to control (preventive measure) hazards identified as

significant. For a hazard to be a significant hazard it must meet two conditions: (1) it must make the food unsafe for consumption; and (2) it must be reasonably likely to occur. FPB identified in section II.B.3. meet the first condition because they can make a food unsafe for consumption (provided the infective dose is consumed). The second condition of reasonably likely to occur is equally important but more difficult to define. The reason for including only hazards that are reasonably likely to occur is that this condition is necessary to prevent a HACCP system from being overburdened with controls for hazards with a negligible or zero likelihood of occurrence. If this condition were not applied, the true safety controls in HACCP system would be diluted because resources would have to be diverted to essentially useless tasks controlling hazards with negligible or zero likelihood of occurrence. The determination of when a hazard is reasonably likely to occur can be debatable and some of the earlier debates (discussed previously) on CCP determinations actually involved the issue of reasonably likely to occur.

There is no one definition of reasonably likely to occur that can be universally apply to all foods and/or food processing conditions. However, guidance can be given

as to how to determine reasonably likely to occur. This determination should be based on epidemiological evidence (i.e., food borne outbreaks, product history, consumer complaints), process authority recommendations, and the scientific and technical literature (e.g., predictive models). An individual or team, in an attempt to establish HACCP preventive measures, should use this information in combination with good judgement and common sense to determine that a hazard is reasonably likely to occur in the food or food process in the absence of any controls. The author believes that ultimately the courts will define reasonably likely to occur, and most likely on a case-by-case basis.

B.5. Prerequisite Programs

HACCP systems must be built upon a firm foundation of Good Manufacturing Practices (GMPs) and adequate sanitation procedures. GMPs and sanitation procedures are considered prerequisite programs to HACCP implementation and address recontamination, cross-contamination, and environmental contamination concerns. Prerequisite programs can be defined as: universal steps or procedures that control the operational conditions within a food establishment allowing for environmental conditions that are favorable to the production of safe food (definition adapted from: AC, 1993

and Seafood Alliance, 1995). Prerequisite programs can include GMPs (21 CFR Part 110), training, premises, equipment (preventive maintenance), personnel, sanitation and pest control, and recalls.

Generally, sanitation should be considered a prerequisite program to HACCP. The use of sanitation Standard Operating Procedures (SOPs) that are effectively monitored and documented can reduce the likelihood of occurrence of a hazard. Thus, if a processing step provides the opportunity for contamination in the absence of proper prerequisite programs, one must assume the hazard is reasonably likely to occur. The implementation of an effective and documented prerequisite program makes that hazard not reasonably likely to occur. If a food processor were to rely on prerequisite programs to reduce the likelihood of a hazard being introduced at a particular operation (step), and upon a HACCP verification/inspection, the prerequisite program is deemed inadequate, the hazard analysis is, in effect, invalidated because it has failed to address a significant hazard that is reasonably likely to occur.

When sanitation has a direct impact on food safety it should be handled within the HACCP Plan. In these cases, the sanitation procedure or operation (step) should lend

itself to all the aspects of a CCP, such as establishing critical limits, monitoring, record keeping and verification procedures. A CIP system is a good example of where sanitation could be handled as a CCP within a HACCP plan, since it can be easily monitored, critical limits and corrective actions can be established, proper records can be maintained, and verified. In contrast, environmental areas over products (e.g., ceilings) should be kept cleaned and could be part of a sanitation documented SOP.

The use of sanitation as a prerequisite program and other prerequisite programs should not be considered new or additional programs. Even in the absence of HACCP programs, the cleanliness of the facility/premises and GMPs must comply with the law. Sanitation should not be limited to the cleaning of equipment. Although clean equipment and a clean environment are essential for producing safe foods, equally important are personnel practices, plant facilities, equipment and operations designed to prevent contamination, pest controls, and warehouse practices. All of these considerations should be addressed in a complete sanitation program designed to comply with existing regulations (Seafood Alliance, 1995).

A somewhat similar view was reported by Notermans et al. (1994). The authors stated HACCP was an extension of

GMPs, and that HACCP would fail in any processing plant where GMPs are insufficient. Only when GMPs (prerequisite programs) can not prevent an introduction (contamination, recontamination, or cross-contamination) of a hazard should that hazard be included in a list of potentially hazardous agents.

B.6. Hazards Associated with Food Categories/Groups

This section contains a list of food categories and the bacterial food borne pathogens that are reasonably likely to occur or be associated with the food in each category. The information is summarized in Table 3. These associations have been reported in the scientific literature and are generally the result of such things as microbiological incidence studies, epidemiological investigations, or reports of food borne outbreaks. The associations are dynamic in nature and subject to change as more is learned about the biology and epidemiology of food borne pathogens. Thus, the information summarized in Table 3 should be reviewed and updated periodically.

Table 3. Food Borne Pathogenic Bacterial Hazards Associated with Food Products

Food Category or Group	Food borne Pathogenic Bacterial Hazards
<p>Meat and Poultry Products</p> <ul style="list-style-type: none"> - Raw Meat and Poultry Products - Shelf-Stable Raw Salted and Salt Cured Meats - Perishable Raw Salted and Salt Cured Meats - Perishable Cooked Uncured Meat - Perishable Cooked Cured Meat - Shelf-Stable Canned Cured Meats - Perishable Canned Cured Meats - Canned Uncured Meats 	<p>Normal bacterial flora consists of mesophilic and psychrotrophic bacteria from the animal itself, soil, water, environment, and types added by man and equipment during processing.</p> <p><i>Arcobacter</i> <i>Campylobacter jejuni</i> <i>Clostridium botulinum</i> (infrequently) <i>Clostridium perfringens</i> <i>Escherichia coli</i> <i>Listeria monocytogenes</i> <i>Salmonella</i> spp. <i>Staphylococcus aureus</i> <i>Yersinia enterocolitica</i> Other Enteric pathogens</p>
<p>Fermented Meats Acidulated Sausages</p> <p>Fermentation must be rapid and sufficient enough to preclude growth of enteric pathogens and <i>S. aureus</i> above their normally low numbers.</p>	<p>Enteric pathogens Enterohemorrhagic <i>Escherichia coli</i> <i>Staphylococcus aureus</i></p>
<p>Dried Meats</p> <p>Dried meats are usually cooked before being dried to reduce the water activity (a_w) to inhibitory level.</p>	<p><i>Salmonella</i> spp. <i>Staphylococcus aureus</i></p>

Table 3. Food Borne Pathogenic Bacterial Hazards Associated with Food Products

<p>Milk and Milk Products</p> <p>- Raw Milk</p>	<p>Raw milk was recognized in the early 20th century as a major public health concern. The widespread requirement that milk be pasteurized (Pasteurized Milk Ordinance) has increased the safety of milk and milk products significantly. The microbiological quality of milk and milk products is influenced by the initial flora the process conditions and post-pasteurization contamination.</p> <p><i>Brucella</i> <i>Bacillus</i> spp. <i>Campylobacter jejuni</i> <i>Clostridium</i> spp. <i>Escherichia coli</i> O157:H7 (EHEC) <i>Listeria monocytogenes</i> <i>Salmonella</i> spp. <i>Staphylococcus aureus</i> <i>Streptococcus</i> spp. <i>Yersinia enterocolitica</i> Other Enteric pathogens</p>
<p>Pasteurized Milk</p> <p>- When post-pasteurization contamination occurs.</p>	<p><i>Bacillus</i> spp. (psychrotrophic)</p> <p>Any enteric pathogen, and particularly <i>Listeria monocytogenes</i> and <i>Yersinia enterocolitica</i> since they can grow at refrigeration temperatures.</p>
<p>Dried Milk</p> <p>- Sensitive products</p>	<p><i>Salmonella</i> spp. <i>Staphylococcus aureus</i></p>
<p>Butter</p>	<p><i>Staphylococcus aureus</i></p>

Table 3. Food Borne Pathogenic Bacterial Hazards Associated with Food Products

<p>Frozen Dairy Products</p>	<p><i>Listeria monocytogenes</i> and <i>Salmonella</i> spp. <i>Staphylococcus aureus</i></p>
<p>Fermented Dairy Products Slow or insufficient fermentation may permit growth of some pathogens. Fermentation must be rapid and sufficient enough to preclude growth of enteric and other pathogens above their normally low numbers.</p>	<p>Enteric pathogens Enteropathogenic <i>Escherichia coli</i> (EPEC) <i>Escherichia coli</i> O157:H7 (EHEC) <i>Listeria monocytogenes</i> <i>Salmonella</i> spp. <i>Staphylococcus aureus</i></p>
<p>Cheeses made from Raw Milk</p>	<p><i>Brucella</i> <i>Campylobacter jejuni</i> <i>Listeria monocytogenes</i> <i>Salmonella</i> spp. Other Enteric pathogens</p>
<p>Eggs and Egg Products</p> <p>- Hard cooked eggs that are subsequently peeled and handled.</p> <p>- Hard cooked eggs that are not peeled.</p>	<p><i>Campylobacter jejuni</i> <i>Listeria monocytogenes</i> <i>Salmonella</i> spp. <i>Yersinia enterocolitica</i> <i>Staphylococcus aureus</i> <i>Clostridium botulinum</i></p>

Table 3. Food borne Pathogenic Bacterial Hazards Associated with Food Products

<p>Seafood</p> <ul style="list-style-type: none"> - Fish - Crustaceans (crabs, shrimp, crawfish, and prawns) - Bivalve Molluscan Shellfish - Pre-cooked Seafood 	<p>Seafoods harvested from open seas are generally not associated with pathogens listed below and are more likely to be contaminated with these pathogens due to insanitary practices during product handling. Seafoods may become directly contaminated in their environment as a result of fecally contaminated waters by man or animal, and thus serve as vectors for food borne disease caused by enteric pathogens. There are generally three ways seafood products become contaminated: (1) naturally occurring pathogens; (2) pathogens in the aquatic environment as a result of human or animal waste and/or runoff; and (3) pathogens contaminated via food processing and handling.</p> <p><i>Aeromonas hydrophilia</i>^{1,a} <i>Campylobacter jejuni</i>^{2,3} <i>Clostridium botulinum</i>^{1,2,3} <i>Clostridium perfringens</i>^{2,3} (i.e., sauce & soups) <i>Escherichia coli</i>^{2,3} <i>Listeria monocytogenes</i>^{2,3} <i>Plesiomonas shigelloides</i>^{1,a} <i>Salmonella</i> spp.^{2,3} <i>Shigella</i> spp.^{2,3} <i>Staphylococcus aureus</i>^{2,3} (i.e., crabmeat) <i>Vibrio cholerae</i> O1 and non-O1^{1,2} <i>Vibrio parahaemolyticus</i>¹ <i>Vibrio vulnificus</i>¹ Other <i>Vibrio</i> spp.¹ <i>Yersinia enterocolitica</i>^{2,3} Other Enteric pathogens^{2,3}</p>
<p>Salted and Smoked Seafood Products</p>	<p><i>Clostridium botulinum</i> <i>Listeria monocytogenes</i> <i>Salmonella</i> spp. <i>Staphylococcus aureus</i> Other Enteric pathogens</p>

Table 3. Food Borne Pathogenic Bacterial Hazards Associated with Food Products

<p>Pickled and Fermented Seafood Products Slow or insufficient pickling and/or fermentation may permit growth of some pathogens. Pickling and fermentation must be rapid and sufficient enough to preclude growth of enteric and other pathogens above their normally low numbers.</p>	<p><i>Clostridium botulinum</i> <i>Listeria monocytogenes</i> <i>Salmonella</i> spp. <i>Staphylococcus aureus</i> Other Enteric pathogens</p>
<p>Modified Atmosphere Packaged (MAP) Seafood</p>	<p><i>Clostridium botulinum</i> <i>Listeria monocytogenes</i></p>
<p>Pasteurized and/or Minimally Processed Seafoods</p>	<p><i>Clostridium botulinum</i> <i>Staphylococcus aureus</i></p>
<p>Aquacultured Seafoods</p>	<p>Enteric pathogens</p>
<p>Molluscan Shellfish - Oysters, mussels, and clams</p>	<p><i>Campylobacter jejuni</i>^{2,3} <i>Clostridium botulinum</i>^{1,2,3} <i>Listeria monocytogenes</i>^{2,3} <i>Salmonella</i> spp.^{2,3} <i>Shigella</i> spp.^{2,3} <i>Vibrio cholerae</i> O1 and non-O1^{1,2} <i>Vibrio parahaemolyticus</i>¹ <i>Vibrio vulnificus</i>¹ Other <i>Vibrio</i> spp.¹ Other Enteric pathogens^{2,3}</p>

Table 3. Food Borne Pathogenic Bacterial Hazards Associated with Food Products

<p>Fruits and Vegetables Any organism associated with the soil, water, or carried by birds and animals may be associated with these products.</p>	<p><i>Bacillus cereus</i> <i>Clostridium botulinum</i> <i>Clostridium perfringens</i> <i>Escherichia coli</i> <i>Listeria monocytogenes</i> <i>Salmonella</i> spp. <i>Shigella</i> spp. <i>Staphylococcus aureus</i> <i>Vibrio cholerae</i></p>
<p>Fermented and Acidified Vegetables Slow or insufficient fermentation and/or acidification may permit growth of some pathogens. Fermentation and acidification must be rapid and sufficient enough to preclude growth of enteric and other pathogens above their normally low numbers.</p>	<p><i>Clostridium botulinum</i> <i>Listeria monocytogenes</i> <i>Staphylococcus aureus</i></p>
<p>Fruit Beverages Most fruit beverages use a combination of heat treatment (pasteurization) and naturally acidic conditions to assure safety. Nonpasteurized products may involve any of the pathogens listed to the right.</p>	<p><i>Escherichia coli</i> O157:H7 (EHEC) <i>Listeria monocytogenes</i> (potential) <i>Salmonella</i> spp. Other Enteric pathogens</p>
<p>Salad Dressings Most commercially prepared salad dressings and mayonaises are microbiologically stable based on a combination of pH (pH 3.6-4.0/ acetic acid) and water phase salt concentration. Nonpasteurized products may involve any of the pathogens listed to the right.</p>	<p><i>Salmonella</i> spp. and other enteric pathogens unpasteurized ingredients are used or if pH and water phase salt not controlled.</p>

Table 3. Food Borne Pathogenic Bacterial Hazards Associated with Food Products

<p>Spices and Gums Primary consideration after harvesting is to dry the plant portion to prevent bacterial growth. Conditions of harvest and handling may permit extensive contamination.</p> <p>- If insanitary conditions at harvest or during storage have occurred or are suspected.</p>	<p><i>Bacillus cereus</i> <i>Clostridium botulinum</i> <i>Clostridium perfringens</i> <i>Escherichia coli</i></p> <p><i>Salmonella</i> spp. <i>Shigella</i> spp. and other Enteric pathogens</p>
<p>Cereal and Cereal Products</p> <p>- Cereal grains (i.e., wheat, oats, corn, rye, rice, barley, millet, sorghum, and soybeans)</p> <p>- Cereal products (i.e., pasta, breakfast cereals, breads, snack products, corn meal, doughs, dry mixes for cakes, and pastry)</p> <p>Microorganisms associated with these products generally represent the environment in which they were grown. Grains, when harvested and in good condition, if properly dried and stored (preventing excess water) present minimal hazards because little bacterial growth can occur.</p>	<p><i>Bacillus cereus</i> <i>Clostridium botulinum</i> <i>Clostridium perfringens</i> <i>Escherichia coli</i> <i>Listeria monocytogenes</i> <i>Salmonella</i> spp. <i>Staphylococcus aureus</i> <i>Yersinia</i> spp. Other Enteric pathogens</p>

Table 3. Food Borne Pathogenic Bacterial Hazards Associated with Food Products

<p>Sweeteners and Starches Low water activity is responsible for microbiologically stability. The refining process for crystalline sweeteners and liquid syrups derived directly from plant material destroy vegetative cells of pathogens. Commercially produced starches and sweeteners are generally not involved in outbreaks of food borne illness.</p> <ul style="list-style-type: none"> - Dry Sugar - Honey 	<p><i>Bacillus cereus</i></p> <p>None</p> <p><i>Clostridium botulinum</i></p>
<p>Confectionary Products</p> <ul style="list-style-type: none"> - Boiled sweets, toffees, fudge, caramel, nougat, marzipan, jellies, creams, chocolate confectionary, fondant cream, marshmallows, and licorice. Also includes granola, wafer, and biscuit products enrobed with chocolate and/or layered with creams. <p>Majority of confectionary products are not susceptible to microbial spoilage due to low water activity ($a_w < 0.85$). Although pathogenic bacteria generally do not grow in these products, the combination of water activity and fat content may permit the microorganisms to survive for an extended period. Thus, sensitive ingredients and environmental contaminants are important in these products.</p> <ul style="list-style-type: none"> - Cocoa and chocolate 	<p><i>Salmonella</i> spp.</p> <p>Other enteric pathogens</p> <p><i>Listeria monocytogenes</i> (potential contaminant)^b</p> <p><i>Salmonella</i> spp.</p>

Table 3. Food Borne Pathogenic Bacterial Hazards Associated with Food Products

<p>Nut Meats Nut meats are derived from processed nuts harvested from trees, shrubs, or plants. Nut meats may be contaminated with soil and field dust during harvesting, so any pathogen associated with the soil could be present. Roasting will destroy most vegetative organisms (spores persist), so mishandling after roasting can be a source of microbial contamination.</p>	<p><i>Salmonella</i> spp. Other enteric pathogens</p>
<p>Canned Foods Canned foods are required to be commercially sterile. Low acid canned foods should not contain <i>C. botulinum</i> spores, however high acid canned foods receive less thermal processing so spores may survive and be present in the food (although the high acid will prevent growth).</p>	<p><i>Clostridium botulinum</i> spores present in high acid canned foods (important if high acid food is used as an ingredient in final food product). <i>Staphylococcus aureus</i> enterotoxin (potential) if improper pre-processing conditions existed, enterotoxin may have been produced (in a susceptible food) and may survive thermal processing.</p>
<p>Water Water used in food processing should be from a safe and suitable source. Untreated water may contain food borne and waterborne pathogens listed to the right.</p>	<p>Enteric pathogens (i.e., <i>Campylobacter jejuni</i>, <i>Escherichia coli</i>, <i>Salmonella</i> spp., <i>Shigella</i> spp., and <i>Yersinia enterocolitica</i>) <i>Listeria monocytogenes</i> <i>Pseudomonas aeruginosa</i> <i>Vibrio</i> spp.</p>

B.7. Hazards Associated with Food Processing

Operations/Steps

The HACCP concept calls for a differentiation between processing operations/steps (i.e., differentiation between critical control points and control points). Notermans et al. (1995b) has proposed a means of differentiating processing operations based on their ability to quantitatively reduce or stabilize the hazard. Their process involves creating a list of all operations and other factors that are known to reduce or stabilize a microbiological population in food processing. Then an individual should determine, for a particular food product, which ones are relevant while the others are deleted from the list. It is next determined if the remaining operations/factors can be utilized to reduce or stabilize a potential hazard. This is followed by the question of whether or not the effect is nullified by a subsequent process or procedure. Finally, if the effect is not nullified, it is necessary to decide whether the operation controls the hazard in a quantifiable manner. The authors provided a flow sheet (decision tree) for the identification of CCPs that have a quantitative effect. It was suggested that other operations that have a qualitative nature are best handled within a GMP framework.

Shapton and Shapton (1991) provided another example of differentiation when they divided chilled food processing operations (steps) into two main categories, primary processing and secondary processing. Primary process operations (steps) are used to either: (1) control the introduction (receipt) of hazards into the process; (2) cause hazard destruction, elimination, or reduction to acceptable levels; or (3) inhibit growth of hazards. Either a single primary processing operation (step) or a combination of operations (steps) may be used to effectively control the identified hazard(s). Improper controls or performance of these processes make it reasonably likely the processing operation (step) has permitted a hazard to be introduced, survive, or grow causing the food to be unsafe for consumption. Examples of primary food processing operations (steps) along with the hazards and preventive measures associated with each are given in Table 4.

Secondary process operations (steps) are generally not intended to destroy, eliminate, or reduce to acceptable levels, the hazards associated with that particular food. These processing operations generally offer the potential for a hazard to increase to an unacceptable level or the contamination (recontamination/cross-contamination) of the

Table 4. Primary Processing Operations and/or Steps^a

Operation/Step	Purpose	Hazards Associated	Preventive Measure
Receiving	May be used to prevent the introduction of inherent hazards into the process from raw materials/ingredients.	Improper controls will mean any hazard associated with a food (See Table 3) will reasonably be likely to occur and be introduced into the food processing process. Once introduced, preventive measures must exist for their control.	Obtain raw materials or ingredients from a suitable safe source. Visual inspection and temperature checks. Use of supplier certificates or vendor guarantees can be used to ensure hazard is not associated or reasonably likely to occur at receiving.
Formulation	May be used to eliminate or prevent growth of hazards (e.g., mayonnaise, cured meats) Combinations of salt, pH, a_w and/or other preservatives may inhibit growth.	Improper formulation will permit the survival or growth of hazards associated with raw ingredients (See Table 3).	Proper formulation of ingredients to achieve inhibition or elimination of identified hazards.
Drying	Used to remove water (lower water activity- a_w) from the product making it unavailable for bacterial growth. Drying must be rapid and sufficient so as to not permit growth of pathogens during the process and in the finished product. A water activity of 0.85 or below will inhibit growth of pathogens including toxin production by <i>S. aureus</i> (See Food borne Pathogenic Bacteria Section). May be used to prevent growth of pathogens.	Improper drying may permit the growth of hazards associated with the raw ingredients (See Table 3). If improper controls were in place before or during the drying operations hazards such as <i>Salmonella</i> or <i>S. aureus</i> enterotoxin may persist in dried product. Bacterial spores will not be inactivated by this process. Properly controlled drying will permit spores to persist (e.g., <i>B. cereus</i> , <i>C. botulinum</i> and <i>C. perfringens</i>).	Proper control of time, temperature, humidity, air flow, method of drying, and other factors affecting the rate and extent of water removal (drying) from the product.

Operation/Step	Purpose	Hazards Associated	Preventive Measure
Salting, or Brining (Pickling)	Used to bind or remove water (lower water activity - a_w) from the product making it unavailable for bacterial growth. Water removal results in partial replacement by salt in the tissue of the food. Salting or brining may be accomplished by either a dry (hard) cure or in a brine solution.	<p>Insufficient salting or brining may result in a salt concentration that is too low or a water activity that is too high to prevent growth of hazards associated with the product or processing environment. Bacterial spores will not be inactivated by this process.</p> <p>Properly controlled salting/brining will permit spores to persist (e.g., <i>B. cereus</i>, <i>C. botulinum</i> and <i>C. perfringens</i>).</p>	Proper application of salt, brine concentration along with control of time, temperature, and other factors affecting the rate and extent of salt addition or water removal from the product.
Sugar Addition or Cure	Used to remove water from product making it unavailable for bacterial growth. Sugar use in such products as jams and jellies could also be listed under the operation "Formulation".	Insufficient sugar may result in a sugar concentration that is too low or a water activity that is too high to prevent growth of food borne pathogens associated with the product or processing environment. Spores will not be inactivated by this process.	Proper application, sufficient sugar, along with control of time, temperature, and other factors affecting the rate, uniformity, and extent of sugar applied or incorporated into product.
Curing	A combination of ingredients which may include a number of factors (e.g., salt, nitrite, sugar, phosphates, polyphosphates, etc.) used to inhibit the growth of food borne pathogens. Often used in combination with a thermal process.	Insufficient curing by either too low a concentration of one or all the curing agents or non-uniform application (e.g. improper mixing blending, injecting, etc.) will permit vegetative food borne pathogens to grow. Insufficient curing in combination with a thermal process may permit <i>C. botulinum</i> spores to germinate, grow, and produce toxin.	Proper application of curing agents, concentration, along with control of time, temperature, and other factors affecting the rate, uniformity, and extent of cure applied to the product.

Operation/Step	Purpose	Hazards Associated	Preventive Measure
Acidification	<p>Used of acid to lower pH in foods and prevent food borne pathogen growth. Foods are divided into two groups based on pH: Low acid foods have a pH > 4.6; High acid foods have a pH ≤ 4.6. Acidification could also be listed under, or be a part of the operation "Formulation".</p>	<p>Insufficient acid addition or failure to reach an equilibrium pH ≤ 4.6 may permit <i>C. botulinum</i> spores to germinate, grow, and produce toxin. Some food borne pathogens are pH resistant and may persist at a low pH for a period of time (e.g., <i>E. coli</i> O157:H7 in acidic foods).</p>	<p>Proper application and sufficient quantity of acid(s) along with control of time, temperature, and other factors affecting the rate, uniformity, of acidification of the product.</p>
Fermentation	<p>Use of either naturally occurring microorganisms or starter cultures that breakdown carbohydrates and produce either edible acids, alcohol or other compounds that can inhibit microbial growth. Some fermentation result in a food product with a pH < 4.6. Some fermentations are used in combination with salt (pickling), sugar, or other preservatives to select for a particular type of fermentation and either inactivate or inhibit the growth of food borne pathogens.</p>	<p>Insufficient fermentation (e.g., starter culture failure, insufficient natural fermentative microorganisms, excessive contamination of raw ingredients, insufficient time to complete fermentation, or improper temperature) may permit the survival, growth, and/or toxin production by food borne pathogens. <i>S. aureus</i> may grow and produce enterotoxin before sufficient acid is produced to inhibit its growth. <i>S. aureus</i> enterotoxin may persist in foods even if reheated. <i>C. botulinum</i> may grow and produce toxin in foods where the pH was not lowered sufficiently by the fermentation to inhibit its growth. Bacterial spores will survive this process and should be considered if fermented food is used as an ingredient in a subsequent food.</p>	<p>Proper control of the process variables to ensure a sufficiently rapid and complete fermentation. Controls to ensure the sufficient pH or alcohol concentration is achieved in an adequate time frame so that hazards are not given the opportunity to grow.</p>

Operation/Step	Purpose	Hazards Associated	Preventive Measure
Smoking	Generally a combination of the application of smoke or smoke flavor along with salt, nitrite, other curing agents and/or application of heat.	Improper controls on time/temperature parameters may permit survival of food borne pathogens. Spores may survive this process. Insufficient or non-uniform application of smoke and/or curing agents may permit survival and growth of food borne pathogens. If appropriate heat treatment applied, but insufficient or non-uniform application of smoke or curing agents occur, <i>C. botulinum</i> may grow and produce toxin.	Proper controls on time, temperature, humidity, and other factors affecting the rate and extent of the smoking process. Proper controls on sufficient and uniform application of heat, smoke, and/or curing agents to destroy and/or inhibit the growth of hazards, particularly <i>C. botulinum</i> .
Cooling	Remove heat from food and lower to a temperature that will inhibit or reduce food borne pathogen growth. Foods should spend a minimal amount of time in the temperature range between 5°C (41°F) and 60°C (140°F). Foods should be cooled rapidly to 5°C (41°F) within a maximum of six hours [e.g., from 60°C (140°F) to 21°C (70°F) in two hours; and from 21°C (70°F) to 5°C (41°F) in four hours].	Insufficiently rapid cooling of previously heat treated foods may permit the germination and growth of sporeforming pathogens (e.g., <i>B. cereus</i> , <i>C. botulinum</i> , and <i>C. perfringens</i>). Insufficient cooling of other foods may permit rapid or increased growth of vegetative food borne pathogens.	Proper controls to ensure sufficient and rapid cooling of food product. Control of time, temperature, and other factors (i.e., product composition, thickness, or mass) affecting the cooling rate and extent of the process.
Freezing	Used to remove heat from food product and bring it to a temperature that will inhibit food borne pathogen growth. Also used to make water unavailable for food borne pathogen growth.	Improper controls on freezing the food product may permit temperature abuse and the growth of food borne pathogens associated with the product. It should be noted that generally gross temperature abuse must occur before food borne pathogen growth can become sufficiently rapid.	Proper controls on time, temperature, and other factors (i.e., product composition, thickness, or mass) affecting either the maintenance of the frozen state or the freezing rate and extent of the process.

Operation/Step	Purpose	Hazards Associated	Preventive Measure
Sanitizing Washes (i.e., washing vegetables or herbs)	Used to reduce hazards to acceptable levels or prevent cross-contamination in raw agricultural products such as vegetable, herbs, and/or fruits.	Improper controls may either permit excessive contamination with food borne pathogens to persist or cross-contamination of subsequently washed product.	Proper controls on the antimicrobial agent concentration in wash waters, contact time, uniform application, and sufficient water volume applied.
Thermal Processing (Heat Treatments)			
a) Blanching	Used principally to inactivate enzymes and set color in raw agricultural products, but can be used to destroy (kill) vegetative food borne pathogens.	Improper controls on time/temperature parameters may permit vegetative food borne pathogens to survive. Spores will survive blanching and should be considered, if product is to be placed in reduced oxygen conditions/packaging or used as an ingredient in a subsequent food.	Proper controls on time, temperature, humidity, and other factors affecting the rate of heat penetration, uniformity, and extent of lethality applied to the product (i.e., product composition, thickness, or mass).
b) Cooking, Boiling, Baking, Roasting, Frying	Cooking is a common term and is generally used to mean the application of sufficient heat to destroy vegetative food borne pathogens in the product.	Improper controls on time/temperature parameters may permit vegetative food borne pathogens to survive. Spores will survive cooking and should be considered, if product is to be placed in reduced oxygen conditions/packaging or used as an ingredient in a subsequent food.	Proper controls on time, temperature, humidity, and other factors affecting the rate of heat penetration, uniformity, and extent of lethality applied to the product (i.e., product composition, thickness, or mass).

Operation/Step	Purpose	Hazards Associated	Preventive Measure
c) Pasteurization	<p>Pasteurization is a term used in the dairy industry that has a legal meaning and has specific time/temperature parameters defined. The terms cooking and pasteurization are often used interchangeably since both use heat to achieve the same goal, the destruction (killing) of all vegetative food borne pathogens.</p>	<p>Improper controls on time/temperature parameters may permit vegetative food borne pathogens to survive. Spores will survive pasteurization and should be considered, if product is to be placed in reduced oxygen conditions/packaging or used as an ingredient in a subsequent food.</p> <p>Addition preventive measures are required to prevent the growth of <i>C. botulinum</i>.</p>	<p>Proper controls on time, temperature, humidity, and other factors affecting the rate of heat penetration, uniformity, and extent of lethality applied to the product (i.e., product composition, thickness, or mass).</p>
d) Sterilization	<p>Used to destroy (kill) all vegetative food borne pathogens and their spores and produce a "commercially sterile" product.</p>	<p>Improper controls on scheduled process (e.g., initial temperature, process time process, temperature, head space, maximum fill weight) may permit survival of food borne pathogens and/or their spores. <i>C. botulinum</i> spores could persist, germinate, grow, and produce toxin.</p>	<p>Proper controls on time, temperature, humidity, and other factors affecting the rate of heat penetration, uniformity, and extent of lethality applied to the product (i.e., product composition, thickness, or mass).</p>
Ionizing Radiation	<p>Similar to thermal processing in that amount of ionizing radiation applies can either destroy (kill) vegetative food borne pathogens or both vegetative and spores of food borne pathogens. Thus ionizing radiation can be divided in similar fashion as thermal processing (See above).</p>	<p>Insufficient or non-uniform application of ionizing radiation may permit food borne pathogens and/or their spores to survive.</p>	<p>Proper controls on amount of ionizing radiation received by the product and other factors affecting the extent of lethality applied to the product.</p>

Operation/Step	Purpose	Hazards Associated	Preventive Measure
Packaging	Used to prevent contamination of food product from environments. Modified atmosphere packaging (i.e., vacuum, controlled or reduced-oxygen packaging) can be used to inhibit growth of some food borne pathogens. May provide suitable environment for anaerobic pathogens (e.g., <i>C. perfringens</i> or <i>C. botulinum</i>).	Contamination of final product by contaminated packaging materials or faulty, leaking or damaged seals is possible if packaging materials and closing (sealing) operations are improper. If MAP used evaluation of the potential for <i>C. botulinum</i> growth and toxin production in that food is necessary.	Proper controls on package and seam integrity. Proper control of <i>C. botulinum</i> growth and toxin production if type of packaging provides opportunity for this hazard.
Storage Temperature	Used to maintain food at a temperature that will inhibit or greatly reduce the growth of food borne pathogens.	Temperature abuse may permit the growth of food borne pathogens or their spores in the product.	Proper controls on time and temperature that will inhibit or greatly reduce the growth of food borne pathogens. Proper and conspicuous labeling that conveys the need for continued persistent refrigerated, frozen, or other specified storage conditions.
Retail Food Handling or Consumer Handling	In certain instances the final safety of the food product depends on proper handling by the retail food handler or consumer. At times, these individuals will be responsible for proper storage temperature, cooking, reading the label for notification of allergens, etc.	Any hazard associated with a food (See Table 3) or introduced during the food processing process, and not controlled with preventive measures in the process will persist.	Labeling that is conspicuous and proper, that includes clear handling instructions for such things as storage temperature, cooking instructions, or ingredients (allergens).

*Table adapted from the following references: AC 1994; FDA 1994; IAMFES 1991; Shapton and Shapton 1991

food product if inadequate prerequisite programs and/or other improper controls exist. This is especially true when these processing operations (steps) follow a primary processing operation (step). All of these processes provide an opportunity for the contamination of the food from either poor employee hygiene, cross-contamination, improper employee handling, pathogen growth in product accumulations, environmental contaminants, or other improper hygienic or insanitary practices. In addition, most of these operations (steps) may provide an opportunity for temperature abuse of the food product. Sufficient temperature abuse may permit increased or rapid growth of some food borne pathogens to excessive levels. The excessive contamination may be sufficient to defeat or overcome any of the preventive measures used to destroy or eliminate food borne pathogens, or reduce them to acceptable levels. For example, temperature abuse during processing may permit *S. aureus* enterotoxin production to occur and subsequent preventive measures would not destroy this hazard.

Examples of secondary processing operations (steps) are provided in Table 5. Some of these operations (steps) may be used as a component or in tandem with some of the primary operations listed in Table 4. Considering the

Table 5. Secondary Processing Operations^a

Agglomerating	Condensing	Fruit/Nut Feeding	Pickling	Sizing
Air Agitating	Container Closing	Garnishing	Pitting	Skimming
Air Incorporation	Container Washing	Glazing	Premixing	Slicing/Cutting
Air Injecting	Conveying	Grating	Pressing	Stacking
Air Purging	Coring	Grinding	Product Holding	Storing
Assembling	Curd Milling	Handling of Food	Pumping	Straining
Back Stopping	Cutting/Slicing	Hardening	Reconstituting	Stuffing
Bagging	De-boning	Homogenizing	Rendering	Tempering
Battering	Dicing/Slicing	Incubating	Reverse Osmosis	Tenderizing
Blending/Mixing	Disposal of Waste	Inspecting/Sorting	Reworking	Thawing
Boning	Draining	Labelling	Ripening	Transferring
Box Forming	Emulsifying	Loading	Sampling	Trimming
Breading	Evaporating	Mechanical Separating	Scanning	Ultrafiltration
Breaking	Extracting	Membrane Processing	Sealing	Washing
Can Drying	Filling	Mixing/Blending	Seaming	Water Treating
Carton Forming	Flaking	Packaging	Separating	Waxing
Cheddaring	Flavoring	Palletizing	Setting	Whipping
Clarifying	Fluming	Peeling	Shipping	
Coding	Forming	Pelletizing	Sifting	

^aTable adapted from the following references: AC 1994; FDA 1994; IAMFES 1991; Shapton and Shapton 1991.

complexity and the dynamic nature of the food industry it is impossible to unequivocally state that all these operations are always secondary operations. The specific food, process, employees, facility, and the extent and effectiveness of prerequisite programs implemented to control these hazards may dictate whether these operations take on a greater or lesser importance in the safety of the food product.

B.8. Raw Material/Ingredient Hazard Analysis Decision Tree

The following decision tree approach to hazard analysis provides a practical step-wise approach to performing a hazard analysis (Figure 1.). All information derived from the hazard analysis should be recorded in a hazard analysis table (Table 6.). The questions in Figure 1 should be asked for each raw material/ingredient used in the food production. The first question asks, can a microbiological pathogen (MP) be associated with the raw material/ingredient (RM/I) used, the food product, or the type of processing/packaging that will be used? This question is intended to be all inclusive with any conceivable hazard being listed. In a HACCP Team's brainstorming session, like that proposed by Mortimore and Wallace (1994), no attempt should be made at this point to limit possible hazards. The reader may wish to consult the

I. [Ask the following questions for each raw material/ingredient, taking into account the overall food product (and intermediate components), and the type and conditions of processing, storage, distribution, and consumer handling).

#1. Can a microbiological pathogen (MP) be associated with either the raw material/ingredient (RM/I) used, food product, or type of processing or packaging that will be used?

↓ YES

List potential MP hazards present. Go to question #2.

↓ NO

No significant MP hazards. Go to next RM/I or Operational Step Questions. Include justification and preventive measures in table, if applicable

#2. Is a potential MP reasonably likely to occur?

↓ YES

Potential MP hazards present. Go to question #3.

↓ NO

No significant MP hazards. Go to next RM/I or Operational Step Questions. Include justification and preventive measures in table, if applicable

#3. Does MP need to grow and/or produce toxins to be a hazard?

↓ YES

Go to question #4.

↓ NO

Significant MP hazard(s). Go to next RM/I or Operational Step Questions.

Figure 1. Hazard Analysis Decision Tree I

#4. Will intermediate components or final food product support the growth of and/or toxin production by MP under intended and normal conditions of processing, storage, distribution, and consumer handling?

↓ YES

Significant MP hazard.
Go to next RM/I or
Operational Step
Questions.

↓ NO

Go to question #5.

#5. Do the intended and/or normal conditions of processing, storage, distribution, and consumer handling need to be controlled to prevent the growth of and/or toxin production by MP?

↓ YES

Significant MP hazard.
Go to next RM/I or
Operational Step
Questions.

↓ NO

Not a significant hazard.
Go to next RM/I or
Operational Step Questions.
Include justification and
preventive measures in table,
if applicable

Figure 1. Hazard Analysis Decision Tree I (con't)

Table 6. Hazard Analysis Table

Raw Material/ Operational Step	Potential Hazard	Significant Hazard	Justification for Exclusion	Preventive Measure

information in section II.B.3. and Table 3 for potential MP, but should not be limited to these choices. If there are no hazards associated with this raw material or ingredient (answer is NO to question #1), include justification and any preventive measures if applicable in the hazard analysis table, and then go on to the next RM/I and ask the RM/I decision tree questions again. If no more RM/I then go on to the Operation/Step questions (Figure 2).

If there are potential MP associated with the RM/I (Answer is YES to Figure 1/Question #1), then go to question #2. This is a key question that asks is the MP reasonably likely to occur. The guidance provided in section II.B.3. and Table 3 should provide this information. Section II.B.3. and Table 3 provide the MP that are reasonably likely to occur in RM/I and food groups. This information is meant to be a guide and may not cover every conceivable situation. Additional references can be used (e.g., AC, 1994), and the reader is encouraged to use their own experiences and common sense. Caution should be exercised when eliminating potential hazards since it is possible there will not be any preventive measure identified to control a wrongly eliminated hazard. If the potential MP is not reasonably likely to occur (answer is NO to question #2), include the

justification and any preventive measures if applicable in the hazard analysis table, either go to next RM/I and ask Figure 1 questions or if no more RM/I to consider go on to Operational (step) questions (Figure 2).

If the potential MP are reasonably likely to occur (answer is YES to question #2), they should remain on the list and go on to Figure 1/Question #3 which asks does the MP need to grow and/or produce toxin(s) to be a hazard. If the answer to Figure 1/Question #3 is NO, then the MP is a significant hazard that is reasonably likely to occur. The reader goes to the next RM/I and asks Figure 1 questions, or if no more RM/I to consider, go on to Figure 2 questions.

If the answer to Figure 1/Question #3 is YES, then potential MP is not necessarily a significant hazard, and Figure 1/Question #4, "Will intermediate components or final food product support the growth of and/or toxin production by microbiological pathogens (MP) under intended and normal conditions of processing, storage, distribution, and consumer handling?" should be asked.

If the answer to Figure 1/Question #4 is YES, then the MP is a significant hazard that is reasonably likely to occur. If the answer to Figure 1/Question #4 is NO, then the potential MP is still not necessarily a significant

hazard and Figure 1/Question #5 should be asked. The question asks "Do the intended and/or normal conditions of processing, storage, distribution, and consumer handling need to be controlled to prevent the growth of and/or toxin production by microbiological pathogens (MP)?"

If the answer is YES, then the potential MP is a significant hazard that is reasonably likely to occur. It is reasonably likely to occur in the RM/I and/or food product and it must grow and/or produce toxin(s) to be hazardous. This will occur unless some control (preventive measure) is used.

If the answer to Figure 1/Question 5 is NO, then the potential MP is not a significant hazard. Although the MP is likely to occur, it must grow and/or produce toxin(s) to be a significant hazard. The combination of two NO answers to Figure 1/Question #4 and Figure 1/Question #5 indicates that this growth and/or toxin production is impossible even without some type of control exerted. Include justification and any preventive measures if applicable in the hazard analysis table, and either go to next RM/I and ask Figure 1 questions, or if no more RM/I to consider, go on to Figure 2 questions.

When all RM/I have gone through Figure 1 decision tree, all significant hazards that are reasonably likely to

occur or be associated with the raw material/ingredient will have been identified. In addition, justifications for exclusion and preventive measures, if applicable, will have been identified and recorded in the a table. These hazards include food borne pathogenic bacteria that may be associated with a RM/I and not necessarily be a significant hazard in that RM/I (e.g., low levels of *B. cereus* spores in rice), but may be given the opportunity to be a significant hazard because of the operational steps or final product composition.

B.9. Food Processing Operation/Step Hazard Analysis

Decision Tree

The decision tree questions in Figure 2 should be asked for each operation/step in the flow diagram. Thus, it is important to have complete, accurate, and verified flow diagram. The first question asks can food borne pathogenic bacteria (FPB) be associated with this operational step or can this step provide an opportunity for contamination and/or introduction of a FPB in the absence of any prerequisite programs. Most likely the answer to this question is YES, and the FPB should be listed in the Hazard Analysis Table. The reader may wish to list FPB by type or in groups (e.g., vegetative enteric pathogens, or anaerobic sporeforming pathogens) rather than listing each bacterium

II. OPERATIONAL STEPS

[Ask the following questions for each operational step taking into account the overall food product (and intermediate components), and the type and conditions of processing, storage, distribution, and consumer handling.]

#1. Can microbiological pathogens (MP) be associated or introduced with this particular operational step either because there is a significant hazard associated with a RM/I from Figure 1, or can this step provide an opportunity for contamination and/or introduction of a MP?

↓ YES

↓ NO

List potential MP hazards present. Go to question #2.

No significant MP hazards. Include justification in table, and preventive measures, if applicable. Go to operational step question #4.

#2. Is a potential microbiological pathogen reasonably likely to occur?

↓ YES

↓ NO

Potential MP hazards present. Go to question #3.

Not a significant hazard. Include justification in table, and preventive measures, if applicable. Go to operational step question #4.

Figure 2. Hazard Analysis Decision Tree II.

#3. Does microbiological pathogen occur at a level that would cause the food to be unsafe for consumption?

↓ YES

Significant microbiological hazard. Go to operational step question #4.

↓ NO

Ask Raw Materials questions #3 through #5. Then go to operational step question #4.

(Modified Raw Material #3.) Will growth of microbiological pathogen (MP) to elevated numbers and/or production of toxins cause it to be a hazard?

↓ YES

Go to Raw Material Question #4.

↓ NO

Not a significant hazard. Include justification in table and preventive measures, if applicable. Go to operational step question #4.

(Raw Material #4.) Will intermediate components or final food product support the growth of and/or toxin production by microbiological pathogens (MP) under intended and normal conditions of processing of processing, storage, distribution, and consumer handling?

↓ YES

Significant microbiological hazard. Go to Operational Step Question #4.

↓ NO

Go to Raw Material question #5.

Figure 2. Hazard Analysis Decision Tree II (continued).

(Raw Material #5.) Do the intended and/or normal conditions of processing, storage, distribution, and consumer handling need to be controlled to prevent the growth of and/or toxin production by microbiological pathogens (MP)?

↓ YES

↓ NO

Significant microbiological hazard. Go to Operational Step Question #4.

Not a significant hazard. Include justification in table, and preventive measures, if applicable. Go to Operational Step Question #4.

#4. Are there any significant hazards associated with the food from this or previous steps or raw materials?

↓ YES

↓ NO

Significant hazard still associated with food or process. Go to question #5.

END-Go to next operational step in flow diagram and repeat questions. No significant hazard introduced up to this point.

#5. Is this step intended to fully or partly control one or more significant hazards?

↓ YES

↓ NO

Step is a PREVENTIVE MEASURE for one or more significant hazards. Include in table and Go to question #6.

Significant hazard still associated with food or process. Go to question #7.

Figure 2. Hazard Analysis Decision Tree II (continued).

#6. Are there still significant hazards associated with the food from this or previous steps or raw materials that this step did not control?

↓ YES

↓ NO

Significant hazard still associated with food or process. Go to question #7.

END - Go to next operational step and repeat questions.

#7. Is this the last operational step?

↓ YES

↓ NO

Significant hazard must have some type of PREVENTIVE MEASURE. Modify ingredient(s), food, or process.

Go to next operational step and repeat questions.

Figure 2. Hazard Analysis Decision Tree II (continued).

separately. No attempt should be made at this point to limit possible hazards. The reader may wish to consult the information in section II.B.3. and Table 4 for potential FPB, but should not be limited to these choices. After the FPB are listed, the reader next asks Figure 2/Question #2 of each FPB or group of FPB listed. If the answer is NO to Figure 2/Question #1, no significant hazard can be associated with this operation (step). The justification and any preventive measures, if applicable, for this answer should be placed in the appropriate column of the Hazard Analysis Table, and the reader next asks Figure 2/Question #4.

Figure 2/Question #2 asks if the FPB is reasonably likely to occur. The reader should consult Table 4 for those hazards reasonably likely to occur with primary processing Steps in the absence of control and take into account the significant hazards associated with the RM/I (from Figure 1) used in the operation (step). Thus, some of the potential FPB will have already passed the reasonably likely to occur test in the first decision tree. If the answer to Figure 2/Question #2 is NO, then the potential FPB that could have contaminated or been introduced, is not a significant hazard because it is not reasonably likely to occur. The reader should include the

justification for excluding the potential FPB, and if it is because of actions taken within a prerequisite program, include the preventive measure(s) in the appropriate columns in the Hazard Analysis Table. An example of this would be, if a potential FPB could be introduced or contaminate a food because of contaminated food contact surfaces (Figure 2/Question #1-YES). The reader may justify a NO answer to Figure 2/Question #2 by explaining that the appropriate sanitation prerequisite programs are effective and documented, and thus contaminated food contact surface are not reasonably likely to occur. The reader would include "Sanitation prerequisite Programs" in the Justification column and "Preparing cleaning and sanitized food contact surfaces" in the Preventive Measure column in the Hazard Analysis Table (Table 6). The reader would then go on and ask Figure 2/Question #4.

If the answer to Figure 2/Question #2 is YES, then the potential FPB is reasonably likely to occur, but still may not be a significant hazard. An example of this would be a low level contamination with *S. aureus* that is reasonably likely to occur, but not a significant hazard unless provided the opportunity to increase to elevated numbers and produce enterotoxin. The reader then goes on to Figure 2/Question #3 which asks does the potential FPB occur at a

level that would cause the food to be unsafe for consumption. This question, and the series of possible questions (depending on how Figure 2/Question #3 is answered), address in part the infective dose issue. For some toxins or FPB with a very low infective dose, just the presence of the toxin or FPB is a hazard, and for other hazards there must be present in high numbers, grow to high numbers, or produce toxins.

If the answer to Figure 2/Question #3 is NO, then the FPB or toxin was introduced or contaminated at a level that is not a hazard and the reader is directed to ask a modified series of Raw Material/Ingredient Decision Tree questions #3 through #5. Significant hazards associated with the RM/I used in the operation (step) and that have already been through these series of questions, need not repeat the process here and reader may go on to Figure 2/Question #4. The modified RM/I questions, as previously described, walk the reader through the hazard analysis and address the issue of the contamination or induction of a low level of FPB, that may not be a significant hazard at that low level, but can be if growth to elevated numbers or toxin production occurs. If the answer to Figure 2/Question #3 is YES, then the reader records that a significant hazard exists in the Hazard Analysis Table, and

goes on to Figure 2/Question #4.

This question asks if there are any significant hazards associated with the food from either this operation (step), previous operations (steps), or raw materials/ingredients. If the answer is NO, there are no significant hazards that have been introduced or remain at this operation (step) and the reader is directed to go to the next operation (step) in the flow diagram and repeat questions. If the answer to Figure 2/Question #4 is YES, then significant hazards have either been introduced, or are still associated with the operation (step) (Table 4), or raw material/ingredient (Figure 1). The reader is directed to go on to Figure 2/Question #5 when significant hazards still exist.

Figure 2/Question #5 asks if this operation (step) is intended to fully or partly control one or more significant hazards. If the answer is NO, then significant hazards will still exist with the process or food product and the reader is directed to Figure 2/Question #7. If the answer to Figure 2/Question #5 is YES, then this operation (step) is a PREVENTIVE MEASURE and should be recorded in the Hazard Analysis Table (Table 6).

The question is asks whether the step is intended to fully or partly control one or more significant hazards

because some preventive measures may control several different hazards or a whole hazard group (e.g., vegetative bacterial pathogens), and some hazards may require several preventive measures in combination or sequence. The reader should be aware that if several preventive measures (partial controls) are used in combination or sequence, as the last partial preventive measure in that combination or sequence goes through the decision tree questions the significant hazard should be considered fully controlled. Once a significant hazard has been fully controlled by a preventive measure it can be considered not reasonably likely to occur from that point on (provided there is no other operation/step that negates a preventive measure, i.e., adding water back to a dried product). Thus, a significant hazard associated with a raw material/ingredient in the food that is fully controlled (e.g., thermal process), would still be associated with the food (because it is associated with the RM/I) when the next operation (step) after the thermal process is considered in the decision tree questions (Figure 2/Question #1). However, the significant hazard will no longer be reasonably likely to occur and will fall out of the decision tree at the second question (Figure/Question #2).

After answering Yes to Figure 2/Question #5 and

recording the preventive measure, the reader is directed to Figure 2/Question #6 which asks if there are still significant hazards associated with the food from either this operation (step), previous operations (steps), or raw materials/ingredients that the preventive measure did not control.

If the answer is NO, then there are not significant hazards associated with the food and process up to this point and the reader is directed to go to the next operation (step) and repeat the questions. If the answer is YES, there are still significant hazards associated with the food or process. The reader is then directed to go to Figure 2/Question #7 which asks is this the last operation (step) in the flow diagram. The purpose of this question is to ensure that all significant hazards have been addressed and that preventive measure exist. If the answer is NO, the reader is directed to go to the next operations (step) and repeat Figure 2 questions. Even though significant hazards are still associated with the food or process, there are subsequent operations (step) that may control the hazards. If the answer to Figure 2/Question #7 is YES, it means that significant hazards are still associated with the food or process for which a preventive measure does not exist. The reader is instructed to modify

the food or process so that all significant hazards are controlled. Certainly one does not need to go through all operation (step) decision tree questions to find out a hazard is uncontrolled, and common sense might permit the reader to modify the food or process at the beginning or midway through the decision tree if it becomes obvious a hazard has been identified for which there is no preventive measure. The value of this decision tree process is that: (1) it walks the reader through all the considerations that should be addressed for each raw material/ingredient and operation (step) in the flow diagram; and (2) it will not permit the reader to go forward with identifying CCPs until all significant hazards have a preventive measure.

Currently, this second point is handled by the CCP decision tree (Codex, 1993; NACMCF, 1992). The use of this author's practical decision tree approach for hazard analysis will make the first CCP decision tree question unnecessary. This makes sense since one should not have to find out in the second step of the process that an omission and subsequent modification needs to be made in the first step of the process. There is little reason to wait until identifying CCP's to find out what should be obvious during a properly performed hazard analysis. The guidance provided on how to perform a hazard analysis for FPB should

be considered a basic structure for similar decision trees that could be developed for other biological, chemical and physical hazards. The author also realizes that this method for performing a hazard analysis may not be universally applicable to all foods and food processes, but he feels it provides the best and most complete guidance to date. A hypothetical example on how to perform a microbiological hazard analysis using the guidance provided for a Swiss Cheese HACCP plan is attached in Appendix B.

III. RISK ANALYSIS

Risk analysis has its origins in determining the relative likelihood of harm posed by chemicals, either man-made or natural, which may be exposed to humans. The basic procedures and information for performing risk analysis can be traced back hundreds of years, however, risk analysis is a relatively new discipline (Cohrssen and Covello, 1989). Risk Analysis is a process that involves three components: risk assessment, risk management, and risk communication (Hathaway, 1994b). Cohrssen and Covello state that risk analysis involves not only the technical assessment of the nature and magnitude of risk (risk assessment), but also the methods to best use the resulting information (risk management and risk communication).

A. Risk Assessment

Risk assessment has been described different ways but most definitions include the components of an objective and scientific assessment of the severity and likelihood of an adverse health effect. The report *Risk Assessment in the Federal Government: Managing the Process* (NRC, 1983) defined risk assessment as the qualitative or quantitative characterization of the potential health effects of particular substances on individuals or populations. Cohrssen and Covello (1989) defined risk assessment as the

technical assessment of the nature and magnitude of risk.

Pariza (1992) stated that risk assessment is an analytical process based on technical information and statistical probabilities. He went on to describe risk assessment as a mechanism for identifying and analyzing potential dangers (risk) in a rational manner, so that appropriate strategies for response can be developed.

Hathaway (1994b) felt that risk assessment can be regarded as the estimation of the severity and likelihood of harm or damage resulting from exposure to hazardous agents or situations.

The NRC report described risk assessment as consisting of four separate steps (NRC, 1983). They are hazard identification, dose-response assessment, exposure assessment, and risk characterization. The Council for Agricultural Science and Technology (CAST) report *Foodborne Pathogens: Risk and Consequences* described each of the following four steps in terms of food borne pathogens (CAST, 1994).

1. Disease characterization/hazard identification: determining whether a chemical, microorganism, or other substance is linked causally thorough food consumption to human health. Pathogens can enter the food chain at many points from farm or sea to

consumer. Depending on the food, organism, and processing or handling conditions, they may survive, grow, die, and/or produce toxins.

2. Dose-response assessment: determining the relationship between the magnitude of exposure and the probability of infective or toxic doses necessary to cause illness from various pathogens differ greatly. Ingestion of greater numbers of microorganisms or concentrations of toxins may result in shorter incubation time and/or more serious disease. Type and amount of food in which the disease agent is consumed may influence the infective or toxic dose. People differ greatly in their susceptibilities as a result of genetics, age, medication taken, stomach acidity, immune status, and health status.
3. Exposure assessment: determining the extent of human exposure before or after application or regulatory or voluntary controls. Exposure will differ: (a) by types of the foods likely to contain certain pathogens; (b) by region of the country (climate affects growth and/or survival of microorganisms, and both climate and population affect likelihood of human contact);

(c) by trading patterns; and (d) by animal husbandry, food-processing, food-preparation, and food-consumption practices.

4. Risk characterization: quantifying cases and case severity, and identifying economic and social impacts of human risk (a) by estimating the costs associated with the impact on selected populations, regions and industries; and (b) by assessing the willingness to pay for risk reduction.

Hathaway (1994b) described the four step process of risk assessment in a slightly different manner.

1. Hazard identification: the qualitative indication that a substance/agent may adversely affect human health;
2. Hazard characterization: the qualitative and quantitative evaluation of the nature of the adverse effects, and may include a dose-response assessment;
3. Exposure characterization: the qualitative and quantitative evaluation of the degree of human exposure likely to occur; and
4. Risk characterization: integration of the above steps into a quantitative estimation of the

adverse effects, likely to occur in a given population, and to be used in decision-making.

The NACMCF created a risk assessment subcommittee in 1993 and in a draft report established a set of five principles/procedures for microbiological risk assessment. The draft included hazard identification, exposure assessment, dose-response (infectious dose) assessment, severity assessment, and risk characterization (Archer, 1993). The draft report noted that microbiological risk assessment presents even more challenges than those encountered when doing chemical risk assessment. Because of the uncertainties associated with microbiological risk assessment, numerous assumptions must be made before a quantitative assessment of the risk of microbiological pathogens can be made.

Pariza (1992) reported that risk assessments are not meant to estimate actual risk, but to be used as tools in prioritizing and suggesting types of regulatory response. He stated that there are many uncertainties in risk assessment and for each of those uncertainties conservative assumptions should be made to ensure that risk is not underestimated. Thus, the greater the uncertainty about a given effect, the more likely it is to be overestimated. Risk assessments, as currently performed, are the products

of very conservative, restrictive calculations and assumptions about complex biological phenomena. Many reports agree that the absence of key and necessary data creates these uncertainties and requires greater estimations that provide the grounds for disagreements on the conclusions of microbiological risk assessments (CAST, 1994; Cohrssen and Covello, 1989; Fishchhoff, 1985; NRC, 1989; Pariza, 1992).

B. Risk Management

Risk management is the second component of risk analysis. The NRC report defined risk management as the process of weighing policy options and selecting the most appropriate regulatory action, but integrating the results of the risk assessment with engineering data, and with social, economic, and political concerns to reach a decision (NRC, 1983). Some other factors that are important in determining risk management priorities include the technical controllability of the risks and the psychological aspects of the risks (e.g., degree to which risks are voluntary, familiar or equitable).

During the performance of a risk assessment there may be an absence of data or a clear indication based on science. One may then be forced to choose a particular approach based on how conservative it is. This may result

from a desire to err on the side of overprotection of the public health. Such judgements made during the risk assessment are designated risk assessment policy, and should not be confused with policy issues affecting risk management decisions. Separation of risk assessment and risk management has been considered beneficial (NRC, 1983; US DHHS, 1986; Hathaway, 1994b). However, separating the scientific findings and risk assessment policy from the societal, economic, and political policy considerations involved in risk management is becoming more interlaced (Hathaway, 1994b). The NRC report (1983) agreed that it may be hard to disentangle the policy considerations in risk assessment from risk management. In fact, the report concluded that risk assessment cannot be made completely free of policy considerations.

Cohrssen and Covello (1989) state risk perceptions are important and can influence both risk assessment and risk management. People perceive risk differently depending on whom the hazard will adversely affect, how widespread, how familiar, how dreaded the effects are, whether individuals voluntarily agreed to accept the risks, and whether there are benefits derived from accepting the risks.

Risks can be expressed several different ways and the choice has important implications for risk management

(Fischhoff, 1985). Decisions need to be made on what particular measure or measures are to be used to characterize the risk. Several approaches have been used, sometimes in combination, to help decision makers choose an acceptable level of risk. Generally there has been no numerical level of risk that has received universal acceptance. Most of the time decision makers rely on scientific and technical experts to determine an acceptable level of risk. Margins of safety or safety factors are used sometimes to protect susceptible individuals, account for worst-case scenarios, or because of uncertainties associated with estimations (Cohrssen and Covello, 1989).

Some analysts use a method of comparative risks to help determine an acceptable level of risk. This involves comparing a risk with risks that individuals or a society have already decided to accept. Another approach involves a comparison of risk with the risks of natural hazards (e.g., lightning strikes) as a basis for acceptable risk decisions. All of these techniques have drawbacks (Fischhoff et al., 1981) especially when expert judgements are needed due to the highly scientific data interpretations are involved. Acceptable risk levels have been upheld by the courts when they were believed to be reasonable. Unfortunately, reasonableness is usually left

undefined in the law, and thus it is left to each regulatory agency and the courts to determine what constitutes a reasonable decision about acceptable risk (Cohrssen and Covello, 1989).

C. Risk Communication

Risk communication is the component of risk analysis where all affected parties exchange information about the levels of health or environmental risks, the significance of the risks, and the decisions actions, or policies aimed at a managing or controlling the risks. Some believe that risk communication should be a part of risk management and can used to encourage risk reduction rather than legislate risk reduction (Kamrin, 1991; cited in Spencer, 1993). Hathaway (1994b) stated that an effective risk management process should evaluate the effectiveness of the risk reduction options chosen and it should effectively communicate and promote an understanding of the decision (DHHS, 1986).

Whether risk communication is a separate component of risk analysis or a part of risk management, if done poorly it can negate an objective risk assessment and proper risk management decisions. Pariza (1992) pointed out that the lay public tends to focus on risk perceptions whereas experts deal with risk assessments. Risk perception is not

an analytical process and is based on inferences, not scientific data. Risk perceptions may have no correlation to actual risk and can be influenced by degree of choice, degree of control, and derived benefits of the risk.

Cohrssen and Covello (1989) state there are difficulties in risk communication that arise from message problems, source problems, channel problems, and receiver problems. Message problems arise from detailed and highly technical data that result in large uncertainties or cannot be understood by the lay public. Source problems consist of lack of trust in the authorities, disagreements among scientific experts, and use of bureaucratic, scientific and/or technical language. Channel problems can include selective and biased media reporting, premature disclosure of scientific findings and distortions or inaccuracies in interpretations. Receiver problems include inaccurate perceptions of risk, lack of interest in risk problems, overconfidence in one's ability to avoid harm, reluctance to make trade-offs between risks, costs and benefits (Spencer, 1993).

D. Microbiological Risk Assessment

The Council for Agricultural Science and Technology (CAST) published a report in 1994 whose objective was to estimate risk and consequence of human illness from

microorganisms contaminating food in the United States and to explain the complexities resulting in specific risks for populations and individuals (CAST, 1994). The report followed the risk assessment approach of the National Academy of Sciences (NAS) (NRC, 1983). The NAS report became the basis for other studies on the risk of food borne illness. *Meat and Poultry Inspection: The Scientific Basis of the Nation's Program* (NRC, 1985) and *Poultry Inspection: The Basis for a Risk-Assessment System* (NRC, 1987).

Recently, there has been an increased interest for the use of microbiological or food borne disease risk assessment (CAST, 1994). The U.S. General Accounting Office (1992) in its report *Food Safety and Quality: Uniform, Risk Based Inspection Needed to Ensure Safe Food Supply* stated that risk assessment is "an essential principle of an efficient and effective inspection program necessary for protecting public health." The National Advisory Committee on Microbiological Criteria for Foods created a risk assessment subcommittee in 1993. The Codex Alimentarius Commission has asked its committees to describe their use of risk assessment, and the Code of Hygienic Practice for Fresh Meats advocate a risk analysis approach and risk assessment models have been described

(Hathaway and McKenzie, 1991; Hathaway, 1994a). EC Council Directive 93/67/EEC was issued laying down the principles for risk assessment of risks to man and environment of certain substances identified in an earlier EC directive (Council of European Communities, 1993).

Risk assessment and cost-benefit analysis are currently important issues in Congress. The House of Representatives has passed a bill (H.R. 1022) that would have agencies carry out scientifically objective, unbiased best estimates of risk. It would require an assessment of substitution risks and of incremental costs and benefits of alternative risk management options. This legislation would require that agencies certify "that the incremental risk reduction or other benefits of any strategy chosen will be likely to justify, and be reasonably related to, the incremental costs incurred...". In addition, the Senate is currently working on risk reform legislation by developing a consensus version of three proposed bills (S.291, S.333, and S.343) in order to bring the blended bill to the floor for a vote early in the summer of 1995. All of these bills propose judicial review and risk/cost-benefit analytical requirements (Anon., 1995). The Food and Drug Administration (FDA) supports the appropriate use of risk assessment and believes that it exercises its

regulatory discretion to minimize the impact on affected industries while acting to protect the public health (Troxell, 1995). In addition, Executive Order 12866 of October 4, 1993 requires that agencies assess the costs and benefits of available regulatory alternatives and choose the one that maximizes net benefits unless a statute requires another regulatory approach (Clinton, 1993).

The CAST report (CAST, 1994) noted there are difficulties with applying the risk assessment approach in food microbiology. Performing microbiological risk assessments is a difficult task because universally agreed upon procedures have not been established. Unlike chemicals, microbiological organisms may not remain static in the food (i.e., their populations may either increase, decrease, or both). They may produce toxins in the food during this time that may or may not be destroyed by processing. There are insufficient data on infective dose, exposure and consumption patterns, host-pathogen relationships, and disease outbreaks. Issues of sample size, non-homogeneous distribution of pathogens, and detection protocol, all affect test results, especially because some food borne pathogens have a low infective dose. Another difficult variable is identification of the true occurrence of acute illnesses from food borne sources.

The more serious the illness, the more likely it will be detected and the food borne illness cause is more likely to be identified when symptoms are distinctive, rather than general. Equally difficult to address are chronic sequelae, possibly of long duration, such as neurological, cardiac, or rheumatoid syndromes, that can occur after food borne infection (Archer, 1984, 1985; Mossel, 1988). The secondary spread of illnesses is another variable that presents challenges to microbiological risk assessment. These illnesses are unlikely to be either identified or linked to a food borne cause. Finally, the carrier state presents another important variable because infective microorganisms can be transmitted directly to individuals by the fecal-oral route or indirectly through food. There also exist great variability in the host-pathogen response which often depends on many unknown variables (CAST, 1994).

These difficulties and more were highlighted in what has been called the "Breckenridge Report" (Sobsey et al., 1991). The report was an exploration of the applicability of the NAS paradigm for chemical risk assessments to microbial risk assessment in drinking water. The report highlighted the previously mentioned current information deficiencies or gaps and identified many more. More importantly the report pointed out there does not exist a

uniform and accepted approach to performing microbial risk assessment, or what should be included. In addition, the report stated that because there is a lack of formalized approaches to risk characterization for microbes in drinking water, it was not possible to define the elements of a risk management strategy and plan. The report noted that information deficiencies or gaps even existed in risk management options (i.e., indicator organisms) for microbes in drinking water. This did not prevent the group from recommending that HACCP is a unified concept for management strategy that could be defined, tested, and implemented as a management plan for drinking water quality. The report stated, that given the obvious parallels between food production and producing drinking water, clearly the HACCP concept could be adapted to the production of drinking water as a management system for microbiological risks.

Even with the uncertainties noted by the above groups, microbiological risk assessments have been described in several studies (Gerba and Haas, 1988; Macler and Regli, 1993; Peeler and Bunning, 1994; Regli et al., 1991; Rose and Gerba, 1991; Rose et al., 1991; Rose and Sobsey, 1993). Most of these investigations involve the use of models where the microbiological agent is either a virus or protozoan cyst and is uniformly distributed in drinking

water (Gerba and Haas, 1988; Regli et al., 1991; Rose and Gerba, 1991; Rose et al., 1991). Rose and Sobsey (1993) performed a quantitative risk assessment for viral contamination of shellfish and coastal waters. Peeler and Bunning (1994) described a hazard assessment that quantitatively assessed the likelihood of a hazard (*Listeria monocytogenes*) occurrence in milk.

The reported risk assessments in drinking water have all dealt with hazards (viruses, protozoan cysts) that do not proliferate in the medium. The assumptions made in these risk assessments generally can not be made for food borne pathogenic bacteria in foods. These risk assessments are based on repeated exposure of an estimated quantity (2L/day) of a product (drinking water) that has an estimated hazard concentration in a homogenous distribution. More importantly, infective dose models exist for the hazards used in these studies. These factors permit a quantitative risk assessment for certain hazards in drinking water.

Rose and Sobsey (1993) published one of the first attempts at quantitative risk assessment for microbiological hazards in foods (bivalve molluscan shellfish). They defined quantitative risk assessment as a statistical estimate of the probability of an event taking

place based on exposure and dose-response models. The authors noted that, although risk assessment approaches have been used for estimating human health impacts from chemical contaminants, using the approach to evaluate the hazard with exposure to microbial agents was relatively new, and at the time, had only been used for drinking water. They used the four fundamental steps used in formal risk assessment. The hazard identification involved an evaluation of epidemiological evidence and current literature that determined the viral hazards associated with contaminated shellfish. The dose-response assessment used a beta-poisson model previously described by Haas (1983) that was used to estimate the risk of low doses of microorganisms. These models were possible because dose-response experiments with human volunteers had been conducted for a variety of viral agents. The exposure assessment was calculated by estimating the numbers of viral plaque forming units (PFU) per gram of shellfish times the number of grams ingested. The per capita consumption of shellfish provide an estimate of the total grams ingested per year, however, the authors used a single serving as a better estimate of risk. They used two serving sizes (60 and 240 grams per serving) which provided a low and high dose exposure level. They used the results

of several scientific studies on the occurrence of viruses in shellfish, and determined an average PFU/100 grams of shellfish from approved waters. The risk characterization was determined by multiplying the probability of infection (for two different viral agents at the two exposure levels) and the morbidity and mortality rates for the viral agents to determine the risk of disease and death. Their risk characterization, based on an average virus level of 6 PFU/60 gram, described the risk of an individual consuming a single serving of shellfish harvested from U.S. approved waters as having a 1 in 100 probability of becoming infected with a moderately infectious enteric virus. When a more infectious viral agent was used (rotavirus) in the model, the risk increased to 5 in 10 probability of becoming infected.

This particular use of quantitative risk assessment for microbiological hazards in shellfish benefitted from several important pieces of information that are not available for use in other microbiological risk assessments and from some intrinsic characteristics of viruses and raw shellfish. The authors admitted that they had essential information that permitted the quantitative risk assessment. One of these was the existing models that allowed the probability of infection after exposure to be

estimated. The other was the monitoring data that allowed an exposure level to be calculated. The use of probability models to estimate the risk of infection after varying doses of bacteria, viruses, and protozoan cysts was described by Haas (1983). Extension of models to food borne pathogenic bacteria in cooked foods has not been attempted, in part, because pathogen levels are unknown. There is greater uncertainty associated with infective doses for bacteria than for viruses. In addition, each food borne pathogenic bacterium and each host population would characterize a separate model. The exposure to food borne pathogenic bacteria would have to account for such variables as the initial concentration, processes which decrease that level, environmental conditions (before and after processing) that could increase or decrease numbers, and the amount of food consumed.

One of the intrinsic characteristics stated by Rose and Sobsey was the microbial hazards identified in the quantitative risk assessment. Enteric viruses are obligate human pathogens and do not replicate outside the human host. Thus, unlike most other food borne pathogenic bacteria that can either increase, decrease, or produce toxins while present in the food product, the authors only had to address a static population of viral agents. In

addition, raw shellfish are not cooked, so the additional variables of surviving the thermal process and cross-contamination did not need to be addressed. Even in the absence of these compounding variables, the authors noted that several assumptions are made regarding both the model and exposure, and that these assumptions may overestimate or underestimate the true risks. Finally, the authors concluded that quantitative risk assessment could be used to characterize water quality and lead to a risk-based classification of coastal waters, development of appropriate monitoring strategies, and better control strategies.

Peeler and Bunning (1994) used risk assessment techniques to perform what the authors called a hazard assessment for *L. monocytogenes* in the processing of bovine milk. Based on the steps involved in Grade A production of milk, they quantitatively assessed the likelihood of the hazard (*L. monocytogenes*) and the magnitude (concentration) of the hazard being present in the product after pasteurization. This investigation is similar to the risk assessments performed with drinking waters in that the authors were working with a hazard that was assumed to be uniformly distributed in a homogenous fluid. However, unlike previously reported risk assessments. Peeler and

Bunning addressed a hazard that could proliferate in the food product during the processing stages. They concluded their investigation was limited to a hazard assessment rather than a risk assessment because the infective dose for *L. monocytogenes* was unknown.

The authors were able to show the effect on the final concentration of *L. monocytogenes* in milk after the pasteurization step when one variable (processing operation/step) at a time was assumed to be out of control. The authors reported that under normal conditions, the probability was less than 2 in 100 that one *L. monocytogenes* cell occurs in every two gallons of milk processed at exactly 71.7°C for 15 seconds. If processing conditions were the more normally used 74.4°C for 20 seconds, the probability was less than 2 in 100 that one *L. monocytogenes* cell occurs in every 3.8×10^{10} gallons. They stated that based on this exercise, two variables, temperature of storage and transport, and time and temperature of pasteurization were the critical control points in the process.

Peeler and Bunning noted that there were subsequent processing steps beyond the pasteurization operation and that a post-processing contamination would nullify precautions taken before the pasteurization and the

pasteurization operation itself. The authors did not take their hazard assessment beyond the pasteurization step. To do this, they would have had to assess the fate of their calculated *L. monocytogenes* concentration based on a certain shelf-life and temperature conditions while compensating for a competing microflora. Even if these calculations were performed, without knowing the infective dose for *L. monocytogenes*, the investigation would be limited to a hazard assessment (as opposed to a risk assessment). Only when an infective dose is known (or can be estimated) can a risk characterization quantitatively express the nature and magnitude of the adverse health effects of a hazard at a certain concentration in a food.

Microbiological quantitative risk assessment is a scientific discipline that is in its infancy. Attempts are underway in the Codex Alimentarius Commission Committee on Food Hygiene to develop uniform Codex definitions for risk analysis and particularly for the principles for chemical and microbiological food risk assessment. Additional efforts have been undertaken by other groups such as the International Life Sciences Institute's (ILSI) Risk Science Institute (sponsored by the Environmental Protection Agency) to develop a framework for microbiological quantitative risk assessment, and achieve wide acceptance

for it in the scientific community. Although there are substantial difficulties, variables, and knowledge gaps involved with microbiological risk assessment, the process holds promise to scientifically and objectively define and describe the risks associated with identified hazards in our food and food production and preparation practices.

E. Relationship Between Risk Analysis and HACCP

Risk assessment is one part of risk analysis. It is a scientifically-based and objective procedure used to estimate the probability of adverse health effects from a specific hazard/source under particular exposure conditions (Reinert et al., 1991). Risk management incorporates risk assessment data with social, economic, and political information to decide either how or whether to reduce or eliminate the potential risks identified in the risk assessment (Reinert et al., 1991). Risk communication plays an important part in the process because it conveys the risk management decisions and rationale for those decisions. Effective risk communication can even play a part in modifying behavior or practices that can reduce or eliminate the potential risks identified in risk assessments.

Risk assessment is generally used by the regulatory community to characterize the risk of hazards (chemical

exposure, food borne illness) that effect entire or large portions of populations and to facilitate the development of national or broad risk management and risk communications strategies for that hazard.

The use of risk analysis began with risk assessments of chemical hazards and developing the risk management and risk communication strategies to either establish safe exposure limits for the population or reduce or eliminate the potential risks. The use of risk analysis for microbiological hazards suffers from the lack of a defined procedure for its performance and that greater information gaps exist for necessary variables than with chemical hazard variables. This is not to say that chemical risk assessment does not have information gaps or areas of controversy (i.e., extrapolation from animal studies to human effect levels). The Codex Alimentarius Commission Committee on Food Hygiene is currently trying to establish within Codex the principles for conducting and employing chemical and microbiological risk assessments for estimating qualitatively, and where applicable quantitatively, the impact of food production, processing, distribution, and marketing practices on the risks associated with foods in international trade. The Committee has strongly recommended the development of

uniform Codex definitions for risk analysis and particularly for principles for chemical and microbiological food risk assessment.

One area that microbiological risk assessment has an advantage over chemical hazards (e.g., carcinogens) is that a reporting system for infectious disease does exist. There is general agreement that this system is imperfect and that many diseases are underreported. However, at least estimates of the amount of underreporting can provide an idea of the true number of cases involved in an area, such as illnesses caused food borne pathogenic bacteria (Bennett et al., 1987). This reportable disease surveillance mechanism run by the Centers for Disease Control and Prevention (CDC) allows a risk characterization (a description of the nature and magnitude of the risk from a hazard) in all foods on broad categories of food (e.g., meat and meat products) without precise information from the first three steps of risk assessment (hazard identification, hazard characterization/dose response assessment, and exposure assessment). This has been attempted in several reports (Roberts and Foegeding, 1991; CAST, 1994) where the number of reported cases can be used to estimate the total number of food borne illnesses resulting from specific food borne microorganisms, and

factoring in such variables as likely deaths, chronic sequelae, secondary and/or tertiary and their associated costs, a risk characterization that describes the nature and magnitude of each specific food borne pathogenic microorganism in the entire food supply. The reporting system along with epidemiological investigations can also provide estimates on where the risks originate or their causes (e.g., failure to proper temperature control) and the number of cases resulting from a particular hazard and cause (Bryan, 1988a; Bryan, 1988b).

If there was a theoretical reporting system for cancer cases where the cause of cancer could be determined in at least some percentage of the cases (e.g., 10% of one type of cancer is the result of exposure to a particular concentration of chemical over a lifetime), a risk assessment could use those reported cases as a basis for a chemical risk characterization that is similar to those reported for food borne pathogenic microorganisms.

The fact that a uniform procedure for performing microbiological risk assessment does not exist should make it difficult to say what its relationship to HACCP is, or what it may be in the future. HACCP, as the concept is currently accepted (Codex 1993; NACMCF, 1992), does not need a formal risk assessment performed to effectively

ensure the safety of food. HACCP can be considered a risk management tool used to control specific food safety hazards. An example of this relationship is provided in the CAST report (1994). The report determined an overall (broad) risk assessment of food borne disease for the food supply. Based on the nature and magnitude of the problem recommended a risk management option or control strategy that involved the use of HACCP by the food industry. The use of HACCP is far more focused than the broad issues addressed by risk assessment. HACCP involves the specific hazards associated with a specific food product in a specific food facility (and maybe a specific line or area within that facility). The use of HACCP as a risk management tool does require a hazard analysis be performed for specific foods (Principle 1). The hazard analysis does contain some aspects or similar attributes of risk assessment. Hathaway (1993) stated that the HACCP approach does not embody formal risk analysis but qualitative use of the elements of risk assessment are inherent to the development of a HACCP system. The characterization of hazards, identification of CCPs, and establishing critical limits of CCPs can be similar to procedures used in risk analysis.

A hazard analysis requires an identification of

significant hazards that are reasonably likely to occur and their preventive measures. HACCP requires that all significant hazards that are reasonably likely to occur have a preventive measure associated with them. The determination that a significant hazard is reasonably likely to occur involves similar attributes used in risk assessment. A significant hazard is a food borne pathogenic bacteria (hazard identification) that if it, or a toxin, is present in sufficient numbers or quantity (Hazard Characterization/Dose-response assessment) in a specific food product to be consumed at a meal (Exposure assessment) will cause a food to be unsafe for consumption. Thus, within a HACCP framework variables like exposure are reduced to serving sizes and become fixed. Then the second condition of whether the hazard is reasonable likely to occur must be applied. This is similar to the requirement of risk characterization in risk assessment. Risk characterization attempts to either qualitatively or quantitatively describe theoretically the nature and magnitude of the risk (the likelihood of an adverse health effect). In a HACCP system, the determination of reasonably likely to occur in a hazard analysis need not characterize the risk other than a binary decision of yes or no. The determination of reasonably likely to occur

involves the use of epidemiological evidence, process authority recommendations, scientific and technical literature, and sometimes common sense. Use of common sense pulls practical real world experiences into the determination of "reasonably likely" that risk assessment generally does not. Once the decision of reasonably likely is made for a significant hazard, the HACCP concept dictates a series of actions (identify preventive measures and Principles 2-7) to follow that control the hazard and ensure food is safe for consumption. Risk assessment does not have the same requirement of a series of predetermined actions tied to it.

To require the use of risk assessment within a HACCP system would be a circular exercise and counterproductive. HACCP is intended to be a rational and effective means to ensure food safety. To involve formal risk assessment procedures into the hazard analysis would overburden the system and lead to confusion since no uniform procedures exist. In addition, the specificity of each food and condition may make a uniform approach impossible. There are some in the scientific community that believe that the use of quantitative risk assessment during the hazard analysis, due to complications involved with imprecise data on infective dose, the analytical tedium, cost, and

imprecision in microbiological methods is just not practical (Anonymous, 1995).

One of the proposed uses of quantitative risk assessment within HACCP involves establishing critical limits at CCPs. Notermans et al., (1995a) described an approach where quantitative risk assessment (QRA) could be used to determine if the criteria (critical limits) at a CCP reduced a food borne pathogenic microorganism to acceptable levels at a CCP. The authors stated that complete elimination of a hazard is impossible in foods and thus acceptable levels must be defined. This is true even for thermal processes because, although they are generally regarded as eliminating hazards, they in fact reduce the probability of survival to some number (based on the amount of lethality delivered). These authors felt that QRA can be used to determine if the level of food borne pathogenic bacteria expected is acceptable or not, based on the criteria or critical limits established at a CCP. If by using QRA, it is determined that the expected level is unacceptable, then either the criteria (critical limits), raw materials, or process needs to be modified to obtain an acceptable level. An example of this was provided in the report by Peeler and Bunning (1994). They showed what the level of *L. monocytogenes* would be, when operating under

normal conditions, with two different criteria (critical limits) at the pasteurization step [71.7°C (161°F) for 15 seconds and 74.4°C (166°F) for 20 seconds]. A more extensive risk assessment at this point would permit risk management decisions about whether either of these levels are acceptable and weighing the social, economical, and/or political costs with choosing one of the two levels or requiring more or less risk reductions. Notermans et al., (1995a) noted that currently QRA has many weaknesses because reliable data are scarce, and not until more scientific and practical data become available could a more realistic use of risk assessment become possible.

There is little doubt that HACCP systems can be strengthened by the scientific and objective information provided in quantitative risk assessments just like any other risk management option would benefit from additional information. However, to require or suggest quantitative risk assessment should be incorporated into the HACCP seven principles will unnecessarily overburden HACCP and further delay the universal implementation of HACCP programs.

IV. CONCLUSIONS

There is a developing consensus among the international food industry, scientific, and regulatory communities that HACCP provides the most effective and rational means to ensure food safety. Although many groups and organizations provide HACCP guidance that recommends one should conduct a hazard analysis, none have provided specific instructions or guidance on exactly how it should be performed. A properly performed hazard analysis is essential because it is the foundation upon which the rest of any HACCP plan is built. Most hazard analysis guidance involves simplistic statements such as, identify the significant hazards that are reasonably likely to occur and their severity, without explaining how to determine significance, reasonably likely, or how severity should be addressed. The practical approach described for the first time in this dissertation provides specific guidance on how to perform a hazard analysis by identifying what are significant food borne pathogenic bacteria and some general preventive measures, determining which hazards are reasonably likely to occur or be associated with raw materials/ingredients and process operations (steps), and providing a decision tree approach that systematically walks an individual through what considerations and thought

processes are needed to perform a hazard analysis. The method described will permit a non-expert to perform a hazard analysis that has identified all significant hazards that are reasonably likely to occur and their preventive measures, providing the basis for determining critical control points in Principle 2. In addition, the information derived from the decision trees, when recorded in tabular form, provides a written record of the hazard analysis for later analysis, modification, or verification.

Several HACCP guidance documents have recommended that the severity of identified hazards should be assessed. The guidance provided in this dissertation, in agreement with the Codex HACCP Working Group document, does not incorporate the assignment of severity to hazards. The assignment of hazard severity does not influence hazard identification or whether a preventive measure should control the hazard. A hazard by definition needs only to cause a food to be unsafe for consumption. The severity or degree to which the hazard makes the food unsafe does not need to be addressed during the hazard analysis since it only requires that the appropriate hazards and preventive measures be identified.

Finally, an analysis of the differences between a hazard analysis and microbiological risk assessment (MRA)

concludes that, although some similarities between these two procedures exist, incorporating either into the other is inappropriate. Since a uniform procedure for performing microbiological risk assessment does not exist, it is unclear what its relationship to hazard analysis or HACCP would be. HACCP, as the concept is currently accepted (Codex 1993; NACMCF, 1992), does not need a formal risk assessment performed to effectively ensure the safety of food. A hazard analysis should be performed for a specific food in a specific process, whereas MRA is a broad analysis of the risk a hazard imposes on populations as a whole. MRA requires extensive data, which is often imprecise, and an equal amount of assumptions, and can best be used by regulatory agencies to help establish national or broad risk management or risk communication policies for public health protection. The incorporation of broad MRA into a process-specific hazard analysis is impractical due to imprecise data on infective dose, assumptions needed, analytical tedium, costs, and imprecision in microbiological methods and would overburden the HACCP concept and ultimately delay or annul the universal implementation of HACCP programs.

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VI. APPENDIX A

APPENDIX A - NACMCF HACCP DOCUMENT

Examples of Questions to be Considered in a Hazard Analysis

The hazard analysis consist of asking a series of questions which are appropriate to each step in a HACCP plan. It is not possible in these recommendations to provide a list of all the questions which may be pertinent to a specific food or process. The hazard analysis should question the effect of a variety of factors upon the safety of the food.

A. Ingredients

1. Does the food contain any sensitive ingredients that may present microbiological hazards (e.g., Salmonella, Staphylococcus aureus); chemical hazards (e.g., aflatoxin, antibiotic or pesticide residues); or physical hazards (stones, glass, metal)?
2. Is potable water used in formulating or in handling the food?

B. Intrinsic Factors

Physical characteristics and composition (e.g., pH, type of acidulants, fermentable carbohydrate, water activity, preservatives) of the food during and after processing.

1. Which intrinsic factors of the food must be controlled in order to assure food safety?
2. Does the food permit survival or multiplication of pathogens and/or toxin formation in the food during processing?
3. Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps in the food chain?
4. Are there other similar products in the market place? What has been the safety record for these products?

C. Procedures used for processing

1. Does the process include a controllable processing step that destroys pathogens? Consider both vegetative cells and spores.
2. Is the product subject to recontamination between processing (e.g., cooking, pasteurizing) and packaging?

D. Microbial content of the food

1. Is the food commercially sterile (e.g., low acid canned food)?
2. Is it likely that the food will contain viable sporeforming or nonsporeforming pathogens?
3. What is the normal microbial content of the food?
4. Does the microbial population change during the normal time the food is stored prior to consumption?
5. Does the subsequent change in microbial population alter the safety of the food, pro or con?

E. Facility design

1. Does the layout of the facility provide an adequate separation of raw materials from ready-to-eat foods if this is important to food safety?
2. Is positive air pressure maintained in product packaging areas? Is this essential for product safety?
3. Is the traffic pattern for people and moving equipment a significant source of contamination?

F. Equipment design

1. Will the equipment provide the time-temperature control that is necessary for safe food?
2. Is the equipment properly sized for the volume of food that will be processed?

3. Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe food?
4. Is the equipment reliable or is it prone to frequent breakdowns?
5. Is the equipment designed so that it can be cleaned and sanitized?
6. Is there a chance for product contamination with hazardous substances; e.g., glass?
7. What product safety devices are used to enhance consumer safety?
 - o metal detectors
 - o magnets
 - o sifters
 - o filters
 - o screens
 - o thermometers
 - o deboners
 - o dud detectors

G. Packaging

1. Does the method packaging affect the multiplication of microbial pathogens and/or the formation of toxins?
2. Is the package clearly labeled "Keep Refrigerated" if this is required for safety?
3. Does the package include instructions for the safe handling and preparation of the food by the end user?
4. Is the packaging material resistant to damage thereby preventing the entrance of microbial contamination?
5. Are tamper-evident packaging features used?
6. Is each package and case legibly and accurately coded?
7. Does each package contain the proper label?

H. Sanitation

1. Can sanitation impact upon the safety of the food that is being processed?
2. Can the facility and equipment be cleaned and sanitized to permit the safe handling of food?
3. Is it possible to provide sanitary conditions consistently and adequately to assure safe foods?

I. Employee health, hygiene and education

1. Can employee health or personal hygiene practices impact upon the safety of the food being processed?
2. Do the employees understand the process and the factors they must control to assure the preparation of safe foods?
3. Will the employees inform management of a problem which could impact upon safety of the food?

J. Conditions of storage between packaging and the end user

1. What is the likelihood that the food will be improperly stored at the wrong temperature?
2. Would an error in improper storage lead to a microbiologically unsafe food?

K. Intended use

1. Will the food be heated by the consumer?
2. Will there likely be leftovers?

L. Intended consumer

1. Is the food intended for the general public?
2. Is the food intended for consumption by a population with increased susceptibility to illness (e.g., infants, the aged, the infirmed, immunocompromised individuals)?

VII. APPENDIX B

APPENDIX B - EXAMPLE HAZARD ANALYSIS

The following is an hypothetical example of how to perform a microbiological hazard analysis using the practical approach described in the text. The attached "Swiss Cheese HACCP Plan" (seven pages) was developed for training purposes by a group of food safety experts. The first six pages of the "Swiss Cheese HACCP Plan" contain the preliminary steps for Principle 1 (as described by NACMCF). All information concerning prerequisite programs, HACCP Team, product description and distribution, intended use and consumers, and a verified flow diagram has been provided and should be used as the basis for the hazard analysis.

The hazard analysis begins by asking the questions in Figure 1 for each raw material or ingredient. All answers, justifications for exclusion, or preventive measures should be entered in a hazard analysis table similar to Table 6 in the text. The hazard analysis then proceeds by asking the questions in Figure 2 for each identified operational steps. All answers, justifications for exclusion, or preventive measures should be entered into a hazard analysis table. The final result and documentation of the hazard analysis is given in the following table (Table B1).

HACCP PLAN FOR
SWISS CHEESE

Manufacturing Site:
Anywhere Cheese Makers, Inc.
1 Pasture Lane
Someplace, USA

***Note: this plan was developed for training purposes only;
this is not an actual HACCP plan.**

SWISS CHEESE

Prerequisite Programs. Before implementing this HACCP plan, the following plant-wide programs were validated by the HACCP team and shown to be adequate, functioning and maintained. The firm conducts routine audits of the programs.

- plant layout, product flow, and employee traffic patterns, which minimize cross-contamination from raw material to post-pasteurization areas;
- potable water supply;
- pest control program;
- cleaning and sanitation SOP's for facilities, equipment, and utensils;
- preventive maintenance program and SOP's for operating, maintaining and calibrating equipment;
- recall procedure, including traceability of raw materials to supplier lots, coding for finished product, and traceability through distribution;
- SOP's for receiving and storing ingredients used in this product;
- purchasing specifications and letters of guarantee for compliance with regulatory requirements;
- antibiotic testing program for incoming raw milk for regulatory compliance;
- SOP's for shipping/distributing product, including preventing cross-contamination from transportation vehicles (i.e. backhauling) and temperature specifications for vehicles; and
- training programs for personnel in general hygienic practice and implementation of this HACCP plan.

Because the hazard analysis was developed with the expectation that these programs will be continuously in-place and functioning, **these programs are essential to the reliable functioning of the HACCP plan.**

HACCP Team. Mr. W, owner and plant manager, Mr. X, cheese maker, Mr. S, quality assurance/microbiology, Mr. Z, university extension specialist (technical advisor to the firm).

Product Description and Distribution. Swiss cheese is prepared from the following ingredients, in order of predominance: milk, sodium chloride (during brining), starter culture (commercially obtained), coagulant (microbiologically derived), and calcium chloride (CaCl_2).

Cheese is vacuum packaged in 20 lb blocks and shipped in refrigerated (35°-40°F) trucks.

Intended Use and Consumers. Product is produced in bulk and shipped to commercial customers for cutting and repackaging for retail sale to the general public.

Process Description. Raw milk is received from a local supplier in a refrigerated tanker truck. After receiving, raw milk is stored in refrigerated (<40°F) for no more than three days. Starter cultures are purchased and stored frozen. All other ingredients are shelf-stable. No rework is used.

All equipment and utensils are cleaned and sanitized prior to starting the batch. At the start of the batch, raw milk is metered through a closed system to the separator/clarifier, which separates the cream from the skim, and pipes them to separate holding tanks. Skim and cream (sufficient to meet milk fat specification) are piped to a blend tank. The milk is pasteurized and pumped into a refrigerated hold tank. Milk is metered into four temperature-controlled cheese vats and heat to ca. 90°F. During heating, each vat is stirred with a motorized stainless steel paddle.

Starter culture #1 is prepared in advance: starter culture medium is rehydrated in water, pasteurized at 180°F for 45 min, then cooled to <100°F before adding thawed starter culture. The inoculated medium is held at 90°-95°F for 2 hrs, according to the starter supplier's directions, and is then stored refrigerated overnight. Starter culture #1 is manually added to the heated milk and mixed. Starter culture #2 is purchased ready-to-use; it is thawed, measured, and added directly to the cheese vats after starter culture #1.

The cheese vats are held at 88°-90°F, and the milk ripens. The cheese maker monitors pH and titratable acidity (TA) during ripening and subsequent process steps. Slow ripening is corrected by the cheese maker. When acidity has developed sufficiently, coagulant and calcium chloride (CaCl₂) are manually added and mixed into the milk using the stainless steel paddles.

The vats are held without agitation during the next 2 hrs while the curd forms. The cheese maker continues to monitor acid development. The curd is cut in the vats with

wire "knives". The vat temperature is raised to 120°F and water is added to accelerate ripening and to shrink the curd. When curd has dropped below pH 6.35, the curd is "pushed back" into a corner of the vat with stainless steel screens and the whey is drained out of the vat. Additional whey is expressed from the curd by putting two 30 lb weights on the top screen. After draining, the curd is cut, covered in nylon mesh, and placed in metal boxes for pressing. The boxed curd is held in a cheese press overnight at room temperature. After pressing, the cheese is removed from the boxes, pH measured, and placed in a chilled, saturated brine tank overnight. The cheese is placed on a stainless steel mesh and aged refrigerated for 7-10 days, and at 75°-80°F for 30-60 days, according to customer specifications. After ageing, the cheese is vacuum wrapped in plastic and stored refrigerated until shipping. Cheese is shipped to the customer in refrigerated trucks.

Hazard Analysis. The hazard analysis was conducted by considering the risk (likelihood of occurrence) and severity of each potential hazard in order to determine which hazards were significant enough to be addressed in the HACCP plan. In conducting this analysis, the team considered that historically, swiss cheese made from pasteurized milk has not been a source of salmonellosis. However it has been linked to sporadic outbreaks of staphylococcal food poisoning due to post-pasteurization contamination. Recent history indicates that the problem of staphylococcal food poisoning from this source has been effectively addressed through adoption by the industry of HACCP-type control measures similar to those outlined in this HACCP plan.

Ingredients. Raw milk is considered a significant source of biological hazards, i.e. *Salmonella* and other enteric pathogens. Pathogens from this source are controlled by pasteurization. Starter cultures are purchased from an approved supplier; these cultures are not considered a significant source of hazards, provided the plant maintains its program of auditing this supplier's product controls. The supplier of the dehydrated starter culture medium is unable to assure the absence of pathogens, e.g. *Staphylococcus aureus*; non-sporeforming pathogens from this source are not considered significant because they will be eliminated by the extended heating during rehydration. Starter culture incubation time, and properties of the final product, make it unlikely that any surviving

pathogenic spores will grow to significant levels after inoculation of the starter medium, or in the cheese. Potable water, used in equipment sanitation, in preparing starter culture #1, and to wash the curd, is obtained from the city. An in-line paper filter is used to screen any debris, but is ineffective for microbiological control. The plant relies on the city's chlorination and filtration systems to assure water potability. No other ingredients, including packaging material, are considered significant sources of biological hazards.

The only chemical hazard warranting consideration is antibiotic residues, which under certain circumstances might cause an acute, allergenic reaction. The raw milk obtained from the plant's supplier has never been in violation of regulatory standards. There is no significant risk from such residues while the plant maintains its raw milk testing program.

Any physical hazard entering with the milk is unable to pass through the milk processing steps to the cheese vat, and so is self-limiting. The nature of the other ingredients results in a low risk for physical hazards.

Process. After pasteurizing and cooling to a non-lethal temperature, the milk blend is susceptible to recontamination with enteric pathogens. This risk is minimal while sanitation SOPs are in-place and being followed. Thus, product testing for pathogens is not performed. Finished product conditions inhibit the growth of pathogens.¹

Incidental product contamination with *S. aureus* may occur from a number of sources after pasteurization. Acid production is essential to prevent staphylococcal growth and enterotoxin production. The rate of acid production is as important as the final quantity of acid produced. Thus, slow vats are as much of concern as dead vats. It is

¹
The role of microbiological analysis of the post-pasteurization plant environment was discussed in-depth. While it was felt that this was not a necessity, the consensus was that such testing may have utility for assessing the effectiveness of sanitation procedures and can be used as a tool to find and correct sources of quality problems.

important that atypical vats of cheese be identified so that subsequent corrective actions can be taken (e.g. testing the cheeses for *S. aureus* concentration and, if necessary, enterotoxin).

The production of acid is monitored in the cheese vat by measuring pH and/or titratable acidity. This information is available to the cheese maker and influences decisions of the cheese maker for adjusting the process, if necessary. The cheese maker has several operating guidelines available for adjusting the process. Factors that influence the rate and final quantity of acid produced include:

- activity and amount of starter culture #1
- phage contamination
- temperature of milk in the vat
- the amount of heat applied during "cooking" of the curd
- the temperature during ageing

Ultimately, a minimum amount of acid must be developed for the safety of the product to remain in control. To assure control over this process, the HACCP team selected to use the Filling/Pressing step, i.e. when the cheese is removed from the box after pressing, as the decision point. At this point, there is a critical limit for product pH (i.e. minimum level of acid production) and time (i.e. maximum time allowed for adequate acid production).

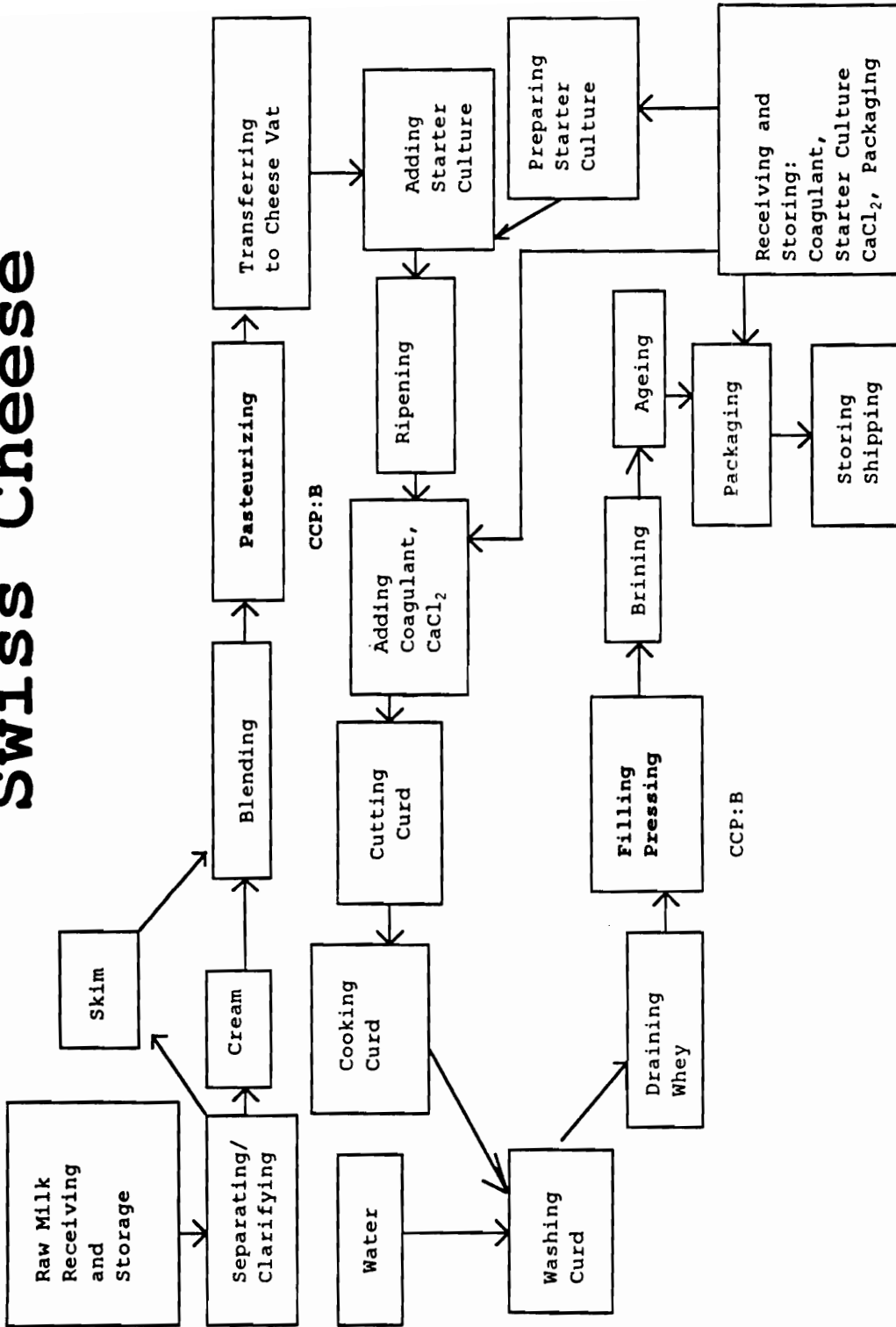
The brining step uses a saturated solution of sodium chloride. Most pathogenic organisms cannot survive, and none will grow, in that level of salinity. Subsequent to brining, the salt concentration in the cheese rind will inhibit growth of any incidental pathogen contamination. Brining is done for product quality reasons. Although it is beneficial, it is not critical for product safety.

In-plant contamination with chemicals (e.g. cleaners, sanitizers, lubricants) is minimal while GMPs and cleaning and sanitation SOPs are in-place and being followed. Adequacy of these programs is verified by daily equipment inspections and periodic plant audits.

Cleaning and preventive maintenance programs for the milk processing equipment include daily and periodic inspections, respectively, of milk processing equipment. Such inspections offer multiple opportunities to prevent equipment fatigue from being a source of metal

contamination. Personnel training in GMPs, and the small scale of the operation, help to minimize physical hazards from entering the product after pasteurization. Consequently, metal fragments from processing operations are not considered a significant hazard.

Swiss Cheese



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Table B1. Hazard Analysis Table

Raw Material/ Operational Step	Potential Hazard	Significant Hazard	Justification for Exclusion	Preventive Measure
Milk	Pathogens (See list from Table 3.)	Yes (Fig. 1)	NA	
Sodium chloride	None	No	NA	
Starter cultures and Starter culture medium	Pathogens (Potential presence of <i>Staphylococcus aureus</i>)	No	Purchased from approved supplier, and plant maintains a program of auditing supplier's product controls. Starter culture incubation time, and properties of the final product, make it unlikely that any surviving pathogenic spores will grow to significant levels after inoculation, or in the cheese.	Approved Supplier and Auditing Programs
Coagulant (microbiologically derived)	None	No		
Calcium chloride	None	No		
Potable water	Pathogens (See list from Table 3.)	No	Plant relies on city chlorination and filtration systems to assure water potability.	City Municipal Water Supply
Packaging	None	No		

Table B1. Hazard Analysis Table (con't)

Raw Material/ Operational Step	Potential Hazard	Significant Hazard	Justification for Exclusion	Preventive Measure
Non-Dairy Receiving and Storing (starter cultures, starter culture medium, coagulant, NaCl, CaCl, packaging)	None	No (Fig. 1)	NA	NA
Raw Milk Receiving	Pathogens (See list from Table 3.)	Yes (Fig. 2)	NA	NA
Raw Milk Storing	Temperature or time abuse may allow growth of pathogens associated with raw milk. (See list from Table 3.)	No (Fig. 2)	Raw milk storage control is under plant prerequisite program. Any growth due to loss of control will be controlled by subsequent pasteurization. If is abused enough for sufficient pathogen growth to survive pasteurization, the milk quality milk will be such that it will be unusable for further processing.	Prerequisite Programs
Separating/ Clarifying	None	No (Fig. 2)	No microbiological hazards are likely introduced or increased.	Prerequisite Programs
Cream/Skim	None	No (Fig. 2)	Cream and skim are prepared according to batch size and are not stored. No microbiological hazards are likely to be introduced or increased.	Prerequisite Programs

Table B1. Hazard Analysis Table (con't)

Raw Material/ Operational Step	Potential Hazard	Significant Hazard	Justification for Exclusion	Preventive Measure
Blending	Temperature or time abuse may allow growth of pathogens associated with raw milk. (See list from Table 3.)	No (Fig. 2)	Product flow, after raw milk storage through blending, is typically a few minutes, and never more than four hours. Even if raw materials containing pathogens are held for the maximum time, the cold milk blend will not warm at a rate, or to a temperature, which will allow pathogens to grow to levels that can survive pasteurization.	
Pasteurizing	Survival of pathogens associated with raw milk. (See list from Tables 3. and 4.)	Yes (Fig. 2)	NA	Proper time/temperature controls to ensure the delivery of an adequate thermal process. Proper delivery of thermal process is critical to destroy enteric pathogens in raw materials.
Transferring to Cheese Vat	Yes, pathogens contamination could be introduced by equipment or environmental contamination at this step and subsequent steps.	No (Fig. 2)	No microbiological hazards are likely to be introduced or increased. All equipment and utensils are cleaned and sanitized prior to starting batch so pathogen introduction by equipment or environmental contamination is unlikely at this step and subsequent steps.	Prerequisite Programs

Table B1. Hazard Analysis Table (con't)

Raw Material/ Operational Step	Potential Hazard	Significant Hazard	Justification for Exclusion	Preventive Measure
Preparing Starter Cultures	Pathogens (Potential presence of <i>Staphylococcus aureus</i>)	No (Fig. 2)	Starter cultures are not considered a significant hazard source, provided the plant maintains its program of auditing supplier's product controls. Supplier of the dehydrated starter culture is unable to assure the absence of pathogens (i.e., <i>S. aureus</i> and nonsporeforming pathogens are not considered significant because they are eliminated in the extended heating during rehydration). Starter culture incubation time, and final product properties, make it unlikely that any surviving pathogenic spores will grow to significant levels after inoculation of starter medium, or in the cheese.	Approved Supplier and Auditing Programs Prerequisite Programs
Adding Starter Cultures to Milk	Pathogen recontamination with <i>Staphylococcus aureus</i> . Enteric pathogens contamination could be introduced by equipment or environmental contamination.	Yes (Fig. 2) No (Fig. 2)	Incidental product contamination with <i>S. aureus</i> may occur from a number of sources after pasteurization. Such contamination will be controlled by proper cheese ripening. Likelihood of product recontamination with enteric pathogens at this and subsequent steps is low while programs are in place for adherence to GMPs and sanitation SOP	Prerequisite Programs, Good Manufacturing Practices (GMPs), and Sanitation SOPs

Table B1. Hazard Analysis Table (con't)

Raw Material/ Operational Step	Potential Hazard	Significant Hazard	Justification for Exclusion	Preventive Measure
Ripening	<i>Staphylococcus aureus</i> growth and enterotoxin production. (See Table 4., under Fermentation)	Yes (Fig. 2)		Proper development of acid, at this step will be critical to ensuring <i>S. aureus</i> control. Process adjusted if necessary. Acid development is assured by monitoring at Fill/Press step.
Adding CaCl ₂ Coagulant	None	No (Figures 1 and 2)	Raw materials not a significant source of hazards, and process of addition is not likely to introduce a hazard.	Prerequisite Programs
Cutting Curd	None	No (Fig. 2)	Curd is cut using wire "knives". No microbiological hazards are likely to be introduced or increased during process. Equipment and utensils are cleaned/sanitized prior to starting.	Prerequisite Programs
Cooking Curd	<i>Staphylococcus aureus</i> growth and enterotoxin production. (See Table 4.)	Yes (Fig. 2)		Insufficient heating to reduce pathogen risk. Overheating can slow fermentation process and proper acid development. Acid development checked at several process steps and if necessary adjusted, but must meet limits at Fill/Press step.

Table B1. Hazard Analysis Table

Raw Material/ Operational Step	Potential Hazard	Significant Hazard	Justification for Exclusion	Preventive Measure
Washing Curd	None	No (Figures 1 and 2)	Plant relies on city chlorination and filtration systems to assure water potability. The raw materials are not significant sources of hazards, and process is not likely to introduce a hazard.	City Municipal Water Supply Prerequisite Programs
Draining Whey	None	No (Fig. 2)	No microbiological hazards are likely to be introduced or increased during this process.	Prerequisite Programs
Filling/Pressing	<i>Staphylococcus aureus</i> growth and enterotoxin production.	Yes (Fig. 2)		Proper acid development at this step will be critical to assuring <i>S. aureus</i> control. Final assurance of proper acid development is monitored at this step.
Brining	Pathogen growth in product or brine. (See Table 4., under Brining)	No (Fig. 2)	The raw materials are not significant sources of hazards, and process of adding them is not likely to introduce a hazard. The brine concentration is inhibitory to pathogenic organisms, but brining is not critical for product safety. No microbiological hazards are likely to be introduced or increased during this process.	Prerequisite Programs

Table B1. Hazard Analysis Table (con't)

Raw Material/ Operational Step	Potential Hazard	Significant Hazard	Justification for Exclusion	Preventive Measure
Ageing	Product contamination during ageing. (See Table 4.)	No (Figures 1 and 2)	The cheese rind inhibits product contamination during ageing. No microbiological hazards are likely to be introduced or increased during this process.	Prerequisite Programs
Packaging	None	No (Figures 1 and 2)	The packaging material is not a significant source of hazards. Packaging further reduces the likelihood of recontamination, but package integrity is not critical for product safety. No microbiological hazards are likely to be introduced or increased during this process.	Prerequisite Programs
Storing/Shipping	Growth of pathogens during storing and shipping if temperature abuse occurs.	No (Fig. 2)	Refrigeration is needed for product quality. Product will be overtly spoiled before temperature abuse can create a safety concern.	Prerequisite Programs

VIII. VITAE

Edward Jeffery Rhodehamel was born May 31, 1957 in Trenton, New Jersey. He completed his secondary education at Herndon High School, Herndon, Virginia in 1975 and entered Virginia Polytechnic Institute and State University the same year. He received his Bachelor of Science degree cum laude in 1979. He received a Master of Science degree from Virginia Polytechnic Institute and State University in Food Science and Technology in 1983. He is currently pursuing the Doctorate of Philosophy degree in Food Science and Technology also at Virginia Polytechnic Institute and State University.

Mr. Rhodehamel accepted an offer in 1986 with Bil Mar Foods, Inc. (a division of the Sara Lee meat group) as the Supervisor of the Microbiological and Chemical Laboratories. He managed the microbiological and chemical laboratories and supervised seven employees to ensure that all Bil Mar products produced were safe and met or surpassed established specifications and USDA labeling requirements.

In 1988, he joined the Food and Drug Administration (FDA) as a Staff Fellow in the *Clostridium botulinum* Research Group of the Division of Microbiology. Mr. Rhodehamel became the *C. botulinum* research group leader in

1990. As the research group leader, he was responsible for assigning research projects to group members and directing the research in areas involving methods development for the isolation and detection of *C. botulinum* and its toxins, thermal resistance studies, safety assessment of new products and technologies (e.g., vacuum or modified atmosphere packaging, sous vide processing, and refrigerated foods), and determination of conditions required for *C. botulinum* growth and toxin production. Mr. Rhodehamel was also assigned scientific and regulatory projects evaluating the microbiological challenge data in aseptic process filings submitted to FDA. He conducted reviews to determine the adequacy of the aseptic processing equipment to achieve and maintain commercial sterility in the aseptic zone. He was routinely consulted by the Division of Enforcement (formerly the Division of Regulatory Guidance) on regulatory actions regarding food safety issues. He was called upon to make health hazard evaluations on enforcement issues and has reviewed several Consent Decree documents/proposals for their adequacy to protect the public health. Another area in which he was heavily involved was the development and application of Hazard Analysis Critical Control Point (HACCP) systems for preventing food borne illnesses.

After the FDA's Center for Food Safety and Applied Nutrition (CFSAN) was reorganized in 1992, Mr. Rhodehamel was transferred to the Division of HACCP Programs to serve as the HACCP Team Leader. Although his new duties involved FDA HACCP initiatives, he continued to be intimately involved with the *C. botulinum* research group and collaborated with most its research efforts. As the HACCP Team Leader, he was responsible for establishing FDA HACCP concepts and policy regarding HACCP programs, and coordinated FDA field and/or industry HACCP initiatives and systems. He was instrumental in the development of FDA HACCP pilot programs and directed the HACCP group on implementation strategies. He coordinated the uniform application of HACCP concepts and principles in various regulations under development in several Offices within CFSAN.

In September 1995, Mr. Rhodehamel joined the Cryovac Division of W.R. Grace Co.-Conn. as the Section Leader, Applications Development and Support Laboratories. In this position, he manages several laboratories that evaluate food packaging applications and provides technical support to both research and development and sales personnel. He also provides food safety assessments of new packaging applications and technologies.

Mr. Rhodehamel is nationally and internationally recognized for his research accomplishments, particularly for his work with *C. botulinum*, highly regarded by his peers, and is an expert on HACCP systems, vacuum and modified atmosphere packaging, and refrigerated foods. Mr. Rhodehamel was an invited speaker/instructor at the 1991 Institute of Food Technologists (IFT) HACCP Short Course. He was also an invited instructor for the FDA State Training Branch's Satellite Teleconference Course HACCP: Charting a Safer Course, August 1994. The satellite teleconference course provided uniform, interactive training simultaneously to over 6000 participants at over 200 official downlink sites throughout the United States and Canada. He has authored two book chapters in HACCP - Principles and Applications, (eds. Pierson and Corlett, 1992). He was a member of the FAO/WHO Codex Alimentarius Commission, Committee on Food Hygiene, HACCP Working Group (a group of international recognized scientific experts in the HACCP field). He has been a member of the U.S. delegation to the FAO/WHO Codex Alimentarius Commission, Committee on Food Hygiene since 1989, and has served as the U.S. delegation Group Leader on four draft documents; Guidelines for the Application of HACCP Systems, General Principles of Food Hygiene, Broader Applications of HACCP,

and Refrigerated Foods. He was invited to serve as one of four internationally recognized instructors of a International HACCP Workshop held at the International Food Technology Exposition and Conference (IFTEC), the Netherlands, November, 1992. He was selected to be the FDA delegate on the International Quadrilateral HACCP Working Group. He was a member of the Seafood HACCP Policy Group that was responsible for determining how HACCP concepts and policy would be incorporated into a final Seafood HACCP Regulation. He was invited, along with a number of other internationally recognized HACCP experts, to be a member of National Sanitation Federation (NSF) International ISO9000/HACCP Advisory Group. He served on the Steering Committees of the Seafood HACCP Alliance and currently serves on the National Center for Food Safety and Technology's committee for the development of a generic HACCP plan library. Mr. Rhodehamel was chosen by then CFSAN Deputy Director Dr. Douglas Archer, to serve as editor for the third revision of the "Foodborne Pathogenic Microorganisms and Natural Toxins" book.

Mr. Rhodehamel has received numerous honors and awards including five presented by Dr. David Kessler, Commissioner, U.S. Food and Drug Administration. They include, 1995 FDA Group Recognition Award as a member of

the HACCP Satellite Training Team for exceptional support and commitment to development and delivery of the satellite course "HACCP - Charting a Safer Course", to Federal, State and local regulators nationwide, 1994 FDA CFSAN Exceptional Achievement Award for demonstrating outstanding leadership and exceptional performance in developing Agency food safety initiatives involving Hazard Analysis Critical Control Point (HACCP) systems, 1994 FDA Group Recognition Award as a member of the Food Safety Assurance Strategy Group for exceptional effort in developing an Agency food safety assurance strategy to implement preventive controls for the food industry, a 1994 Award for Exceptional Performance in development and implementation of the FDA Food Safety Initiative, and 1992 FDA Group Recognition Award as a member of the Seafood Program Implementation Group for outstanding achievements in the development and implementation of seafood safety programs throughout the FDA.

Mr. Rhodehamel has served as an instructor in FDA Basic Food Microbiology Training Courses and several FDA State Training Branch courses, such as Current Concepts in Food Protection-An Introduction to HACCP, Microbiological Aspects of Food Processing, Vacuum Packaging, and including the Satellite Teleconference Course HACCP: Charting a Safer

Course.

Mr. Rhodehamel is on the editorial board of the Journal of Food Protection and has reviewed submitted manuscripts for the following journals; Journal of Food Science, Journal of Infectious Diseases, Journal of Food Safety, and Trends in Food Science and Technology. Mr. Rhodehamel has been selected as an ad hoc reviewer in the Food Safety Program of the National Research Institute (NRI) Competitive Grants Program of the U.S. Department of Agriculture and the Natural Sciences and Engineering Research Council of Canada (NSERC) research grant proposals. He also served as a Scientific Advisor for three years (1991-1993) to the Agency for International Development (AID) Program in Science and Technology Cooperation by performing scientific peer review of international food safety research grant proposals.

Mr. Rhodehamel is a member of the following professional and honorary societies; Institute of Food Technologists, American Society for Microbiology, International Association of Milk, Food, and Environmental Sanitarians, Association of Food and Drug Officials, Sigma Xi - National Research Honorary, Phi Sigma - National Biology Honorary, Phi Kappa Phi - National Scholastic Honorary, Gamma Sigma Delta - National Agricultural

Honorary, and Sigma Xi - National Research Honorary. Mr. Rhodehamel has served as a Member-at-large for the Food Microbiology Division of the Institute of Food Technologists.

Mr. Rhodehamel's stature in the research community is demonstrated by his attendance, participation, and research presentations at the annual meetings of the American Society for Microbiology, Institute of Food Technologists, International Association of Milk, Food, and Environmental Sanitarians, and international meetings such as Pasteurized Food Products Conference and International Food Technology Exposition and Conference. His work has resulted in sixteen published articles, two book chapters, three Bacteriological Analytical Manual (BAM) chapters, three manuscripts in preparation, twenty-one published abstracts, and over sixty presentations.