Quality Assurance for the Food Industry

A Practical Approach

J. Andres Vasconcellos

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DEDICATION

To Dr. Jorge Welti-Chanes

and his wife

Dr. Luga Santos de Welti

who literally saved my life

PREFACE

The concept of quality is often confused with the idea that a product of quality is a luxury item, which in turn implies a costly item. From a practical point of view, however, quality is nothing more than customer satisfaction. At the manufacturing level, quality is defined as an increased level of productivity and safety. It is not possible to talk about quality of a product without considering its safety, and vice versa.

Food companies, regardless of their size and reach (multinational corporations or small local companies), make an effort to attain a high standard of quality/safety in each phase of their operations. In the U.S., a country that maintains one of the world's safest food supplies, this status is maintained, thanks in large part, to a quality/safety monitoring system that watches over food production and distribution at every level — locally, statewide, and nationally. Food inspectors and food scientists working for city and county health departments, state public health agencies, and various federal departments and agencies provide continual monitoring. Local, state, and national laws, guidelines, and other directives dictate their precise duties. They make up the U.S. food quality/safety team.

In Latin America, the potential benefits of trade within the U.S.–Mexico–Canada bloc (also known as the North American Free Trade Agreement [NAFTA]) has spurred businesses and industries, particularly in the agriculture and food manufacturing areas, to search for new ways to improve the quality and safety of products for export. Efforts are being made to promote management and technical expertise, undertaken with the understanding that NAFTA will expand to include all of Latin America. Governments and corporations in these countries understand that the economic survival of their region depends in large part on increased education, which will, in turn, establish a workforce capable of producing desirable export goods. Governments and businesses recognize that quality is a fundamental aspect of achieving the competitive level demanded by the new world market.

This book started out as a collection of notes from the quality assurance classes that I teach at Chapman University; from my experience working at Hunt-Wesson Foods with a large variety of food products, including: tomatoes (ketchup, sauce, paste, stewed tomatoes, and other products), peanut butters, Mexican and Chinese foods, Swiss Miss (chocolate drinks and pudding) products, popcorn products, fat and oil products, and refrigerated products; and later as a consultant for food companies domestically and abroad. Over the past few years, while teaching at Chapman University, at the University of the Americas, or working as a consultant in several countries, I found an increasing number of food producers interested in the implications of total quality management and of quality assurance programs for their operations. This interest seemed similar to what had been occurring to a larger extent in the U.S. through the teachings of Walter A. Shewhart, W. Edwards Deming, Joseph M. Juran, Armand V. Feigenbaum, Philip B. Crosby, and Kaoru Ishikawa and Genichi Taguchi. Reading their works reinforced my desire for writing a book in which I could offer, from my own experience, the practical aspects of both total quality management and of quality assurance.

Many companies understand the concept of quality. They also understand that it is impossible to establish a single division solely devoted to "quality," as it is a function and responsibility of each and every company employee. These companies have adopted, or are adopting, programs that encompass all the stages of their product's manufacture. The understanding of this concept and the implementation of programs designed to apply the concept, are defined as "Total Quality Management" or, to use a personal definition, "Integral Quality." The implementation of an integral quality program demands total employee participation. The results are reduced production defects and manufacturing costs, increased product sales, and the subsequent financial rewards. At the manufacturing level, the tool for this sort of program is known as "Quality Assurance."

The principles of quality assurance as a function of total quality management and the methodology necessary to establish and implement a quality assurance program for a food manufacturing plant are examined. This requires a concerted effort on the part of the company, with the identification and evaluation of previously unconsidered parameters.

This book provides a comprehensive review of quality assurance, from the concepts and practical applications of total quality management to all aspects of the manufacturing procedures. The text provides students and food professionals with a broad foundation in this area of the food industry.

The book begins with a review of the principles and the methodology necessary to establish a total quality management system. Chapter 1 presents information related to total quality administration, including the

concepts based on the doctrines of "strict" liability and "total accountability," management and product quality, the working environment, the concept of quality, and the standard for quality used by the food industry. Chapter 2 covers theories, principles, and applications of total quality management, the tools used in its application, and a historical review of its origins, concepts, implementation, and the contributions by the men who were pioneers in the field.

In Chapter 3, the importance of the theories of applications, the functions and need for a quality assurance program and its role in product manufacturing are discussed, stressing the need for employee education and training, process improvement, and interactions between a company's quality assurance, quality control, product development, marketing, sales, and consumer affairs departments.

Chapter 4 reviews certification programs for raw materials and ingredients, and considers the organization and maintenance of supplier quality programs through quality control, HACCP audits, and identity-preserved ingredient systems. Chapter 5 presents a comprehensive review of statistical concepts as applied to food manufacturing operations and quality control, which are illustrated with practical examples.

In Chapters 6, 7, and 8, the book continues with a description on how to carry out quality audits; analysis and characteristics, purposes, requirements, and the consequences of a lack of quality audits. Specific quality audits are reviewed and examples are presented for better illustration and understanding. Among these, the following are given special attention:

1. Product manufacturing audits. Including programs for in-process operations control, analytical methodology, ingredient qualification and storage, and manufacturing records.
2. Food plant sanitation audits. Including Good Manufacturing Practice regulations; plant sanitation audits (concepts, deviations, and violations; classification and evaluation of deviations and violations); objectives; control and implementation of good sanitary practices.
3. Product quality audits. Including purpose and procedures; data collection and analysis; product quality evaluation.

Finally, Chapter 9 includes a comprehensive study of HACCP and its applications and concepts.

We expect and hope that the contents of this book will be of significant practical assistance to those technical professionals dedicated to the improvement of the constantly growing food industry.

J. Andrés Vasconcellos, Ph.D.

AUTHOR

J. Andrés Vasconcellos, Ph.D., earned a B.Sc. in chemical engineering from the University of Guayaquil, Ecuador. He continued his food engineering studies (reverse osmosis concentration of fruit juices) at the University of California, Davis, also completing an M.Sc. in food science, working on processing and manufacturing of edible fats and oils and their nutritional implications. Subsequently, he earned an M.Sc. in nutrition and a Ph.D. in agricultural biochemistry and nutrition from the University of Arizona.

Dr. Vasconcellos taught at the University of Guayaquil, Ecuador, at the Technological Institute of Monterrey, Guaymas, Mexico, and at the University of the Americas, Puebla, Mexico. He worked in the food industry as production manager for OLEICA, S. A., the largest fats and oils company in Ecuador, and for Hunt-Wesson Foods, Fullerton, California, in the areas of quality assurance, research and development, and regulatory affairs, over the course of 18 years. At the same time, he accepted a position as adjunct professor at Chapman University, Orange, California, where, after 20 years, he continues to lend his services as an adjunct professor of food science and nutrition and as director of the Short Courses Program.

Dr. Vasconcellos is a distinguished visiting professor with the University of the Americas, Puebla, Mexico and an Emeritus Member of the Institute of Food Technologists and of the American Society for Nutritional Sciences.

After early retirement from Hunt-Wesson Foods, Dr. Vasconcellos established his own company, VascoTech & Sciences, where he acts as its technical and executive director, lending technical support and advice to many companies in the United States and Latin America.

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I have had the intention of writing this book since the time I was working for Hunt-Wesson Foods, where I was exposed to the fascinating experience of quality assurance for the food industry. My background — both academic and practical experience — in chemical and food engineering, food processing, biochemistry, and nutrition allowed me to understand and "visualize" processes, and excel in my work. Equally important was the fact that I was surrounded by and sharing responsibilities with outstanding professionals who helped me and with whom I could work at a high level of excellence, contributing to make Hunt-Wesson's quality system among the best in the food industry, under the expertise and guidance of Joel Gallin, our boss. Curt Roberts, Rich Fenstermaker, Frank Richards, Gordon Farrimont, Joe Fry, Dave Navarrete, and Dr. T. S. Lin, among others, helped me to fully appreciate the value and importance of quality assurance as a professional field of the food sciences. My experiences with them encouraged me to write this book. I am grateful to my former colleagues, for their friendship and camaraderie in our work.

The demands of a full-time job, plus teaching at Chapman University, did not leave me time for writing. However, at the end of 2000, Dr. Jorge Welti-Chanes, academic vice chancellor of the University of the Americas, Puebla, Mexico, invited me to spend the following year teaching in the Food Engineering Department; I saw my opportunity to write, as well as teach. During the first half of 2001, I was able to complete a good part of the necessary work. Unfortunately, as a result of an accident suffered 4 years earlier, which had been undiagnosed until I was in Mexico, I suffered a series of circumstances that threatened my life, and did not permit me to continue my writing. During that dark period of my life, friends and colleagues at the University of the Americas provided me and my family with the most wonderful support. There is no form of repayment for their actions, except to extend a very special expression of gratitude

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At home, I must thank my parents-in-law, Dr. and Mrs. Alfred Mathieu; for over 30 years and especially during these last 2 years, their support and love have been constant. They have my sincere and deep gratitude and love. I must also thank my sisters and brothers. A very special note of gratitude and a prayer to the memory of my beloved parents, José Andres Vasconcellos-Avilés and Idalia Rosado de Vasconcellos, whose example and sacrifices are more meaningful as the years go by; I am the person that I am because of their love, their nurturing, and the examples they set before me. Their memory shines brightly in my heart and guide me as a man and as a father and husband in every act.

I thank my wife Marilyn from the bottom of my heart, for all the strength shown during those dark days that tested her character, and for her valuable help during my writings. I thank my children, my joy, my pride: Miguel and his new wife Erlina; Cito and his wife-to-be Sandra; Cristina; and Eduardo. I give thanks for Sydney Nicole, my precious

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Last, but definitely not least, I must extend special thanks to Dr. Eleanor Riemer, my editor at CRC Press, who nurtured this book with patience, enthusiasm, and good humor; my thanks and appreciation also go to Sara Kreisman for her kind and sensitive support.

CONTENTS

Chapter 1

INTRODUCTION: CONCEPTS

The specific manufacturing area presented in this book is the food industry. The principles of quality assurance (QA) as a function of total quality management (TQM) and the methodology necessary to establish and implement a QA program are analyzed. These principles are useless without adequate technical and scientific training and a proper level of professional experience, all of which ensure that the program most appropriate to the individual company is established. These aspects imply a concerted effort on the part of the company, with the identification and evaluation of previously unconsidered parameters.

The goals of this book are to discuss different ideas about quality, starting with the basic concepts and principles behind TQM, and to present examples of programs that can be applied to the food industry using simple, proven formats. Another goal is for the student to gain an overall understanding of a QA program and, with a reasonable amount of experience, be able to set up an adequate system in his or her own company.

Quality assurance is a modern term for describing the control, evaluation, and audit of a food processing system. Its primary function is to provide confidence for management and the ultimate customer, in most cases, the consumer. The customer is the person a company must satisfy and who ultimately establishes the level of quality of the products a company must manufacture: He is the management's guide to quality.

A company builds its product specifications and label requirements around customer preferences. Only by having a planned quality program can food companies continue to succeed in supplying the customer with the desired products. No other component in a QA program is more important than developing a strong organization in terms of both ability and mission. This requires careful thought and discussion. Haphazard organization and planning can result only in people working at cross-purposes.

Corporations are not the only principals concerned with organization and management. Industry's counterparts, the government regulatory

agencies, manage staffs that outnumber the employees of most food processors and are involved with the same food-related issues, although from a different reference point. What government regulators say and do have as great a bearing on product planning as any decisions made by industry personnel. This influence is based on two decisions by the United States Supreme Court that unequivocally held the chief executive officer of any company responsible for the actions of his or her subordinates, regardless of any consideration of company size, good intentions, lack of knowledge, or other mitigating circumstances.[1]

THE DOCTRINE OF "STRICT" LIABILITY

This doctrine dates back to 1943, to the so-called "Dotterweich case." It is sometimes referred to as "absolute" or "vicarious" liability. It states that the president of any food company can be found guilty of a violation of the Federal Food, Drug and Cosmetic Act (FD&C Act) even though he or she may not have been personally involved with the given transgression. The defendant is barred from relying on any assertion that he or she was ignorant of an offense.[2]

THE DOCTRINE OF "TOTAL ACCOUNTABILITY"

In 1975, the "strict" liability doctrine was upheld and expanded by the Supreme Court, when John R. Park, President of Acme Markets, Inc., which operated more than 800 food stores, was found guilty of violations due to rodent infestation in one of his companies' warehouses. The Supreme Court maintained that "the requirements of foresight and vigilance" demanded of chief executives be upheld.[3]

Congress has held numerous hearings on new food legislation during which some witnesses have indicated that constitutional rights are being encroached by adhering to such a strict standard. The prevailing opinion, however, asserts "in the sensitive area of food safety, the public's welfare takes precedence over any consideration of individual claims."[3]

The court decision in the Park case, that the Chief Executive Officer of a corporation can be held accountable for the action of his subordinates, is very significant when addressing the question of organization and is particularly important in regard to consumer safety, and therefore, QA and Quality Control (QC) programs within the industry.

MANAGEMENT AND PRODUCT QUALITY

In the food industry, quality is a requirement for consumer acceptance. Total quality, or integral quality, means that all industrial operations,

manufacturing, and the final product are subjected to acceptable processing and conformance with requirements. Integral quality begins with the support of upper management; time and effort are required to involve all personnel in the explanation of the need for the control of product quality. Management must provide proper job instructions to all employees, as some employees may not be aware of good practices. The successful operation of any production, manufacturing, or formulation process is dependent upon the degree of control that can be exerted on the process. Quality programs recognize elements such as "quality in production" and "control of production" as being essential aspects. These principles require that a producer or manufacturer plan the production or manufacturing process in such a manner that the process can be carried out under controlled conditions. This "process control" element is now recognized as being critical for the successful operation of a manufacturing industry in order to ensure that quality targets can be consistently achieved.

To obtain quality results, therefore, the initiative must be taken at the highest managerial levels. A prudent chief executive must establish clear channels of communication between the persons making the decisions at the plant level and those executives responsible for setting policy. Senior managers should have access to operational data, and line supervisors should be able to report developments as they occur. Impediments to the exchange of information can only lead to low quality of operations and of the final product, and to many other problems.

For a company to attain production quality, management must make an effort to train all personnel in the concept of statistical techniques and the application of statistical practices to the production line, so that they may help to solve the problems of producing quality products.

Organizational Plan

According to Gould and Gould,[4] a modern food plant is organized "around the M's"; the first "M" of the food industry is management, responsible for ensuring that the company returns a profit on the invested capital. To make a profit, management must fully utilize the resources of materials, machines, manpower, methods, money, and the departmental managers within the plant. According to these authors, the most important M is manpower, vital to producing a quality product at a profit.

The working environment is the most critical factor for employees, and is often called the "common cause" of manpower wastage and production problems in food plants. Management needs to provide workers with the proper environment, appropriate tools, training, and instructions for them to do their jobs correctly. Dr. Joseph Juran has argued since the early 1950s that the "common causes" of problems in a manufacturing

environment represent up to 85% of the system faults[4] and are considered, in a TQM program, faults that can be removed only by management. They include the factors shown in Table 1.1.

Total Quality Program

A total quality or an integral quality program implies the establishment of specific goals for quality improvement and the analysis of the costs associated with nonconformance of products and processes to established quality levels. The evidence and consequences of nonconformance must be conveyed to all personnel through newsletters, videotapes, personal contacts, statistical charts, and in open forums.

A company's management must provide total support to a total quality program, conveying a consistency of purpose and continuity to the program organization, as well as to create excitement and enthusiasm at all levels of operations and in each individual employee. A manager should fully understand that workers work in the system, but managers work on the system. He or she must see to it that the company produces the highest quality product at the lowest possible cost, the fundamental purpose of a quality management program. A manager is responsible for the system as a whole and for its continued improvement.

The Working Environment

Workers

In the context of modern total quality concepts, the workers should assume the responsibilities, risks, and rewards associated with making their own decisions; this is to say that they should be empowered and considered an important component of the decision process, for they are the only people who make detailed observations of a system on a day-by-day basis. To help a company grow and thrive in today's competitive marketplace, the workers need to play a major role in its success. They must make decisions that will enhance the productivity of the company, and they must take ownership of both successes and problems. Worker performance is directly related to how the system operates. Problems within the system are usually first detected by the workers. If workers complain about poor maintenance, and have the statistical data and facts to back up their complaints, good managers should not consider them to be troublemakers, but rather welcome their comments as contributions to the success of a quality program.

The general philosophy of today's most successfully managed companies is that a shift has taken place from the QC technologist (and his or her laboratory) to the line employees and their responsibility for producing

Table 1.1 Common Causes of Manpower Wastage in a Manufacturing Plant

Failure to get the best from capable employees
Lack/incomplete job instructions for new employees
- Failure to explain in detail the nature of the work
- Failure to explain what is expected in terms of quality and quantity of work
- Failure to instruct new employees in all aspects of safety
- Failure to select suitably qualified and experienced employees
- Impatience with new employees who learn slowly

Failure to integrate new employees into the working environment
- Failure to get other workers to show a friendly, helpful attitude toward new employees
- Failure to establish sound relationship and regular contact with new employees

Varying quality of incoming materials
Machines poorly maintained and/or calibrated
Poor design of the process
Lack of statistical information or performance data
Failure to train an understudy
Failure to recognize or commend exceptional performance
- Failure to promote an employee when it is possible and appropriate
- Lack of interest in employee progress and affairs
- Not providing employees needed support and help

Lack of attention to employee's ability and temperament
- Keeping an employee in a job for which he is not mentally or physically suitable
- Failure to view employees as individuals in order to motivate them

Lack of due consideration to problems resulting from uncomfortable working conditions, such as humidity, noise, confusion, temperature (heat or cold), poor ventilation, poor light, dirt, etc.
Failure to admit mistakes
Failure to control turnover of capable employees
Failure to correctly interpret the company's real aims and policies to workers
Not inducting new employees appropriately: policies, procedures, pay, terms and conditions of employment, facilities, etc.
Making promises that cannot be fulfilled in regard to wages, promotion, etc.
- Not keeping promises that could have been fulfilled

Not appreciating the direct and indirect costs of labor turnover
- Discharging employees without sufficient cause
- Improper use of the discharge procedure as a penalty

Poor supervision
- Too much "bossing"; not enough intelligent direction
- Keeping an employee on a job for which he may have a strong dislike
- Too strict or too lax enforcement of discipline
- Criticizing a worker in front of the group
- Favoritism; treating one person better than others
- Taking sides in employees' arguments

quality products efficiently. The QC technologist is still an integral part of the company plan to ensure product quality, but accountability has shifted to the line employees because they now understand the company's standard of quality. They know their jobs depend on the efficient production of a quality product and that the laboratory will be evaluating and auditing their performance. One way to do this is to have workers inspect the item from the prior operation before proceeding. In this way quality feedback can be given on a much timelier basis. Each operation performs both production and quality inspection. In this way, a quality manager can pinpoint causes where most problems occur in a production line.

There are two reasons for employee participation.[5] The first one is to increase employee commitment to the resultant outcomes, as they will feel a greater stake or sense of ownership in what is decided. The second reason is that employees have a great deal of knowledge and skill relevant to the issue at hand (i.e., increasing quality, identifying problems, improving work processes), and their input should lead to higher quality decisions.

Managers and Supervisors

The manager works on the system as a whole. He takes action based upon the observations of the workers. Managers who share power and responsibilities make the workplace more efficient and make themselves more competent and productive. Workers enjoy being involved in the decision process and will develop pride and enthusiasm and become more effective when given a voice in the operation of the system. A good integral program will consider and take advantage of this fact.

The key to the success of an integral quality program and to the motivation of each employee is the manager or supervisor.

Apart from technical skills, a good manager needs constant training in human relations, including incentive standards, discipline, how to settle grievances, and how to train others. Further, he needs training in cost analysis, leadership principles, and how to manage, motivate, and communicate.

A manager should set a good example, display enthusiasm, be job oriented, and show interest in his people. He needs to be a good listener, respectful, tactful, and courteous. Most of all, a good manager should be sound in his judgment. He is the bridge between top management and the worker, as he is in daily contact with each employee under his supervision. To the employee, the manager or supervisor is management. Therefore, his morale affects the morale of the worker.

A successful manager relies on the supervisory staff to help make his many decisions, as each person has specialized knowledge and interest. Further, each can focus on his area of expertise. The supervisory staff must be committed, visibly involved, and project a strong leadership attitude.

They must be truthful, consistent with their facts, and confident when dealing with others; clearly define objectives and goals; improve support and trust levels among employees; develop healthy intergroup relations and reduce unhealthy conflict; and reduce stress in the workplace. They should be encouraged to use "we" instead of "I." The people under their supervision need to be brought into the process; when the supervisor's job is done, his or her people must be able to say "WE did a good job."

According to Wilbur and Ronald Gould, in their book *Total Quality Assurance for the Food Industries,*[4] the general key traits in a successful manager include:

- Positive attitude
- Initiative; willingness to dig in and get started
- Ambitious; always broadening his view, developing new skills, and willing to take a risk
- Self confidence; a competitor, one who gets the job done
- Courage; willingness to train a successor
- Flexibility; not set in his ways
- Resilience; having the ability to bounce back
- Stamina; mental attitude to cope with endless stress
- Ability to judge people; ability to help people develop their own strengths
- Goal setter; long-range planning, including budgets and deadlines
- Collaborator
- Imaginative
- Creative
- Objective
- Stability possessing great self discipline

Several American companies have made efforts to adopt this type of policy. Interest was stirred a few years ago by the success of Japanese industry in maintaining different management, supervisory, and job motivation programs for their workers and, at the same time, promoting exercise and other health-related programs. The interest in the relatively new concept of total quality management encouraged American firms to adopt the Deming philosophy of management, and to apply the technical approach of "robust design" (http://akao.larc.nasa.gov/pap/robdes/robdes.html) as promoted by Dr. Genichi Taguchi.[6,7]

Regardless of all the commotion caused by these concepts, only a few companies can claim success. In most cases, courses, seminars, and other programs have ended in written notes in the notebooks of mid-management America, with no real practical application at any level, although many companies claim they are using these programs.[8]

Apart from the waste of economic resources and time, the practice by American companies of pretending to learn and utilize the concepts of integral quality is evidence of the sad reality of the need to re-train American upper management in the revolutionary concepts of modern total quality programs of operations.

Building Teams of Empowered Employees

Under the umbrella of a Total Quality program, a company can build qualified teams of empowered employees that can practically guarantee a quality manufacturing system. In conforming such teams, however, the following aspects should be considered as an ongoing part of the program:

- Employee training
- Work teams
- Empowerment
- Quality at the source
- Steering committees or quality circles

Employee Training

Implementing the TQM philosophy requires that all the employees from the shop floor to the boardroom, suppliers, and even the customers be involved on this training program. A training program is aimed not only at statistical quality control techniques, but also at the broader concepts of TQM.

Some companies use their own training programs, but there are some professional organizations available, such as Philip Crosby & Assoc. (www.philipcrosby.com), Qualtec (www.sixsigmaqualtec.com), and Vasco-Tech & Sciences (www.vascotech.com).

Work Teams and Empowerment

A well-designed program of TQM must start with employee training and empowerment of workers as individuals and as work teams. On this, managers must first give the authority to act. Procedures should be concise, organizing work teams, pinpointing job assignments and providing the means for intercommunication within the organization. In the preparation of such tasks, a realistic appraisal should be made of business needs and the resources and manpower available for meeting these demands.

For the line workers and their supervisors to discharge their duties effectively, they must be given proper training and wide latitude without fear of reprisals, as they bear the responsibility of maintaining a steady

output of quality products. Not only are these groups closer to the problems of quality, they are far more efficient than corporate staffs in handling the deluge of requests from customers. In turn, these employees must accept the full responsibility for every facet of the production process and cooperate with each other so that the product being manufactured maintains the desired standards at all times.

Quality at the Source

This process puts the production worker in the driver's seat of controlling the product quality. Some of the principles are:

- Every worker becomes a QC station.
- Every worker is responsible for inspecting his or her own work, identifying any defects and repairing the products.
- Each worker is given the right to stop the line to avoid producing defective parts.

Steering Committees or QC Circles

Under the impact of these concepts, some American companies adopted the "steering committee" system for working with employees. Some companies use the term "task force" or "fact finding committee" and "quality circle" in lieu of "steering committee." The terms refer to a work environment with the object of solving problems in a given situation. A steering committee is a voluntary group of workers sharing areas of responsibility. Usually small groups of no more than eight to nine employees meet periodically (weekly, bi-monthly, etc.) to discuss, analyze, and propose solutions to quality problems; to undertake work-related projects designed to advance the company; and to improve working conditions by using quality control concepts. Projects can go beyond the quality aspects of the operations, usually including such areas as productivity, tool design, safety, maintenance, and environmental protection. The steering committee members are trained in group communication processes, quality strategies, and measurement and problem-solving techniques. They are encouraged to draw on the resources of the company's management and technical personnel to help solve problems, and they generate and evaluate their own feedback. In this way they are responsible for employees communicating with one another.

A supervisor may become the leader of the committee or work as a group member. He is not the "boss" during committee meetings. These steering committees or quality circles usually meet away from the workplace, and receive no cash incentives for their meetings. This management

concept originated in the U.S. several years ago but never really attracted much attention until after the automobile crisis, when U.S. management started to question the great success the Japanese were having with employee motivation. The Japanese were utilizing the steering committee concept in many of their businesses. The committee's leader should be trained in leadership skills, adult learning techniques, motivation, and communication techniques. He must be knowledgeable in the use of measurement techniques and quality strategies including cause-and-effect diagrams and cards (CEDAC), histograms, run diagrams average (X bar), range (R) charts, sampling systems, data collection, scatter diagrams, charting techniques, and statistical interpretation.

All of these techniques, when properly utilized, will help to improve the productivity of the company. Some benefits include an overview of product quality, line controls, sanitation, food regulations, waste, absenteeism, product rejection, accidents, pool workflow, excessive inventories, inefficiencies, spoilage, etc. The whole concept provides an opportunity for workers to develop their skills. It allows workers to have fuller participation in the operation of the company, and it provides a vehicle for the worker to have a sense of dignity.

In summary, an effective food plant operation includes good people and adequate training to help them accomplish that which is expected of them: the right person in the right job. Through proper communications, workers can appreciate their roles and know exactly how they are contributing to the success of the company.

Management, including the supervisor, must help workers succeed and hold all personnel accountable for their performances. Those who perform up to and beyond expectations must be rewarded accordingly. Most important, every effective organization must have good management who plan carefully and work through the supervisors. The supervisors, in turn, should work with those under their leadership.

A good manager gives direction to the system, coordinating all the activities. He should control the system to produce quality products efficiently. Management is the key to any firm's future.

WHAT IS QUALITY?

Quality, it has been said, should make a product what it is, conforming to requirements or specifications. In this context, quality may be defined in different manners depending on the interest of the manufacturers, or how they want to impress it upon their customers. One difficulty in using this approach is that the definition of quality is neither precise nor consensual. Quality-like terms such as effectiveness, satisfaction, and leadership, are descriptors rather than concepts, and no objective reference

exists. Its definition is in the minds of the definers, so no single definition is correct for every circumstance. In each case, quality has always been used as a qualifier in describing some product or service: high-quality product, high-quality education, high-quality art, high-quality health care, etc.[9] Thus, in industrial manufacturing practices, quality can have several definitions, as follows:

- Product-based. Based on features or attributes of the product that enhance quality, e.g., organically manufactured food products as opposed to regular products.
- User-based. The user determines the quality of the product. Joseph Juran defines this user-based quality as "fitness for use," e.g., ready-to-eat microwaveable dinners as opposed to other forms of manufactured dinners.
- Manufacturing-based. Conformance to specifications. Manufacturing engineering specifies the product characteristics and the more closely manufacturing can conform to those requirements, the better the quality of the product.
- Value-based. The element of price is introduced into the definition of quality. Quality is the degree of excellence at an acceptable price and the control of variability at an acceptable cost. Value comprises price and quality of product and service.

Dimensions of Quality

The definition of quality also must take into consideration its dimensions, which include strategic as well as operational aspects that play an important role in characterizing the product presented to customers. In this context, there are two types of quality:

- Design. This determines the market segment. It is not only an engineering decision, but involves customers, manufacturing, and other stakeholders.
- Conformance. David A. Garvin[10,11] came up with eight dimensions of quality to link customer requirements to engineering design.
  1. Performance. Refers to the primary operating characteristics of the product or service; they are usually measurable, e.g., miles per gallon, number of rooms, baths, etc. in a house.
  2. Features. Additional characteristics that enhance the product's or service's appeal to the user, e.g., deleaded ink used for newspapers, glare-reducing coatings on bulbs, etc.
  3. Reliability. The likelihood that a product will not fail within a specific time period, e.g., services that guarantee mail delivery (certified mail, etc.).

4. Conformance. The precision with which the product or service meets the specified standards. Approaches such as using pre-specified tolerance limits.
5. Durability. Measures the length of a product's life, e.g., shelf life of food products, light bulbs. When a product can be repaired, estimating durability is more complicated.
6. Serviceability. The speed with which the product can be put into service when it breaks down, as well as the competence and behavior of the service person. The speed of service can be measured by response time and mean time to repair (MTTR).
7. Aesthetics. The subjective dimension indicating the kind of response a user has to a product. It represents the individual's personal preference — the ways an individual responds to the look, feel, sound, taste, and smell.
8. Perceived quality. Also a subjective dimension; it is the quality attributed to goods or services based on indirect measures. Inferring the quality of an airline by the cleanliness of the flip-down tray. Well-maintained tools and an immaculate workplace may indicate a good workman.

In summary, the term *quality*, without being defined by some standard, means very little. As stated by Gould and Gould,[4] industry defines quality as a measure of purity, strength, flavor, color, size, maturity, workmanship and conditions, or any other distinctive attribute or characteristic of the product. On the other hand, the trade generally uses the term in the sense of the finest product attainable.

Food processors have learned that consumers recognize brands that maintain their quality at the standard set for that particular product, and on this basis, high-quality products never fail to sell; the attainment of such quality is the outgrowth of good, sound QA practices.

In recent years, the focus on quality has changed and, more and more, quality has begun to take on the appearance of organizational performance. Managers have become converted to the pursuit of quality as the single most important organizational objective.[12]

Standards of Quality

There are different ways of arriving at a standard for product quality. The four most common standards are:[4]

1. **Legal Standards** Federal, state, or municipal agencies commonly establish these. Legal standards are mandatory and are set up by law or through regulations. They represent the Federal Food, Drug, &

Cosmetic Act minimum standards of quality, the various state minimum standards of quality, or the municipal minimum standards of quality.

Legal standards are generally concerned with the lack of adulteration involving insects, molds, yeasts, and pesticides; the maximum limits of additives permitted; or by establishing specific processing conditions so that extraneous materials do not contaminate foods.

2. **Company or Voluntary Label Standards** These standards represent those established by various segments of the food industry. They represent a consumer image and may become a trademark or symbol of product quality. Voluntary standards are generally used by private companies or supermarkets and tend to vary depending upon the particular requirements of a given label.
3. **Industry Standards** Those whereby an organized group attempts to establish given quality limits for a given commodity. Industry standards are implemented due to pressure from marketing organizations or by specific commodity groups where legal standards are not involved. Examples are the standards for cling peaches, peanut butter, and some frozen foods.
4. **Consumer or Grade Standards** These represent the consumers' requirements for a product. Generally, they are based on past consumer experience. The U.S. Department of Agriculture standards for grades represent the best standards in this area. Other examples are military standards, the Veterans Administration standards.

Methods for Determining Quality

Many methods are available to evaluate food samples for a given quality characteristic or component. Depending upon the characteristic(s) of interest and the objective of the analysis or analyses, it is necessary to be familiar with the different types of methods, the principles underlying the procedure(s) to be used, and the validity of the method, including some inherent properties such as specificity, precision, accuracy, sensitivity, and equally important, reproducibility.

The choice of a method for a given analysis of a food sample is made easier by the availability of official methods of analysis compiled and published by professional scientific organizations. Such methods have been carefully developed and standardized, and often are evaluated for accuracy of results between collaborative laboratories in academia and industry, following identical procedures.

The methods of analysis used by the food industry can be classified in two groups: (1) subjective methods and (2) objective methods.

Subjective Methods

These methods are based on the opinions of individual evaluators or investigators; they consist of a physiological reaction resulting from prior training experiences of the individual, the influence of personal preference, and powers of perception.

These methods are subjective because the individual is required to give his or her opinion as to qualitative and quantitative values of the characteristics under study. They usually involve the various sense organs and therefore may also be referred to as sensory methods. Examples are flavor, odor, color, or touch.

Objective Methods

These methods consist of determinations from which the personal influences of the investigators are entirely excluded and are based on recognized standard scientific tests applied to a sample of the product or products. Objective methods are examples of the modern idea of QC in which the human element has been excluded.

Objective methods are divided into three general groups:

1. **Physical Methods** These are the quickest methods and require the least amount of training. The physical methods for quality evaluation of a product deal with such attributes as size, texture, color, consistency, and imperfection, or with process variables such as headspace, fill weight, drained weight, vacuum, etc.
2. **Chemical Methods** Chemical methods are used for quantitative evaluations and for determination of nutritive values and qualitative levels. Chemical analyses are, in general, long and tedious. As a result, the industry and allied interested parties have developed methods that are termed "quick tests," such as those for enzyme reaction rates, enzyme concentration, moisture content, soluble solid concentration, pH, or acidity determinations that can be used on the manufacturing floor during processing. In many cases these tests can be closely correlated with the longer procedures and accurate values determined.
3. **Microscopy Methods** These methods have excellent applications in QC programs. They require considerable training of the technical personnel to properly interpret results. They can be divided into two general categories:
   a. *Adulteration and Contamination* Used to indicate the presence of bacteria, yeast, mold, insect fragments, insect excreta, or foreign

materials. Each test is specific, and the technologist must have the proper background to be able to differentiate the various types of adulteration and contamination that might be present in the products.

b. *Differentiation between Cell Types, Tissue Types, and Microorganisms of Various Stored Foods* Examples of the applications of these methods are tissue testing for deficiency of fertilizer materials, stored food in the tissues of plant materials, and microorganisms causing spoilage or undesirable fermentation changes.

OFFICIAL METHODS OF ANALYSIS IN THE FOOD INDUSTRY

There are professional scientific organizations that serve the analytical methods needs of the food industry in the U.S. They are also recognized and accepted in most cases as referees for quality assessment and qualification of foods in international trade. Among these are the American Organization of Analytical Chemists, the American Association of Cereal Chemists, the American Oil Chemists' Society, the American Public Health Association, the American Water Works Association, the American Spice Trade Association, the Infant Formula Council, the Corn Refiners Association, and the Food Chemical Codex.

The Association of Analytical Communities International (AOAC International)

Formerly known as the Association of Official Analytical Chemists, AOAC International is committed to being a proactive, worldwide provider and facilitator in the development, use, and harmonization of validated analytical methods and laboratory QA programs and services. AOAC International also serves as the primary resource for timely knowledge exchange, networking, and high-quality laboratory information for its members.

AOAC International was founded in 1884 as the Association of Official Agricultural Chemists, under the auspices of the U.S. Department of Agriculture (USDA), to serve the analytical methods needs of government regulatory and research agencies, particularly to adopt uniform methods of analysis for fertilizers. Today, the goal of AOAC International is to provide methods that will be fit for their intended purposes, i.e., will perform with the necessary accuracy and precision under usual laboratory conditions.[13]

Methods validated and adopted by AOAC International and the data supporting the method validation are published in the *Journal of the AOAC*

International. Such methods must be successfully validated in a formal interlaboratory collaborative study before being accepted as an official first action method by AOAC International. Details of the validation program are presented in the front matter of the AOAC International's "Official Methods of Analysis." First action methods are subject to scrutiny and general testing by other scientists and analysts for at least 2 years before final action adoption.

The Official Methods of Analysis of AOAC International[14] are often specified by the FDA with regard to legal requirements for food products, and are generally followed also by the Food Safety and Inspection Service (FSIS) of the USDA to check nutritional labeling information and for the presence of undesirable residues or residue levels.[13]

The American Association of Cereal Chemists

The American Association of Cereal Chemists (AACC) was founded in 1915 for the purpose of standardizing methods of analysis among cereal laboratories. AACC publishes "Approved Methods for the Analysis of Cereals and Cereal Products," a set of approved methods first published in 1922, presently in its 10th edition.[15] These methods are relied-upon sources in the field of cereal science and technology. The AACC process of adopting the "Approved Methods of Analysis" is consistent with the process used by the AOAC International. They are continuously reviewed, critiqued, and updated, with supplements containing new and revised procedures provided on an annual basis.

The American Oil Chemists' Society

The American Oil Chemists' Society (AOCS) publishes a set of "Official Methods and Recommended Practices" (AOCS Methods)[16] consisting of over 400 methods relating to fats, oils, oilseeds, oilseed proteins, soaps, synthetic detergents, fatty acids, oleochemicals, and glycerin and lecithin technology, valuable to the oil and fats industry. Information and methods are regularly updated through international cooperation of the activity of numerous subcommittees and liaison with world standards organizations.

The American Public Health Association

The American Public Health Association (APHA) is concerned with a broad set of issues affecting personal and environmental health, including federal and state funding for health programs, pollution control, programs and policies related to chronic and infectious diseases, a smoke-free society, and professional education in public health. APHA publishes several

methods for analysis of foods including Compendium of Methods for the Microbiological Examination of Foods,[17] Standard Methods for the Examination of Dairy Products,[18] and Standard Methods for the Examination of Water and Wastewater[19] published jointly with the American Water Works Association (AWWA) and the Water Environment Federation.

The American Spice Trade Association

The American Spice Trade Association (ASTA) is a U.S.-based organization whose worldwide membership is comprised of the leading firms in the spice industry. ASTA has been serving and leading the spice industry since 1907, and although still called the American Spice Trade Association, its scope is truly global, representing and serving members in over 34 spice-producing nations.

ASTA publishes ASTA Analytical Methods that comprises the recognized official methods for analysis of spices and derived products.[20]

The Food Chemicals Codex

The Food Chemicals Codex is an activity of the Food and Nutrition Board of the Institute of Medicine, supported by the U.S. Food and Drug Administration. Created more than 40 years ago, following the passage of the Food Additives amendments to the Federal Food, Drug, & Cosmetic Act in 1958, the Food Chemicals Codex is intended to provide standards for the purity of food chemicals, promoting uniform quality and ensuring safety in the use of such chemicals. The first edition of the Food Chemicals Codex, published in 1966, was limited to chemicals added directly to foods to achieve a desired technological function. Succeeding editions upgraded the specifications for these substances and added specifications for substances that come into contact with foods and some regarded as foods, rather than as additives. The goal of the Food Chemicals Codex is to continue defining the quality of food-grade chemicals in terms of identity, strength, and purity, based on the elements of safety and good manufacturing practices. Food Chemicals Codex[21] is published by the Food and Nutrition Board of the National Research Council/National Academy of Science, and contains methods for the analysis of foods and additives.

REFERENCES

1. Sloat, J.W., 1975. Executive's personal risk is high if FDA cites unsanitary storage or holding, *Food Prod. Dev.*, September 28.
2. Hyman, P.M., 1975. Criminal prosecution of individuals under the Federal Food, Drug, and Cosmetic Act, *Food Techn.*, 29(5), 58, 60, 62.

3. O'Brian, M.T. and Peters, J.W., 1975. Court ruling bolsters FDA prosecution stance. Top executives can be held liable for FD&C violations, *Food Prod. Dev.*, July-August, 20.
4. Gould, W.A. and Gould, R.W., 2001. *Total Quality Assurance for the Food Industry*, 3rd ed., CTI Publications, Inc., Timonium, MD.
5. Packard, T., 1989. Participation in decision making, performance, and job satisfaction in a social work bureaucracy, *Administration in Social Work,* 13(1), 59.
6. Taguchi, G., 1992. *Taguchi on Robust Technology Development: Bringing Quality Engineering Upstream*, ASME Series on International Advances in Design Productivity. American Society of Mechanical Engineers Press, New York.
7. Taguchi, G., Chowdhury, S., and Taguchi, S., 1999. *Robust Engineering: Learn How to Boost Quality While Reducing Costs & Time to Market,* McGraw-Hill, New York, NY.
8. Vasconcellos, J.A., 2002. Quality Assurance for the Food Industry. A Practical Approach. Personal notes.
9. Druckman, D., Singer, J.E., and Van Cott, H., 1997. Techniques for making organizations effective, in Enhancing Organizational Performance, Committee on Techniques for the Enhancement of Human Performance, Commission on Behavioral and Social Sciences and Education, National Research Council, National Academy of Sciences, Washington, D.C.
10. Garvin, D.A., 1987. Competing on the eight dimensions of quality, *Harvard Business Review*, November/December, 101.
11. Garvin, D.A., 1988. *Managing Quality: The Strategic and Competitive Edge*, Free Press, New York.
12. Deming, W.E., 1986. *Out of the Crisis*, Cambridge University Press, Cambridge.
13. Nielsen, S.S., 1998. *Food Analysis*, 2nd ed., Aspen Publishers, Gaithersburg, MD.
14. AOAC International, Official Methods of Analysis, 17th ed., 2002. Association of Analytical Communities International (AOAC International), Gaithersburg, MD.
15. American Association of Cereal Chemists (AACC), 2000. *Approved Methods of the AACC*, 10th ed. American Association of Cereal Chemists, St. Paul, MN.
16. American Oil Chemists' Society, 1996. *Official Methods and Recommended Practices*, 4th ed., American Oil Chemists' Society, Champaign, IL.
17. Downes, F.P. and Ito, K., 1998. Compendium of Methods for the Microbiological Examination of Foods, 4th ed., American Public Health Association, Washington, D.C.
18. Marshall, R.T., 1993. *Standard Methods for the Examination of Dairy Products*, 16th ed., American Public Health Association, Washington, D.C.
19. Clesceri, L.S., Greenberg, A.E., and Eaton, A.D., 1998. *Standard Methods for the Examination of Water and Wastewater*, 20th ed., American Public Health Association, Washington, D.C.
20. American Spice Trade Association, 1997. *ASTA Analytical Methods,* 4th ed., American Spice Trade Association, Inc., Englewood Cliffs, NJ.
21. National Academy of Sciences, Food Chemicals Codex, 4th ed., 1996. Food and Nutrition Board, National Research Council. National Academy Press, Washington, D.C.

Chapter 2

TOTAL QUALITY MANAGEMENT

Total Quality Management (TQM) is a theory of management based on the principles of quality assurance. It consists of the integration of all functions and processes within an organization in order to achieve continuous improvement of the quality of goods and services. As such, TQM is described as a process for managing quality; a philosophy of perpetual improvement. TQM relies on the fundamental principle that is the core of any business: maximize productivity while minimizing costs. Its goal is customer satisfaction.

THEORIES AND APPLICATION

Historically, commercial organizations in economically advanced nations have focused on preventing defective goods and services from entering the market. In the last 15 years, the trend has been toward producing goods and services by first assaying customer needs and then designing accordingly. In emerging East Asian economies the focus has been more on quality assurance right from the start. Of all the management issues faced during this period, none has had the impact of or caused as much concern as total quality in American products and services. According to senior executives in the U.S., the banner of total quality has become essential to ensure competitiveness in global markets. Quality expert Joseph M. Juran calls this fact a major phenomenon in this age.[1,2]

Total Quality Management, a buzzword phrase of the 1980s, can be defined as a structured system for satisfying internal and external customers and suppliers by integrating the business environment and the continuous improvement of processes with development, improvement, and maintenance cycles, while changing organizational culture.[3] There are many other

definitions of Total Quality Management, but all agree on its primary objective: to achieve customer satisfaction by involving customers.

The interest in quality in the U.S. is due in part to foreign competition and the trade deficit.[4] Analysts estimate that the vast majority of U.S. businesses will continue to face strong competition from the Pacific Rim and the European Economic Community for the first part of the 21st century as a result of a serious erosion of corporate America's ability to compete in global markets over the past 20–30 years.[5]

The problem has not gone unnoticed by government officials, corporate executives, and the public. The concern of business executives is reflected in their perceptions of quality, and culminated in the enactment of the Malcolm Baldrige National Quality Improvement Act of 1987 (Public Law 100-107), which established an annual United States National Quality Award. In a 1989 American Society for Quality Control (ASQC) survey, 54% of executives rated quality of service as extremely critical and 51% rated quality of product as extremely critical.[6] American-made products scored less than 8 on a 10-point scale for quality by 74% of respondents. Similarly, a panel of Fortune 500 executives agreed that American products deserved no better than a grade of C^{+}.[6]

Public opinion regarding American-made products is somewhat less than enthusiastic. Less than half of those surveyed gave American products high marks for quality.[7] Employees also have misgivings about quality in general and, more specifically, about quality in the companies in which they work. They believe that there is a significant gap between what their companies say and what they do. More importantly, employees believe that their talents, abilities, and energies are not being fully utilized for quality improvement.[8]

Despite the pessimism reflected by these groups, progress is being made. In a survey of American owners of Japanese-made cars, 32% indicated that their next purchase would be a domestic model; the reason given most often was the improved quality of cars built in the U.S. (survey by the Integrated Automotive Resources, Wayne, PA). Ford's "Quality is Job One" campaign may have been a contributing factor. There is also evidence that quality has become a competitive marketing strategy in the small business community, as Americans are beginning to shun mass-produced, poorly made, disposable products.

Other promising developments include the increasing acceptance of TQM as a philosophy of management and a way of company life as an essential factor for American companies to remain competitive in global markets. Customers are becoming more demanding and international competition is fiercer. Companies that deliver quality will prosper in the next century.

The Concept of Total Quality Management

Total Quality Management (TQM) is based on a number of ideas. It means thinking about quality in terms of all functions of the enterprise, and it can be viewed as a management-led approach in which top management commitment is essential, a start-to-finish systems approach that integrates interrelated functions at all levels. TQM considers every interaction between the various elements of the organization. The emphasis is on quality in all aspects and functions of the company operation, company-wide, not just the manufacturing function or provision of a major service to the external end-customer. Employee awareness and motivation are essential. All are responsible for ensuring quality in terms of satisfying the customer in all they do, and the approach is one of prevention of errors and faults rather than detection and correction. Thus, the overall effectiveness of the system is higher than the sum of the individual outputs from the subsystems.

The subsystems include all the organizational functions in the life cycle of a product, such as design, planning, production, distribution, and field service. Management subsystems also require integration, including strategy with a customer focus, the tools of quality, and employee involvement (an important linking process that integrates the whole). A corollary is that any product, process, or service can be improved, and a successful organization is one that consciously seeks and exploits opportunities for improvement at all levels. The load-bearing structure is customer satisfaction. The watchword is Continuous Improvement.

Following the Japanese, most TQM programs extensively employ teamwork to provide improved planning analysis and problem solving, communication, motivation, and collective responsibility.

The 1990s were set to be the decade of quality. Preoccupation with quality improvement as a competitive force swept across North America and established bridgeheads in Europe in the 1980s. Some of the American quality gurus, such as Armand Feigenbaum, went as far as identifying quality as the single most important force in organizational success and growth for the 1990s and for the new millennium.

The Basis for Superior Quality Performance

By the mid- to late-1980s, TQM was all the rage. Billions of dollars were invested in training, consulting, and management education efforts in an attempt to close the quality gap between the U.S. and Japan. The concept and principles, though simple, seemed to be creeping into existence by bits and pieces through the evolution of the ISO 9001 Management Quality

System standard. Companies that implemented TQM included Ford Motor Company, Phillips Semiconductor, SGL Carbon, Motorola, and Toyota Motor Company.

In 1987, Congress created a national quality award competition named in honor of Commerce Secretary Malcolm Baldrige. The Baldrige Award has been a central element both in promoting American quality progress and providing a framework for evaluating an organization's management effectiveness. This latter aspect is even more prominent with major changes that have been made in the 1997 award criteria, emphasizing business results, markets, and strategic planning.

One of the keys to implementing TQM can be found in its definition and in the fact that TQM is a structured system. Describing TQM as a structured system means it is a strategy derived from internal and external customer and supplier wants and needs determined through daily management and cross-functional management. Pinpointing internal and external requirements allows continuous development, improvement, and maintainence of quality, cost, delivery, and morale. TQM is a system that integrates all of these activities and information.

TQM and ISO 9000

The latest changes for the ISO 9001:2000 Standard's Process Model seem to complete the embodiment that TQM philosophy is that quality is a process that can be managed. In regard to ISO 9001, the following information gives an understanding of the elements of the TQM process.

TQM is a philosophy of perpetual improvement while ISO 9000 is a Quality System Management Standard. The ISO Quality Standard sets in place a system to deploy policy and verifiable objectives. As such, ISO implementation is a basis for TQM implementation. Where there is an ISO system, about 75% of the steps are in place for TQM. The requirements for TQM can be considered ISO plus.[9] In short, implementing TQM is being proactive concerning quality rather than reactive.

THE STRUCTURE OF TQM

When all of its elements are implemented properly, TQM is like a well-built house: solid, strong, and cohesive. If TQM is not planned for and implemented correctly, it will be structurally weak and will probably fail. TQM is the foundation for activities such as meeting customer requirements, reducing development cycle times, Just in Time/Demand Flow Manufacturing, improvement teams, reducing product and service costs, and improving administrative systems training.

THE PRINCIPLES OF TQM

TQM's primary objective is to achieve customer satisfaction by involving everybody dealing with product manufacturing, directly or indirectly. To do this, TQM operates on the basis of the following principles:

1. Involve and respect people: everyone associated with the organization, including personnel, customers, and suppliers. Management must be involved by providing leadership.
2. Processes, not people, are the problem.
3. Every employee is responsible for quality.
4. Everyone is a customer and a supplier.
5. Prevent problems. Do not wait for them to occur and then fix.
6. Involve the processes of preparing and delivering products and services to customers.
7. Quality improvements must be continuous.
8. Quality can and must be managed.
9. Plan and organize for quality improvement.
10. The quality standard is: defect free.
11. Goals are based on requirements, not negotiated.
12. Life cycle costs, not front end costs.

The 10 Steps to TQM

Maintenance of these principles is based in turn on 10 steps recognized as fundamental to a TQM program.

1. Pursue new strategic thinking
2. Know your customers
3. Set true customer requirements
4. Concentrate on prevention, not correction
5. Reduce chronic waste
6. Pursue a continuous improvement strategy
7. Use structured methodology for process improvement
8. Reduce variation
9. Use a balanced approach
10. Apply to all functions

TOTAL QUALITY MANAGEMENT TOOLS

In the quality management field, there are statistical methods for analyzing numerical data focusing on results. However, in the world of business, it is also crucial to analyze language data such as customer requirements and ideas, and thus focus on processes. In both fields, the practice of

TQM uses tools that help to reach the desired goals and results that characterize success. According to the experts, the seven statistical quality control tools for analyzing and interpreting numerical data include: (1) data sheet, (2) cause-and-effect diagram, (3) scatter diagram, (4) flowchart, (5) Pareto chart, (6) histogram, and (7) control chart.

When working with ideas, the seven management and planning tools used are: (1) affinity diagram, (2) interrelationship digraph, (3) tree diagram, (4) matrix diagram, (5) prioritization matrices, (6) process decision program chart, and (7) activity network diagram.

Regardless of the recommendations for the use of these techniques for quality control or as management tools, they can be used in either area, depending upon circumstances and needs. As an example, the cause-and-effect diagram (manufacturing) can be interrelated to the affinity diagram (administration). By understanding all of its processes, companies are able to define them, implement controls, monitor performance, and measure improvements by using these techniques. This is the fundamental basis of TQM.

Following is a general review of these management tools.

Statistical Analysis Tools

Data Sheet

Data from a table, form, query, view, or stored procedure displayed in a row-and-column format.

Cause-and-Effect Diagram

Kaoru Ishikawa, who pioneered quality management processes and in the process became one of the founding fathers of modern management, created the cause-and-effect diagram. Causes are arranged according to their level of importance or detail, resulting in a depiction of relationships and hierarchy of events. This helps to identify areas where there may be problems, and allows for comparison of their relative importance. Cause-and-effect diagrams are typically constructed through brainstorming techniques.

Causes in a cause-and-effect diagram are frequently arranged into the four most common major categories.

- Manpower, methods, materials, and machinery (for manufacturing)
- Equipment, policies, procedures, and people (for administration and planning)

The cause-and-effect diagram (Figure 2.1) is also known as "Ishikawa diagram" or "fishbone diagram" because it was drawn to resemble the

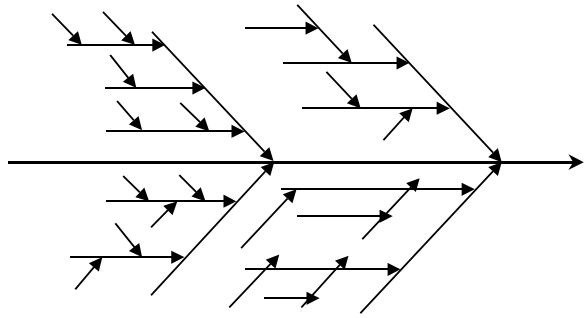


Figure 2.1 Cause-and-effect diagram.

skeleton of a fish, with the main causal categories drawn as bones attached to the spine of the fish.

Scatter Diagram

A scatter diagram or scatter chart (Figure 2.2) is similar to a line graph, except that the data points are plotted without a connecting line drawn between them. Scatter charts are suitable for showing how data points compare to each other.

At least two measured objects are needed for the query (one for the *x*-axis and one for the *y*-axis).

Scatter diagrams are used to study possible relationships between two variables. Although these diagrams cannot prove that one variable causes the other, they do indicate the existence of a relationship, as well as the strength of that relationship. In a scatter diagram the horizontal axis contains the measured values of one variable and the vertical axis represents the measurements of the other variable.

The purpose of the scatter diagram is to display what happens to one variable when the other variable is changed. The diagram is used to test the theory that the two variables are related. The slope of the diagram indicates the type of relationship that exists.

More than one measure object can be used for the *y*-axis as long as the objects are of the same type and scale; i.e., number of 16-oz bottles and number of 8-oz bottles.

Flowchart

A flowchart (Figure 2.3) is defined as a graphic representation employing standard graphic icons, usually a series of blocks with each block representing one major process, that describes an operation that is studied or

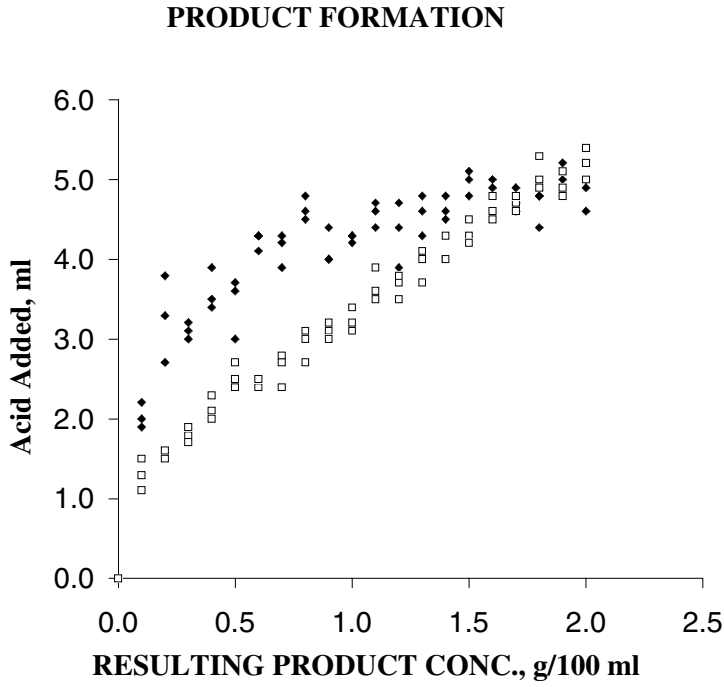


Figure 2.2 Scatter diagram.

is used to plan stages of a project. Flowcharts provide an excellent form of documentation for a process operation, and often are useful when examining how various steps in an operation work together. A flowchart is an important project development and documentation tool; it visually records the steps, decisions, and actions of any manufacturing or service operation and defines the system, its key points, activities, and role performances.

In a flowchart, the description of each process is written inside the blocks. Any other significant information is usually written outside the blocks. Each block is connected with an arrow to show where that process leads.

The graphic icons generally used are:

- the start/stop icon: ○
- the decision icon: ◇
- the result icon: □
- an icon to represent the flow itself, an arrow: →

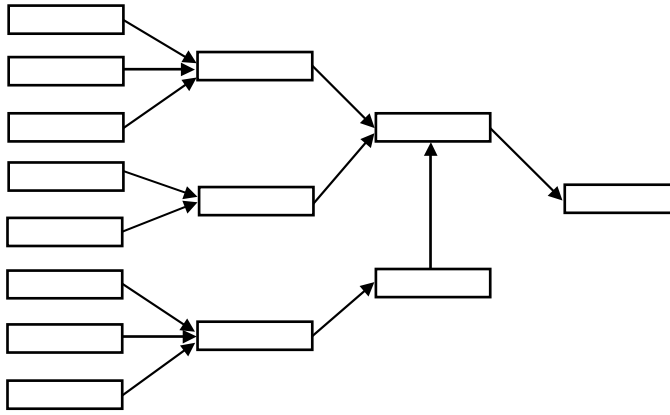


Figure 2.3 Flowchart.

Pareto Chart

Alfredo Pareto was an Italian sociologist who suggested that "80% of all wealth in this country is owned by 20% of the people." This supposition, known as the "Pareto Principle" was further developed by business and industry leaders who found that most of the quality problems were confined to a small number of machines or workers. In other words, "80% of problems come from 20% of the equipment or workforce."

The Pareto Principle is used by business and industry to work to continually improve quality, whether it is a product or a service. Quality improvement involves tackling one issue at a time. By addressing the ones causing the most difficulty (the 20% that are causing 80% of the problem), improvements can be made and monitored for continuous progress. Pareto charts are used to decide what steps need to be taken for quality improvement.

A Pareto chart (Figure 2.4) graphically summarizes and displays the relative importance of the differences between groups of data. A Pareto chart can be constructed by segmenting the range of the data into groups (also called segments, bins, or categories). The number of data points in each group is determined and the Pareto chart constructed; however, unlike the bar chart, the Pareto chart is ordered in descending frequency magnitude. The groups are defined by the user.

The Pareto chart is valuable in answering questions such as: What are the largest issues facing a team or business? What 20% of sources are causing 80% of the problems (80/20 rule)? What efforts should be focused on to achieve the greatest improvements?

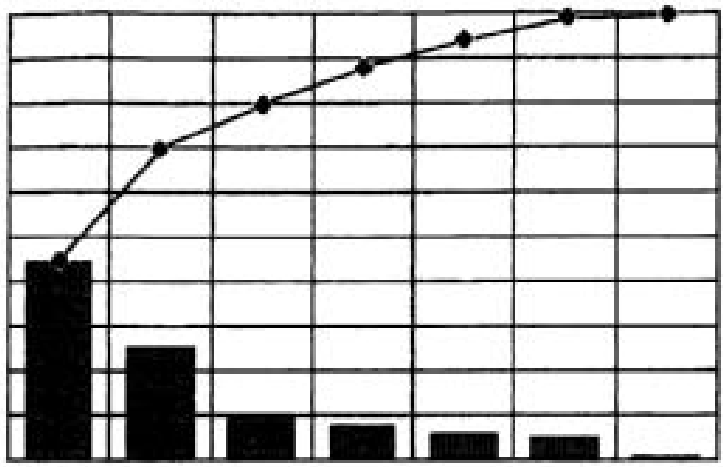


Figure 2.4 Pareto chart.

Histogram

A histogram (Figure 2.5) is used to graphically summarize and display the distribution of a process dataset. It can be constructed by segmenting the range of the data into equal-sized bins (segments, groups, or classes). The vertical axis of the histogram is the frequency (the number of counts for each bin), and the horizontal axis is labeled with the range of the response variable. The number of data points in each bin is determined and the histogram constructed. The user defines the bin size.

A histogram can help answers questions such as: What is the most common system response? What distribution (center, variation, and shape) do the data have? Do the data look symmetric or skewed to the left or right? Do the data contain outliers?

Control Chart

Control charting is one of the most technically sophisticated tools of statistical quality control. Dr. Walter A. Shewhart of the Bell Telephone Labs developed it in the 1920s as a statistical approach to the study of manufacturing process variation for the purpose of improving the economic effectiveness of the process. These methods are based on continuous monitoring of process variation.

A control chart (Figure 2.6) is a graphical display of a quality characteristic that has been measured or computed from a sample vs. the sample number or time. The chart contains a center line that represents the average

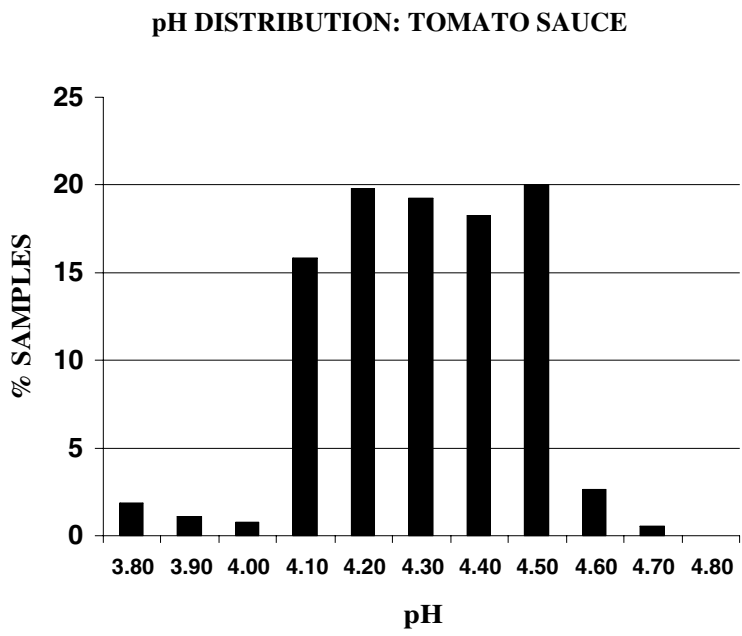


Figure 2.5 Histogram.

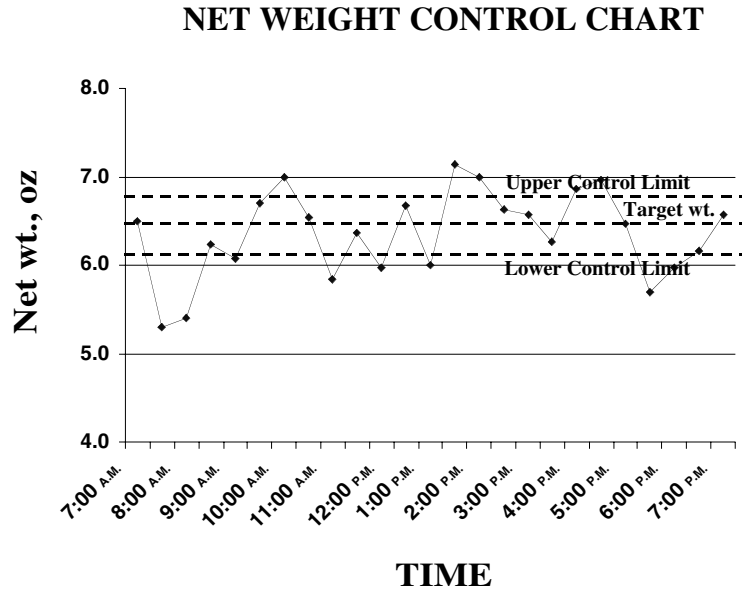


Figure 2.6 Example of a control chart.

value of the quality characteristic corresponding to the in-control state. Two other horizontal lines called the upper control limit (UCL) and the lower control limit (LCL) are also drawn. These control limits are chosen so that if the process is in control, nearly all of the sample points will fall between them. As long as the points plot within the control limits, the process is assumed to be in control and no action is necessary.

A point that plots outside of the control limits is interpreted as evidence that the process is out of control; investigation and corrective action are required in such a case to find and eliminate the causes responsible for this behavior. The control points are connected with straight-line segments for easy visualization.

Control charts are universally used to present quality data. They are sufficiently simple to interpret so that misunderstandings are avoided. Regardless of type, control charts all contain a few fundamental characteristics:

- They contain upper and lower control limits within which all observations will lie if the process is under control.
- They contain a center line which is usually considered the target value for the process.
- They generally show numbers along the vertical axis to define the values of the control limits and observations.

Control charts are used as a proven technique for improving productivity, as an effective tool in defect prevention, to prevent unnecessary process adjustments, to provide diagnostic information, and to provide information about process capability. A typical example of a control chart in the food industry is that used for net weight control.

X-Bar and R Charts

The X-bar and the R charts (Figure 2.7 and Figure 2.8) are the most commonly used of the control charts and the most valuable. They are easy to prepare, simple to understand, and extremely useful in locating problems. They are ideal tools to improve product quality and process control and can help to drastically reduce scrap and rework while assuring the production of only satisfactory products. In the food industry they can be used for controlling every step of a production process, for the acceptance or rejection of lots, and for early detection of equipment or process failures.

The X-bar and the R charts are used for control of variables that are expressed in discrete numbers such as inches, pounds, pH units, angstroms, percent solids, or degrees of temperature.

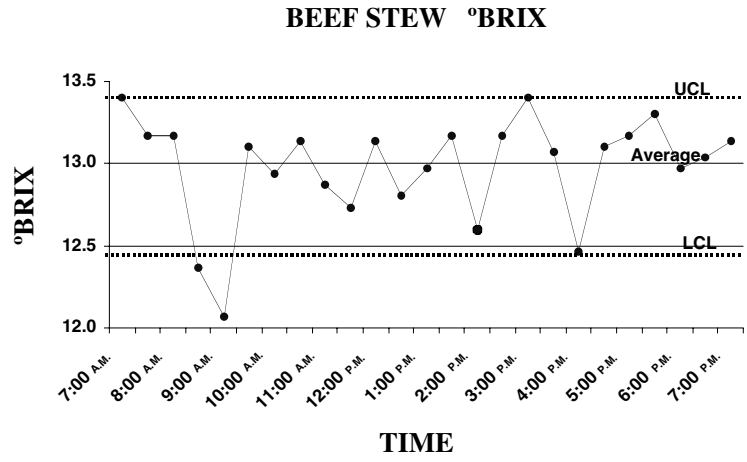


Figure 2.7 Average (X) chart.

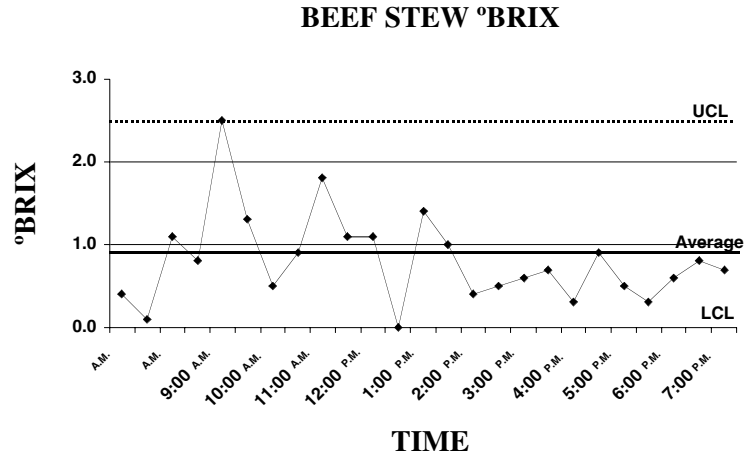


Figure 2.8 Range chart.

An X-bar is usually written as $\overline{X}$ and is the average value of several measurements, each of which is called X. A possible weakness of an $\overline{X}$ chart is that individual points are represented by an average of data that might contain a wide range of values but are masked by the smoothing effect of the $\overline{X}$ chart. To overcome this difficulty, the range of data from which each average is obtained is also required, and in turn its control values (upper and lower) must also be calculated.

The R chart is developed from the ranges of each subgroup data, which are calculated by subtracting the maximum and the minimum value in each subgroup.

Since the R chart indicates that the process variability is in control, the X-bar chart can then be constructed. The center line is the mean of the sample means.

Attribute Charts

In addition to X-bar and R charts, a group of charts called "attribute charts" are also used for control of defect analysis. They are particularly useful for controlling raw material and finished product quality and for analyzing quality comments in consumer letters. An attribute is a characteristic of a product, a process, or a population that can be counted but cannot be described in incremental numbers. It is a characteristic that is satisfactory or unsatisfactory, defective or nondefective, good or bad, heavy or light, etc. The only numbers that can be applied are the number or percentage of the satisfactory or unsatisfactory units. They are generally easier to construct and to use on a routine basis, although they occasionally lack the power of variable charts to spot problem areas quickly. A major advantage is the simple nature of the concept. Hubbard[10] lists the following four types of attribute charts: p-charts (fraction or percent defective, with constant lot size and with variable lot size), np-charts (number of defectives), and c- or u-charts (number of defects).

p-Charts

The p-chart shows the percent of samples in a manufacturing process, being nonconforming or defective relative to either a fixed or varying sample size. p-Charts are also called control charts for fraction nonconforming. They are of two types:

p-Chart with constant lot size. Used to determine control of percent defective units and to establish whether the process is in control for the day (week, month). Constant means within 20%.

p-Chart with variable lot size. Usually intended to control percent defective units where the number of units varies from sample to sample. Used to determine if a process is in control for each lot's control limits.

np-Charts

The np-chart monitors the number of times a condition occurs relative to a constant sample size and assures that the process is in control.

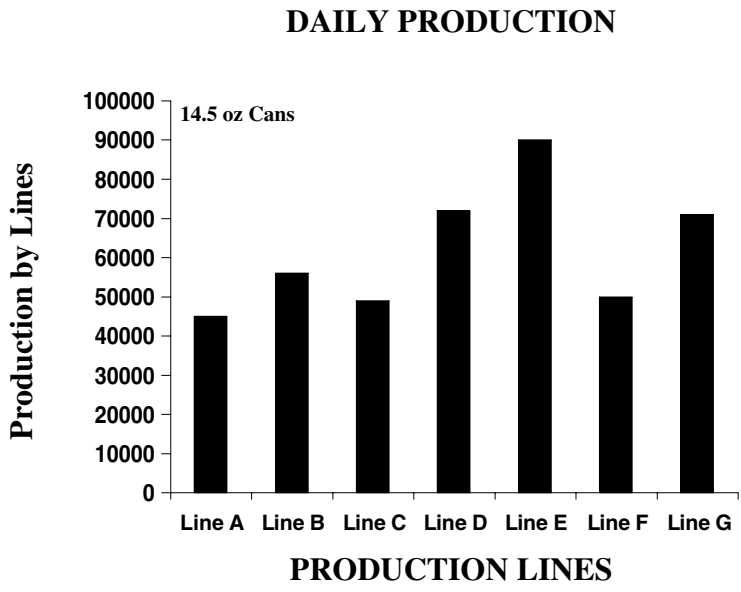


Figure 2.9 Bar chart.

c- or u-Charts

Used to determine if the number of defects in a single product is within control limits.

Other Types of Charts

Other types of charts and diagrams used to graph and report manufacturing or quality control data and that are in common use include the following:

Bar Chart A bar chart (Figure 2.9) is used to graphically summarize and display the differences between groups of data.

A bar chart can be constructed by segmenting the range of the data into groups (segments, bins, or classes). For example, if the data range from machine to machine, the data will consist of a group from machine 1, a second group of data from machine 2, a third group of data from machine 3, and so on.

The vertical axis of the bar chart is labeled frequency (the number of counts for each bin), and the horizontal axis is labeled with the group names of the response variables.

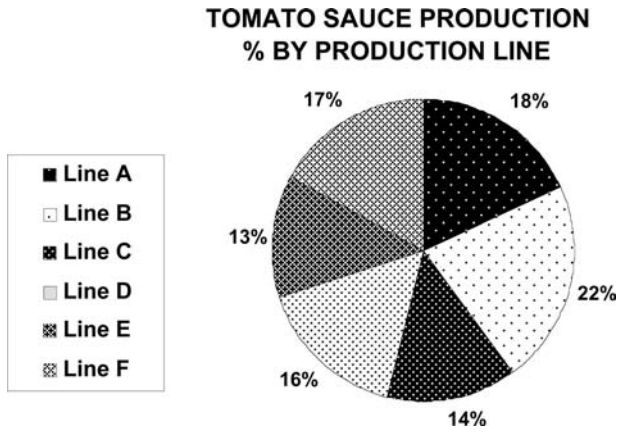


Figure 2.10 Pie chart.

The number of data points that reside within each bin is determined by the user and the bar chart constructed.

A bar chart answers the questions: What are the differences in system response between the groups? Does the data contain outliers?

Pie Chart A pie chart (Figure 2.10) is a circle graph divided into pieces or segments, each displaying the size of some related piece of information. Pie charts are used to display the sizes of parts that make up some whole (i.e., percentages of a whole at a set point in time). They do not show changes over time. To create a pie chart, it is necessary to supply a value and a name for each segment (each slice) and the title of the graph.

Pie charts should not include more than eight segments and each segment should be labeled with percentages of absolute amounts. Patterns or colors can be used to distinguish the segments.

The pie chart in Figure 2.10 shows the % production of tomato sauce by each production line. The information provided allows for comparisons of production efficiency and can contribute to the detection of malfunctioning conditions and their subsequent correction.

Spider Chart Spider charts (radar charts) (Figure 2.11) graphically display the performance of multiple variables on a single page providing easy-to-read data.

The normalized data spider chart depicts an activity's performance compared to other like activities. The activity's actual performance measurement value (raw data) is normalized for these spider charts. This is

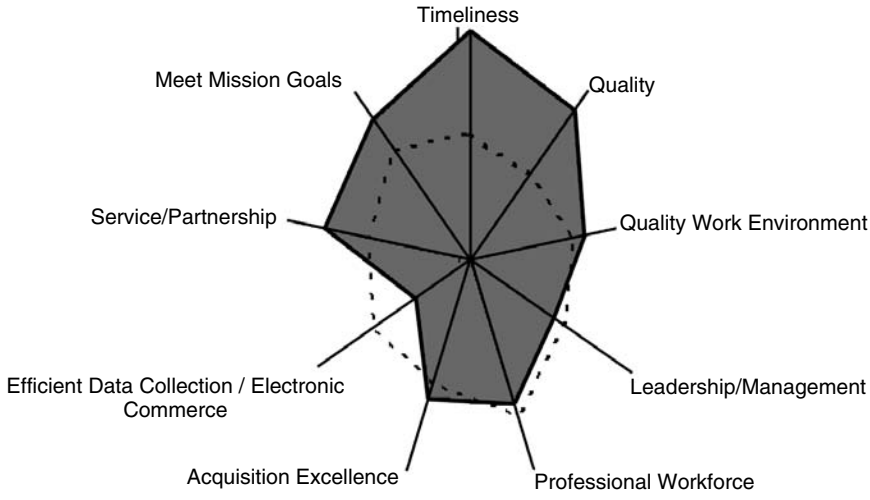


Figure 2.11 Spider chart.

done to graphically display the difference in performance measurement values between activities when the range of values is too close to be distinguished.

The raw/normalized data spider chart shows a comparison between the activity's actual performance values (raw data) with their normalized data value.

Management and Planning Tools

Affinity Diagrams

An affinity diagram (Figure 2.12), also known as the KJ method after its creator Kawakita Jiro, is a process used by a group to gather and organize ideas, opinions, issues, etc. from a raw list — usually generated through brainstorming — into groups of related thoughts that make sense and can be dealt with more easily.

The emphasis is on a rational, gut-felt sort of grouping done by the members of the team. In doing so, it is important to let the groupings emerge naturally, rather than according to preordained categories. This approach makes it possible to break an operation down into categories to focus the analytical efforts on one area at a time. It is similar in use to an operational analysis, except that the affinity diagram groups similar items together instead of listing them in chronological sequence.

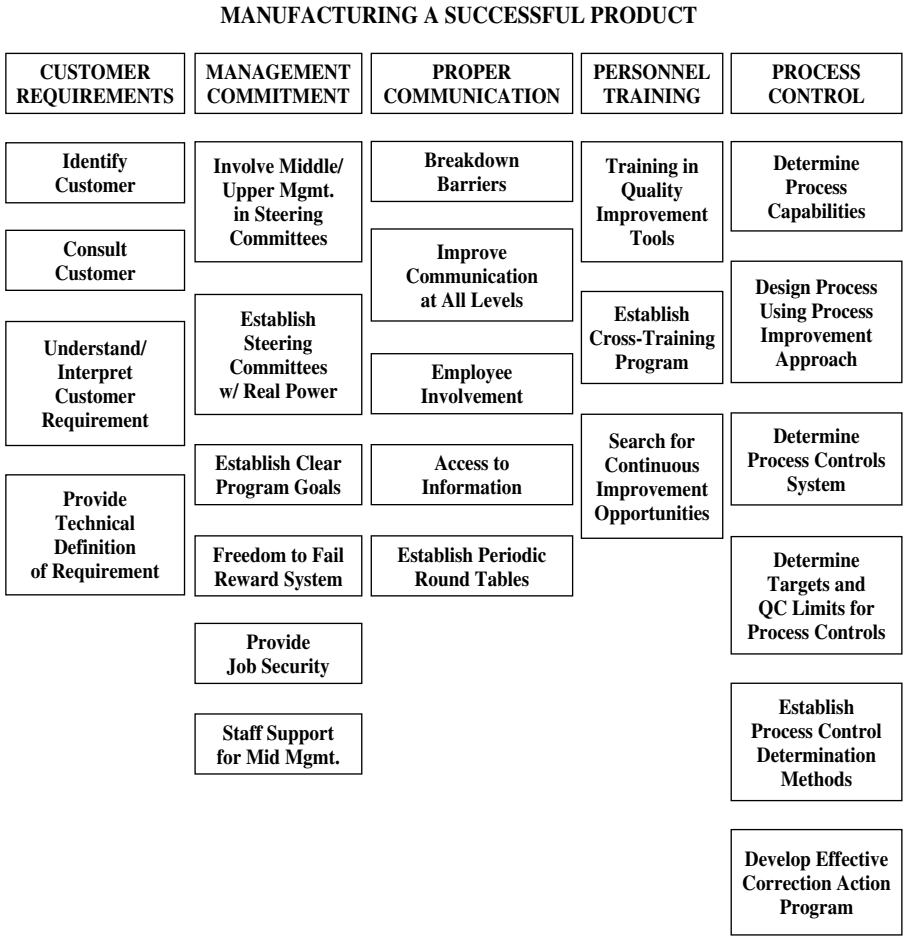


Figure 2.12 Affinity diagram.

As a management tool, Kaoru Ishikawa recommends using the affinity diagram when facts or thoughts are uncertain and need to be organized, when preexisting ideas need to be overcome or clarified, and when unity within a team needs to be created.

Interrelationship Digraphs

A relations diagram, also known as an interrelationship digraph, is a tool for finding solutions to problems that have complex causal relationships. It helps to untangle and find the logical relations among the intertwined

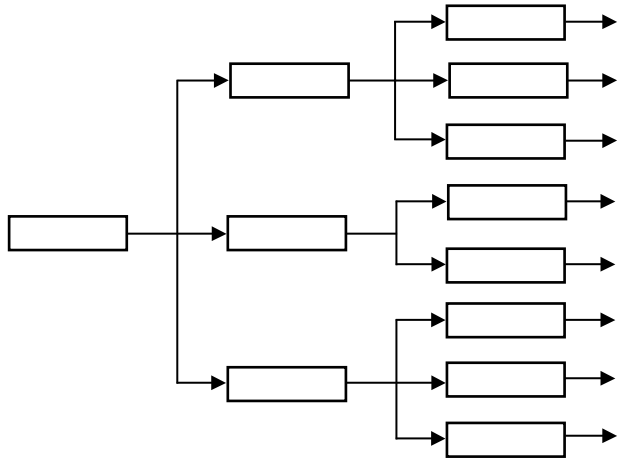


Figure 2.13 Tree diagram.

causes and effects and is a process that allows for multidirectional rather than linear thinking to be used.

Tree Diagram

The tree diagram**,** systematic diagram, or dendrogram (Figure 2.13) is a technique for mapping out a full range of paths and tasks that need to be done in order to achieve a primary goal and related sub-goals. The tree diagram is an adaptation from the functional analysis system technique (FAST) diagram in value engineering. It shows in a simple way and with clarity not only the magnitude of a problem but also, when used carefully and thoroughly, it provides a better understanding of the true scope of a project and helps to figure out the tasks that must be undertaken to achieve a given objective. The tree diagram is one of the seven management and planning tools described by Shigeru Mizuno.[11]

The tree diagram is designed to assist the user in reviewing and systemically rearranging data in the affinity diagram, to classify the data and identify omitted elements. The tree diagram takes a purpose and logically breaks it down into action items. It allows breaking any broad goal, graphically, into increasing levels of detailed actions that must or could be done to achieve the stated goals. When read from left to right it progresses logically from general to specific, answering the question "how accomplished?" If read from right to left, it answers the question "why?"

Factors to Compare	Methods for Comparison – Advantages		
	1	2	3
A			
B			
C			
D			

Figure 2.14 Matrix diagram.

Matrix Diagram

A matrix diagram (Figure 2.14) assists the user to visually examine the relationship between data groups.

The matrix diagram shows the relationship between two or more sets of items. It can be very useful in facilitating an analysis of the relationship of each item in one set to all items in the other set and often triggers some thinking that would not have happened if this organized approach was not used. It is also helpful to see patterns of relationships: which items don't relate to anything and which ones do.

A matrix diagram consists of a number of columns and rows whose intersections are compared to find out the nature and strength of the problem. This allows the user to arrive at key ideas, analyze the relationship or its absence at the intersection, and find an effective way of pursuing the problem-solving method. This enables conception of ideas on two-dimensional relationship bases. The intersection points are also called "idea conception points."

Matrix diagrams are used to reveal the strength of relationships between sets of items, tasks, or characteristics. In using matrix diagrams the following steps are of value:

1. Identify the sets of data to be compared.
2. Put the first set of items along the vertical axis. Put the second set of items along the horizontal axis.
3. Draw in grid lines.
4. Determine the symbols to be used to rate the relationships.

   Provide a legend: i.e.,9 = strong+ = strong relationship
   3 = some ***or*** 0 = some relationship
   1 = weak D = no relationship
   0 = none

5. Enter the appropriate symbols into each box.

Example: Where to Go on Vacation?

Vacation	*Time to Travel There*	*Fun for Everyone*	*Clothing Needed*	*Cheapest Cost*	*TOTAL*
Disneyland	3	9	3	1	16
Grand Canyon	3	3	3	9	18
Hawaii	1	3	1	1	6
Yellowstone Park	9	3	3	9	24
Cancun, Mexico	9	9	9	3	30

A matrix diagram allows a team or individual to systematically identify, analyze, and rate the presence and strength of relationships between two or more sets of information.

Prioritization Matrices

Prioritization matrices are useful when applying a systematic approach to weigh or prioritize criteria toward evaluating solutions against the criteria. The use of prioritization matrices helps teams focus and come to a consensus on key items.

Application of Prioritization Matrices:

- Obtain the list of items to be prioritized through customer input, brainstorming, affinity diagrams, or other appropriate sources such as legislative requirements. If there are more than 20 items to compare, reduce the list through an affinity exercise or by eliminating the items that are obviously a very low priority.
- Determine who will participate in the prioritization exercise and the most appropriate matrix to use considering the strengths and limitations of the matrices.
- Populate the horizontal and vertical columns of the matrix with a list. If customer "wants" are being prioritized, make every effort to bring the customer together with the team to complete the prioritization exercise. If this is not feasible, provide the matrix to the customer(s) for completion.

Process Decision Program Chart

The Process Decision Program Chart (PDPC) is a very useful and powerful method to overcome an unfamiliar problem or goal to be achieved. With the help of a PDPC, it is possible to map out all conceivable events or

contingencies that can occur in the implementation stage and also to discover feasible countermeasures to overcome these problems.

A PDPC graphically displays many contingencies and alternatives to a problem, which can be determined in advance to select a strategy for dealing with them.

Implementation plans do not always progress as anticipated. When problems, technical or otherwise, arise, solutions are frequently not apparent. According to Mizuno,[11] the PDPC method is useful in determining which processes to use to obtain desired results by evaluating the progress of events and the variety of conceivable outcomes. The PDPC method helps to prepare countermeasures that will lead to the best possible solutions.

The PDPC method can be used to:

- Explore all possible contingencies that could occur in the implementation of any new or untried plan that has risks involved
- Establish an implementation plan for management by objectives
- Establish an implementation plan for technology-development themes
- Establish a policy of forecasting and responding in advance to major events predicted in the system
- Implement countermeasures to minimize nonconformities in the manufacturing process
- Set up and select adjustment measures for negotiating process

Activity Network Diagram

The activity network diagram, also known as an arrow diagram, project evaluation and review technique (PERT), or critical path method (CPM), is a network technique using nodes for events and arrows for activities for project planning, scheduling, and monitoring. It is a very useful tool when planning activities of a known but a complex task or project. With the help of this tool it is possible to work out an ideal project plan as well as daily plans for several tasks, and to monitor their progress in an effective manner.

As mentioned earlier, these seven new tools are very useful to top and middle management for strategic planning, goal setting, and problem solving. Knowledge of the basic seven tools is a must for every person from top management to lower-level employees.

Gantt Chart

The Gantt chart (Figure 2.15) was developed as a production control tool in 1917 by Henry L. Gantt, an American engineer and social scientist. The Gantt chart shows planned work and finished work in relation to time.

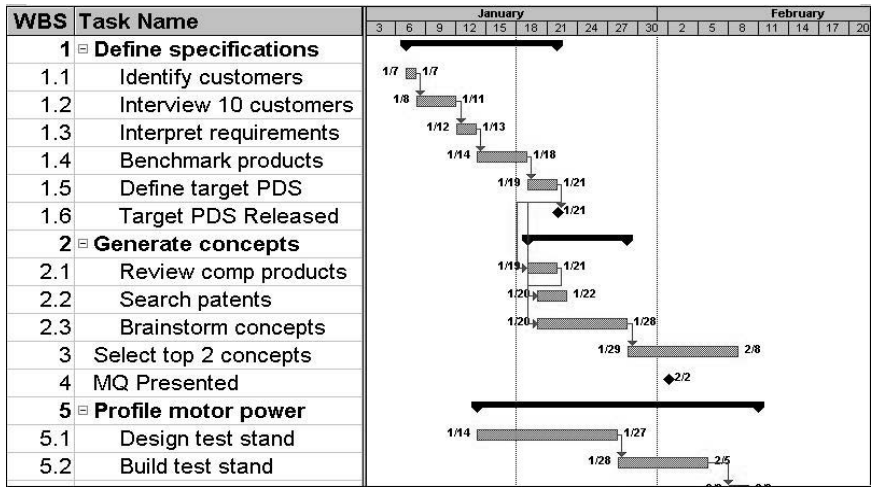


Figure 2.15 Gantt chart.

It is constructed with a horizontal axis representing the total time span of the project and a vertical axis representing the tasks that make up the project. Each task in a list has a bar corresponding to it. The length of the bar is used to indicate the expected or actual duration of the task. Gantt charts are used in project management to provide a graphical illustration of a project schedule that helps to plan, coordinate, and track specific tasks in a project. Gantt charts may be simple versions created on graph paper, or more complex automated versions created using project management applications such as Microsoft Project or Excel.

Gantt charts give a clear illustration of project status. One limitation with the Gantt charts is that they don't indicate task dependencies; they don't show how one task falling behind schedule affects other tasks. The PERT chart, another popular project management charting method, is designed to do this.

Entity-Relationship Diagram

An entity-relationship diagram (ERD) (Figure 2.16) is a data modeling technique that creates a graphical representation of the entities, and the relationships between entities, within an information system.[12]

The three main components of an ERD are:

1. The entity is a person, object, or place or event for which data are collected. For example, when considering the information system

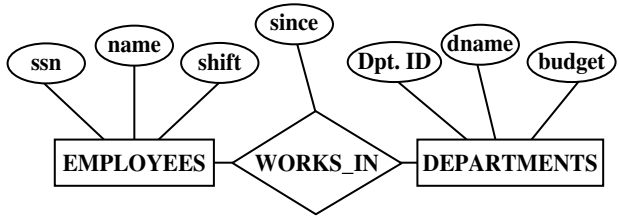


Figure 2.16 Entity relationship diagram (ERD).

for a business, entities would include not only customers, but the customer's address and orders as well. The entity is represented by a rectangle and labeled with a singular noun.

2. The overall logical structure of a database can be expressed graphically with an ERD. In it, the components are:
   - Rectangles, representing entity sets
   - Ellipses, representing attributes
   - Diamonds, representing relationship sets
3. Lines, linking attributes to entity sets and entity sets to relationship sets.

A relationship may be represented by a diamond shape, or more simply, by the line connecting the entities. In either case, verbs are used to label the relationships.

Key to Quality

Processes must be managed and improved. The key to improving processes that define, produce, and support the products is improving quality in every aspect and part of the operation. This generally involves different steps identified as follows:

- Defining the process
- Measuring process performance
- Reviewing process performance
- Identifying process shortcomings
- Analyzing process problems
- Making a process change
- Measuring the effects of the process change
- Communicating between supervisor and subordinates

The operators and the line workers get the processes "in control." They must work with other employees and managers to identify process problems and eliminate them.

The managers and supervisors, in turn, work on the processes. They must provide training and tool resources to their personnel to make possible an appropriate environment for a process in control. The managers and supervisors measure and review process performance and are able to contribute to process-improved performance with the help of those who use the process.

TQM VISION AND MISSION

The corporate TQM vision should state:

- What the organization wants to be, not what it is
- A future market area, such as global/international
- A simple statement (a one-page vision is inappropriate) understood from top management to line workers, as well as the public, customers, and suppliers

The corporate TQM mission should state:

- How to achieve the corporate vision within a certain time frame
- Activities to achieve the corporate vision submitted by stakeholders
- A simple statement (a one-page mission is inappropriate) understood from top management to line workers, as well as the public, customers, and suppliers

A corporate mission is how to achieve the corporate vision. The mission statement sometimes includes values, which are descriptions of what the organization believes in, reasons why the organization exists, and standards and behaviors that refer to policies and behavioral patterns.

INTEGRATED BUSINESS PLAN

The integrated business plan is a set of long-term targets and means for achieving goals in quality, cost, delivery, and morale.

Quality includes defects, failures, number of customer complaints, and customer satisfaction. The items regarding cost include production costs, price strategies, and general finances like sales revenue and product market share and profits. Delivery includes new product development cycle, number of on-time deliveries, response time, and distribution.

Morale includes satisfaction of stakeholders, employee satisfaction, number of well-educated employees, and training programs.

Other equally important aspects include research and development (number of new products or services, R&D costs, accuracy of research) and business strategies (plants location, headquarters location, and business expansion considerations).

The following summarizes key issues and terminology related to TQM.[13,14]

- **Management behavior.** Includes acting as role models, use of quality processes and tools, encouraging communication, sponsoring feedback activities, and fostering and providing the cost of quality as the measure of nonquality (not meeting customer requirements) and a measure of how the quality process is progressing.
- **A cultural change**. Appreciates the primary need of meeting customer requirements, implementing a management philosophy that acknowledges this emphasis, encouraging employee involvement and embracing the ethics of continuous improvement.
- **Enabling mechanisms of change.** Includes training and education, communication, recognition, management behavior, teamwork, and customer satisfaction programs.
- **Implementing TQM by defining the mission.** Identifies the output and the customers, negotiates customer requirements, develops a supplier specification that details customer objectives, and determines the activities required to fulfill those objectives.
- **Creating a supporting environment**. Propitiate the items cited above.[13–15]

SOME HISTORY OF TOTAL QUALITY MANAGEMENT

Quality control as we know it, probably had its beginnings in the factory system that developed following the English Industrial Revolution of the 1850s. At that time, production methods were rudimentary at best. Products were made from nonstandardized materials using nonstandardized processes, resulting in products of varying quality. The only standards used were measures of dimensions, weight, and in some instances, purity. The most common form of quality control was inspection by the purchaser under the common law rule of caveat emptor ("let the buyer beware").[16] At about the same time, the concept of "go–no go" tolerance was introduced, allowing for a less-than-perfect fit between two or more parts.[17] This concept in turn created the concept of upper and lower limits, allowing more freedom in production and lowering costs.

Around the turn and early part of the 20th century, quality consciousness increased at a tremendous rate, with much interest in the application of statistical quality control; Frederick Taylor developed his system of scientific management, which emphasized productivity at the expense of quality. Control of quality focused on final inspection of the manufactured product, and a number of techniques were developed to enhance the inspection process, most involving visual inspection or testing of the product following manufacture. Centralized inspection departments were organized to check for quality. An extreme example of this approach was the Hawthorne Works at Western Electric Company, which at its peak in 1928 employed 40,000 people in the manufacturing plant, 5200 of whom were in the inspection department. Although available since the beginning of the century, methods of statistical quality control were added later.

Modern quality management was initiated with the works of Walter A. Shewhart, Joseph Juran, and W. Edwards Deming at Bell Telephone Laboratories in the 1920s and later. After World War II, Bell people carried modern quality concepts to Japan. Bell Laboratories work showed that modern quality management was an important contribution to humankind. Lord Cherwell, science advisor to Winston Churchill during World War II, stated that Bell Laboratories' most important contribution to the British effort in World War II was the concept of quality control and quality assurance.[18]

The need to increase factory production during the years of World War II, while using many people new to the workforce, brought unprecedented demands on industry. Quality control techniques were used widely to help meet production quotas and generally were recognized as making an important contribution to the war effort.[18] Kaoru Ishikawa in his book *What is Total Quality Control? The Japanese Way* explains, "One may even speculate that the second World War was won by quality control and by the utilization of modern statistics."[19]

In Japan, during the revolution from statistical quality control to TQM, products emerged with greater quality, resulting in consumer confidence. This was recognized globally, and a trend toward TQM emerged in many other countries. The quality level and the uniformity of the products manufactured were excellent.[10] Some experts maintain that while the quality management in these companies is talked about as having refocused from reducing defects to building customer satisfaction, the actual penetration into management levels has yet to achieve the "total" aspect. However, the practice of policy management in Japan has been growing under TQM and most recently has become organized into a policy management system.[20] Some experts indicate that as Japanese quality control transforms from statistical quality control to a comprehensive quality management system, the philosophy of policy management will emerge.

TQM will become more management oriented, and policy management will play an even more central role.[20] A great deal is owed by Japan to J.M. Juran for setting this direction. In his 1960 management lectures, the issues of management responsibility, policy generation, target setting, and breakthrough planning were thoroughly covered. *Juran's Quality Handbook*[21] gives the concept of the control point as the first of all steps for control. One of the Japanese businesses adopting the control item was Teijin Ltd., a textile producer in Osaka, which coined the term "position-specific control items." Komatsu Ltd. followed in 1964 with a comprehensive control structure to provide linkages, which it called the "flag method." This method allowed the plant manager to deploy his policy goals to each level that reported to him and to graph the progress toward each target using a Pareto diagram on paper resembling flags flying from poles.[21]

The term *policy management* is said to have first appeared in 1968 when Bridgestone Tire received the Deming Prize. By this time, Bridgestone and Toyota had done a fair amount of study and trials with the approach. Until then, Japanese companies were only aware of Edward Schleh's management by objective (MBO).[20]

In the U.S., policy management was introduced during the 1980s when many industries were suffering from overseas competition. Along with quality function deployment — the TQM approach to new product development — policy management was seen as a way to assure the quality of various business activities. That meant that the activities engaged in by the organization were designed to fulfill its objectives.

Traditional quality control measures were, and still are, designed as defense mechanisms to prevent failure or eliminate defects.[22] Accountants are still taught that expenditures for defect prevention are justified only if they are less than the cost of failure.[22]

The Pioneers of Scientific Quality Management

Frederick Taylor

The American ideal of corporate efficiency took form in the early 20th century. As corporations consolidated at the end of the 19th century, reform-minded progressives encouraged the spread of professional management. Corporations pursued national markets, and they needed experts in production, distribution, and labor. The need for such expertise led to the advent of the management consultant.

A highly regarded consultant arising out of this era was Frederick Winslow Taylor,[23] whose name was synonymous with "scientific management," a revolutionary movement that proposed the reduction of waste through the careful study of work. Peter Drucker, in his book *Management:*

Tasks Responsibilities Practices, ranked Taylor, along with Darwin and Freud, as one of the seminal thinkers of modern times.[24]

Born in 1856 into a wealthy Philadelphia family, Taylor became one of the most influential people of his time and someone who has had an impact on management service practice as well as on management thought up to the present day. At age 25, Taylor earned an engineering degree at the Stevens Institute of Technology in New Jersey while holding a full-time job. Taylor disappointed his parents by working in a metal products factory, first as a machinist and pattern maker at the Enterprise Hydraulic Works in Philadelphia.[25]

After his apprenticeship at the hydraulic works plant, he became a common laborer at the Midvale Steel Company. He started as a shop clerk and quickly progressed to machinist, foreman, maintenance foreman, and chief draftsman. Within 6 years he advanced to research director, then chief engineer. Shocked at the factory's inefficiency and the practice of its skilled workers purposely working slowly, he applied himself to studies in the measurement of industrial productivity. Taylor developed detailed systems intended to gain maximum efficiency from both workers and machines in the factory and proposed solutions that he believed would solve both problems. By studying the time it took each worker to complete a step, and by rearranging equipment, Taylor believed he could discover what an average worker could produce in optimum conditions and that the secret of productivity was finding the right challenge for each person, and then paying him well for increased output. The promise of higher wages, he figured, would create added incentive for workers to exceed this "average" level. Taylor's core values were the rule of reason, improved quality, lower costs, higher wages, higher output, labor–management cooperation, experimentation, clear tasks and goals, feedback, training, mutual help and support, stress reduction, and the careful selection and development of people.[25]

Willing to bend the facts to suit his theories, Taylor's methods paid off, when on the eve of World War I, "Taylorism" became the first big management fad. The Taylor method prescribed a clockwork world of tasks timed to the hundredth of a minute and of standardized factories, machines, women, and men. Naturally, ordinary workers resented having to work faster than they thought was healthy or fair. An extreme version of Taylor's mind-set found its way into the operation of Nazi death camps and communist totalitarianism.

Taylor and his adherents didn't actually use their time studies as the sole basis for setting normative output. He was the first to present a systematic study of interactions among job requirements, tools, methods, and human skills, to fit people to jobs both psychologically and physically, and to let data and facts do the talking rather than prejudice, opinions,

or egomania.[25] Acknowledging that workers could not sustain peak level performances all day long, they used a margin of error or a fudge factor of as much as a third to set a more realistic level. This of course struck at the credibility that Taylor's system was based on scientific laws. Taylor passed away in 1915.

Walter A. Shewhart

The industrial age was easing into its second century when a young engineer named Walter A. Shewhart came along and altered the course of industrial history. Shewhart was born in New Canton, IL on March 18, 1891.

In 1918, Shewhart joined the Western Electric Company, a manufacturer of telephone hardware for Bell Telephone. Bell Telephone's engineers had already realized the importance of reducing variation in the manufacturing process to improve the reliability of their transmission systems, buried underground, to reduce the frequency of failures and repairs. They realized that continual process adjustment in reaction to nonconformance actually increased variation and degraded quality. In 1924, Shewhart framed the problem in terms of "assignable-cause" and "chance–cause" variation and developed the control chart as a tool for distinguishing between the two. He realized that the use of tolerance limits was shortsighted because they only provided a method for judging the quality of a product that had already been made.[17]

Shewhart stressed that bringing a production process into a state of statistical control, where there is only chance–cause variation, and keeping it in control, was necessary to predict future output and to manage a process economically. The control limits on Shewhart's control chart provide a ready guide for acting on a process to eliminate assignable causes of variation,[26] allowing management to focus on future production through the use of statistical probability. This approach caused the emphasis to shift from costly correction to prevention of problems and to process improvement.

Shewhart worked to advance the thinking at Bell Telephone Laboratories from their foundation in 1925 until his retirement in 1956, publishing a series of papers in the *Bell System Technical Journal*. His monumental work, *Economic Control of Quality of Manufactured Product,* published in 1931,[26] is regarded as a complete and thorough exposition of the basic principles of quality control. Shewhart's control charts were adopted by the American Society for Testing Materials (ASTM) in 1933 and were advocated to improve production during World War II in American War Standards. It was during this period that W. Edwards Deming founded a systematic critique of databased management, premised on Shewhart's

insights. Following the war, Deming went on to champion Shewhart's methods, working as an industrial consultant to Japanese and later to U.S. corporations from 1950 to 1990.

Shewhart received many awards, including the Holley Medal of the American Society of Mechanical Engineers and Honorary Fellowship of the Royal Statistical Society and American Society for Quality. For 20 years he was editor of the Wiley Series in Mathematical Statistics. During the 1990s, Shewhart's genius was rediscovered by a third generation of managers, naming it the "Six Sigma" approach.[27,28]

Shewhart, ASQ's first Honorary member, successfully brought together the disciplines of statistics, engineering, and economics and became known as the father of modern quality control.

The lasting and tangible evidence of that union for which he is most widely known is the control chart, a simple but highly effective tool that represented an initial step toward what Shewhart called "the formulation of a scientific basis for securing economic control."[29] Shewhart's influence on ASQ runs deep. Shortly before his death, he remarked to members that they "extended the field beyond my early visions and saw areas of service that pleased and amazed me. I hope that you continue."[29] He died at Troy Hills, NJ, on March 11, 1967.

W. Edwards Deming

Following World War II, the quality of products manufactured in the U.S. declined as manufacturers tried to keep up with the demand for nonmilitary goods that had not been produced during the war. During this period a number of pioneers began to advance a methodology of quality control in manufacturing and to develop theories and practical techniques for improved quality. Much of this transformation was associated with the introduction of statistical quality control into Japan by the U.S. Army over the period 1946 to 1950 and the visits by American quality pioneers to Japan in the early 1950s.

The most visible of these pioneers were W. Edwards Deming, Joseph M. Juran, Armand V. Feigenhaum, and Philip B. Crosby.[30]

Deming, the most recognized of the early pioneers, is credited with popularizing quality control in Japan in the early 1950s. He is best known for developing a system of statistical quality control, although his contribution goes substantially beyond those techniques.[31]

W. Edwards Deming was born on October 14, 1900 and earned his Ph.D. in mathematical physics in 1927. He then worked in the U.S. Government Service for many years, particularly in statistical sampling techniques. He became particularly interested in the works of Walter Shewhart, whom he had met while working at the Bell Laboratories in

New Jersey. He was impressed by Shewhart's work and believed that his principles could be equally applied to nonmanufacturing processes. He applied Shewhart's concepts of statistical process control to his work at the National Bureau of the Census during the preparation for the 1940 population census. This led to six-fold productivity improvements in some processes. As a result, Deming started to run statistical courses to explain his and Shewhart's methods to engineers, designers, etc. in the U.S. and Canada. He broadened Shewhart's manufacturing approach to include nonmanufacturing and human variation and encouraged managers to focus on variability and understand the difference between "special causes" and "common causes."

Deming believed that the special causes of variation in a product, process, or service were those that prevented its performance from remaining constant in a statistical sense. These special causes can often be identified as changes of operator, shift, or procedure, for example, and sometimes local operators can solve them. On the other hand, common causes are those that remain once the special causes have been eliminated. They are due to design or operation of the process or system. The operators may identify them, but only management authority can eliminate these common causes. Deming believed that managers who lacked this understanding of variation and confused the two types of variation could actually make matters worse. He revised his views on responsibility for variation, and by the mid-1980s he estimated that management was accountable for up to 94% of the potential improvement.

After the war Deming was sent to Japan as an advisor to the Japanese Census. Japan had started to apply statistical control concepts in the early 1920s, but moved away from them when the war began.[32] In 1946, Deming established quality control tools and techniques as the approach to affect the turnaround of Japanese industry and became involved with the Union of Japanese Scientists and Engineers (JUSE) after its formation. A delegation from Bell Telephone Laboratories in America visited Japan this same year and demonstrated Deming's quality control techniques. Deming's name became known and JUSE invited him to lecture to the Japanese on statistical methods. In the early 1950s he lectured to engineers and senior managers on the "Elementary Principles of Statistical Control of Quality," including concepts now regarded as part of TQM or company-wide quality. In 1956 Deming was awarded the Shewhart medal by the American Society for Quality Control. Four years later, his teachings were widely known in Japan and the Emperor awarded him the Second Order of the Sacred Treasure.

Deming's philosophy begins with top management but maintains that a company must adopt the 14 points of his system at all levels. He believed that quality must be built into the product at all stages in order to achieve a high level of excellence. He developed what is known as the Deming

chain reaction: as quality improves, costs will decrease and productivity will increase, resulting in more jobs, greater market share, and long-term survival.

Deming defined quality as a predictable degree of uniformity and dependability, at low costs and suited to the market. He maintained that 96% of variations have common causes and 4% have special causes. He viewed statistics as a management tool and relied on statistical process control as a means of managing variations in a process.

Although it is the worker who will ultimately produce quality products, Deming stressed worker pride and satisfaction rather than the establishment of quantifiable goals. His overall approach focused on improvement of the process, in that the system, rather than the worker, is the cause of process variation.

It was not until the 1970s, however, that Deming started to make an impact in the West. This appeared to happen in 1979 when the President of Nashua Corporation met with Deming. An NBC television documentary broadened his audience in 1980. It was entitled, "If Japan Can, Why Can't We?" Deming played a substantial role in increasing the visibility of the manufacturing process and advancing an awareness of the need to improve. Throughout the 1980s various books were written by others to document and explain his work. His own book *Out of the Crisis* was published in 1986 and he was awarded the National Medal of Technology in America the following year. The British Deming Association was formed also in 1987 to spread awareness of the Deming philosophy.

In his seminars in America in 1980, he spoke of the need for the total transformation of the western style of management. He produced his 14 Points for Management in order to help people understand and implement the necessary transformation. They apply to small or large organizations and to service industries as well as to manufacturing. However, the 14 points should not be seen as the whole of his philosophy, or as a recipe for improvement. They need careful discussion in the context of one's own organization.[31]

Deming's 14 Points for Management are summarized as follows:

1. Create consistency of purpose with a plan
2. Adopt the new philosophy of quality
3. Cease dependence on mass inspection
4. End the practice of choosing suppliers based solely on price
5. Identify problems and work continuously to improve the system
6. Adopt modern methods of training on the job
7. Change the focus from production numbers (quantity) to quality
8. Drive out fear
9. Break down barriers between departments

10. Stop requesting improved productivity without providing methods to achieve it
11. Eliminate work standards that prescribe numerical quotas
12. Remove barriers to pride of workmanship
13. Institute vigorous education and retraining
14. Create a structure in top management that will emphasize the preceding 13 points every day

Deming saw some obstacles afflicting most companies in the Western World, including:

- A lack of constancy of purpose
- Emphasis on short-term profits, etc.
- Evaluation of performance, merit rating, or annual review
- Mobility of management
- Management by use of only visible figures, with little or no consideration of unknown or unknowable figures

He identified additional obstacles as a range of attitudes that can get in the way of the necessary transformation, e.g., "our quality control department takes care of all our problems of quality." W. Edwards Deming died at the age of 93.

Joseph M. Juran

Joseph Juran, born in 1904, the son of an immigrant from Romania, started out professionally as an engineer in 1924. He initiated his industrial career at Western Electric's Hawthorne plant before World War II and later worked at Bell Laboratories in the area of quality assurance. Eventually he established his own consulting firm, the Juran Institute, in Wilton, CT. In 1951 his first book *The Quality Control Handbook* was published and led to his international eminence. Chapter 1 of the book was titled "The Economics of Quality" and contained his now-famous analogy to the costs of quality: "there is gold in the mine." JUSE invited Juran, like Deming, to Japan in 1954. His lectures introduced the managerial dimensions of planning, organizing, and controlling, and focused on the responsibility of management to achieve quality and the need for setting goals.[33–37] He, like Deming, believed that management and the system are responsible for quality. Large companies started internal training, courses for foremen were offered on national radio, and booklets were even made available at newspaper kiosks.

Juran has had a varied career in management and his interest has been wider than just quality, having been concerned with the underlying

principles common to all managerial activity. He has published 12 books, which have collectively been translated into some 13 languages. He has received more than 30 medals, honorary fellowships, etc. in 12 countries. Like Deming, these include the highest decoration presented to a non-Japanese citizen, the Second Order of the Sacred Treasure.

Juran defines quality as "fitness for use" in terms of design, conformance, availability, safety, and field use, more specifically and in his own words as "fitness for use as perceived by the customer."[36] Thus, his concept more closely incorporates the point of view of the customer. He is prepared to measure everything and relies on systems and problem-solving techniques.

Attainment of quality according to Juran is described as a perpetual spiral of progress or continuous striving. Steps on this spiral are, in ascending order, research, development, design, specification, planning, purchasing, instrumentation, production, process control, inspection, testing, sale, service, and then back to research again. Each time the steps are completed, products or services increase in quality.[17]

Unlike Deming, Juran focuses on top-down management and technical methods rather than worker pride and satisfaction.

Juran sees quality planning as part of the trilogy of quality planning, quality control, and quality improvement. The key elements in implementing company-wide strategic quality planning are in turn seen as identifying customers and their needs; establishing optimal quality goals; creating measurements of quality; planning processes capable of meeting quality goals under operating conditions; and producing continuing results in improved market share, premium prices, and a reduction of error rates in the office and factory.

Juran's 10 steps to quality improvement are:

1. Build awareness of opportunities to improve
2. Set goals for improvement
3. Organize to reach goals
4. Provide training
5. Carry out projects to solve problems
6. Report progress
7. Give recognition
8. Communicate results
9. Keep score
10. Maintain momentum by making annual improvement part of the regular systems and processes of the company; set goals for improvement

Juran promotes a concept known as managing business process quality, which is a technique for executing cross-functional quality improvement.

Juran's contribution may, over the longer term, be greater than Deming's because Juran has the broader concept, while Deming's focus on statistical process control was more technically oriented.[38]

Armand V. Feigenbaum

Dr. Armand V. Feigenbaum is the originator of the 850-page book *Total Quality Control: Engineering and Management*.[39] The first edition of *Total Quality Control* was completed while he was still a doctoral student at MIT. The Japanese discovered his work in the 1950s at about the same time Juran was visiting Japan. This discovery came about first via his role as vice president of worldwide quality at the General Electric Company, where he worked until the late 1960s, when he set up his own consulting firm, General Systems, Inc. While at General Electric he had extensive contacts with companies such as Hitachi and Toshiba. Second, it was associated with the translation of his 1951 book: *Quality Control: Principles, Practices and Administration* and his articles on total quality control. Feigenbaum argued for a systematic or total approach to quality, requiring the involvement of all functions in the quality process, not just manufacturing. The idea was to build in quality at an early stage, rather than inspecting and controlling quality after the fact.

Armand Feigenbaum was the founding chairman of the International Academy for Quality and is a past president of the ASQC, which presented him with the Edwards Medal and Lancaster Award for his international contribution to quality and productivity. In 1988 he was appointed to the board of overseers of the United States Malcolm Baldrige National Quality Award Program.

Like Deming and Juran, Feigenbaum achieved visibility through his work with the Japanese using a total quality control approach. He promoted a system for integrating efforts to develop, maintain, and improve quality by the various groups in an organization. To do otherwise, according to Feigenbaum, would be to inspect for and control quality after the fact rather than build it in at an earlier stage of the process.

His system theory of total quality control includes four fundamental principles:[17]

1. Total quality is a continuous work process, starting with customer requirements and ending with customer satisfaction.
2. Documentation allows visualization and communication of work assignments.
3. The quality system provides for greater flexibility because of a greater use of alternatives provided.

4. Systematic reengineering of major quality activities leads to greater levels of continuous improvement.

He emphasized the administrative viewpoint and considered human relations a basic issue in quality control activities. Individual methods, such as statistics or preventive maintenance, are seen as only segments of a comprehensive quality control program.

Quality control itself is defined as an effective system for coordinating the quality maintenance and quality improvement efforts so as to enable production at the most economical levels which allow for full customer satisfaction.

He stressed that quality does not mean "best" but "best for the customer use and selling price." The word "control" in quality control represents a management tool with four steps:

1. Setting quality standards
2. Appraising conformance to these standards
3. Acting when standards are exceeded
4. Planning for improvements in the standards

Effective control over the factors affecting product quality is regarded as requiring controls at all important stages of the production process. These controls or jobs of quality control can be classified as:

- New-design control
- Incoming material control
- Product control
- Special process studies

Feigenbaum sees modern quality control as stimulating and building up operator responsibility and interest in quality. The need for quality mindedness throughout all levels must be emphasized, as is the need to sell the program to the entire plant organization and the need for the complete support of top management. Management must recognize that it is not a temporary quality cost-reduction activity. From the human relations point of view, a quality control organization is seen as both a channel for communication for product-quality information and a means of participation in the overall plant quality program. Finally, Feigenbaum argues that a total quality program should be allowed to develop gradually within a given plant or company.[40] He argues, "quality is in its essence a way of managing the organization, and like finance and marketing, quality has now become an essential element of modern management."[41]

Against this background, total quality control is seen as providing the structure and tools for managing so that there is a continuous emphasis on quality leadership: genuine investment in, and implementation of, modern technology for quality throughout sales, engineering, and production, and top-to-bottom human commitment to quality and productivity.

Feigenbaum emphasizes that there are three keys to achieving the quality competitive leadership that is so crucial in the global market. First, a clear understanding of international markets and of how people buy in these markets; second, a thorough grasp of a total quality strategy that provides the business foundation for satisfying these customers; and third, the hands-on management know-how for creating the necessary company environment for quality and for establishing the stretch goals required for quality leadership.[42]

Feigenbaum consistently emphasizes in his work that total quality programs are perhaps the single most powerful change agent for companies today. As a result, company management must assume the responsibility to make an important leadership contribution that is essential to the growth of their respective companies, to the growth of national economies of which they are part and, indeed, to improved standards of life for consumers everywhere.

Philip B. Crosby

Philip Crosby was a leader of the resurgence of interest in quality during the 1980s. He graduated from Western Reserve University, after naval service during the Korean War. His early experience was as a quality manager on the first Pershing missile program. He worked his way up within ITT and for 14 years he was a corporate vice president and director of quality, with worldwide responsibilities for quality.

In 1979 Crosby published *Quality Is Free*: *The Art of Making Quality Certain*,[43] which became a bestseller. He stated that quality is free because the small costs of prevention will always be lower than the costs of detection, correction, and failure. In response to the interest shown in the book, he left ITT that year to set up Philip Crosby Associates Inc. At the Quality College established in Florida, he started to teach organizations how to manage quality as advocated in his book. Crosby also published *Quality without Tears: The Art of Hassle-Free Management,*[44] and a group of three management books that are popular and easy to read: *Running Things. The Art of Making Things Happen*,[45] *The Eternally Successful Organization: The Art of Corporate Wellness*,[46] and *Leading: The Art of Becoming an Executive.*[47]

Crosby's name is perhaps best known in relation to the concepts of "Do It Right the First Time" and "Zero Defects." He believed that zero defects motivates line workers to turn out perfect products. Crosby argues

that poor quality in an average firm costs about 20% of revenues, most of which could be avoided by adopting good quality practices, and he considers traditional quality control, acceptable quality limits, and waivers of substandard products to represent failure rather than assurance of success. Therefore, he defines quality as conformance to the requirements, which the company itself has established for its products based on its customers' needs. According to Crosby, most companies have organizations and systems that allow (and even encourage) deviation from what is really required. Thus, manufacturing companies spend around 20% of revenues doing things wrong and doing them over again; this can represent up to 35% of operating expenses for service companies.

Crosby does not believe that workers should take prime responsibility for poor quality; the reality, he says, is that you have to get management straight. In the Crosby scheme of things, management sets the tone on quality and workers follow its example; what zero defect means is not that people never make mistakes, he says, but that the company does not start out expecting them to make mistakes.

His goal is to give all staff the training and the tools of quality improvement, to apply the basis precept of prevention management in every area. This is aided by viewing all work as a process or series of actions conducted to produce a desired result. He also views quality improvement as an ongoing *process* since the word "program" implies a temporary situation.

Crosby's quality management philosophy is based upon his "Four Absolutes of Quality Management":

1. Quality is defined as conformance to requirements.
2. The system for causing quality is prevention of problems, not appraisal of them.
3. The performance standard must be zero defects, not "that's close enough."
4. The measurement of quality is the price of nonconformance, or the cost of quality.

Crosby stresses motivation and planning and does not dwell on statistical process control and the several problem-solving techniques of Deming and Juran. He emphasizes performance standards instead of statistical data as other experts do. Crosby has his own 14 steps to quality improvement that he considers to be the way that the quality improvement process is implemented in an organization:

1. **Management commitment.** Top management must become convinced of the need for quality and must clearly communicate this

to the entire company by written policy, stating that each person is expected to perform according to the requirement or cause the requirement to be officially changed to what the company and the customers really need.

2. **Quality improvement team.** Form a team composed of department heads to oversee improvements in their departments and in the company as a whole.
3. **Quality measurement.** Establish measurements appropriate to every activity in order to identify areas in need of improvement.
4. **Cost of quality.** Estimate the costs of quality in order to identify areas where improvements would be profitable.
5. **Quality awareness.** Raise quality awareness among employees. They must understand the importance of product conformance and the costs of nonconformance.
6. **Corrective action.** Take corrective action as a result of steps 3 and 4.
7. **Zero defects planning.** Form a committee to plan a program appropriate to the company and its culture.
8. **Supervisor training.** All levels of management must be trained in how to implement their part of the quality improvement program.
9. **Zero defects day.** Schedule a day to signal to employees that the company has a new standard.
10. **Goal setting.** Establish improvement goals for individuals and their groups.
11. **Error cause removal.** Employees should be encouraged to inform management of any problems that prevent them from performing error-free work.
12. **Recognition.** Give public, nonfinancial appreciation to those who meet their quality goals or perform outstandingly.
13. **Quality councils.** Composed of quality professionals and team chairpersons, quality councils should meet regularly to share experiences, problems, and ideas.
14. **Do it all over again.** Repeat steps 1 to 13 in order to emphasize the neverending process of quality improvement.

All of these pioneers believed that management and the system, rather than the workers, are the cause of poor quality. They have largely absorbed and synthesized each other's ideas, but generally speaking they belong to two schools of thought:

1. Those who focus on technical processes and tools
2. Those who focus on the managerial dimensions

Deming provides manufacturers with methods to measure the variations in a production process in order to determine the causes of poor quality. Juran emphasizes setting specific annual goals and establishing teams to work on them. Feigenbaum teaches total quality control aimed at managing by applying statistical and engineering methods throughout the company, and Crosby stresses a program of zero defects. Despite the differences, a number of common themes arise:

1. Inspection is never the answer to quality improvement nor is "policing."
2. Involvement of and leadership by top management are essential to the necessary culture of commitment to quality.
3. A program for quality requires organization-wide efforts and long-term commitment, accompanied by the necessary investment in training.
4. Quality is first, schedules secondary.

The Japanese Contribution

Kaoru Ishikawa

Dr. Ishikawa was born in 1915 and graduated in 1939 from the Engineering Department of Tokyo University with a degree in applied chemistry. In 1947 he was made an assistant professor; in 1960 he earned his doctorate of engineering and was promoted to professor. He was a founder of the Union of Japanese Scientists and Engineers, a body that promoted quality developments in Japan during the post-war recovery period. He studied under W. Edwards Deming during the late 1940s and early 1950s and was instrumental in developing the unique Japanese strategy for total quality: the involvement of the entire organization, not only production personnel. Some of his accomplishments include the success of the quality circle in Japan, in part due to innovative tools such as the cause-and-effect diagram. Through the use of such tools, he provided easy-to-use analytical methods that could be used by all workers, including those on the production line, to analyze and solve problems.

Ishikawa saw the cause-and-effect diagram as a device to assist groups or quality circles in quality improvement. As such, he emphasized open group communication as critical to the construction of the diagram. The Ishikawa diagram is useful as a systematic tool for finding, sorting out, and documenting the causes of quality variations in production and organizing mutual relationships between them. Other techniques Ishikawa has emphasized include control charts, scatter diagrams, and sampling inspection.

Although the early origins of the now-famous quality circles — a Japanese philosophy which he drew from obscurity into worldwide acceptance — can be traced to the U.S. in the 1950s, Professor Ishikawa is best known as a pioneer of the quality circle movement in Japan in the early 1960s, now reexported to the West.

Although he believed strongly in creating standards, he felt that standards were like continuous quality improvement programs — they too should be constantly evaluated and changed: "Standards are not the ultimate source of decision making; customer satisfaction is." According to Professor Ishikawa, seven critical factors were essential for the success of total quality control in Japan:[17]

1. Company-wide total quality control participation
2. Education and training in all aspects of total quality
3. Use of quality circles to update standards and regulations, which are in constant need of improvement
4. Quality audits by the president and quality council members (senior executives) twice a year
5. Widespread use of statistical methods with a focus on problem prevention
6. Nationwide quality control promotion activities, with the imperative of keeping Japanese quality number one in the world
7. Open mental attitude on the part of both management and workers, toward one another and toward the customer, welcoming complaints, and encouraging risks

The impact of Ishikawa quality teachings on Japanese industry was startling. Within a period of 10 years, the electronic and telecommunications industries were transformed, with the entire nation revitalized by the end of the 1960s.

Dr. Ishikawa was awarded the Deming Prize and the Nihon Keizai Press Prize, the Industrial Standardization Prize for his writings on quality control, and the Grant Award in 1971 from the ASQC for his education program on quality control.

In 1968, in his role as chairman of the editorial committee of *Genba-To-QC* (*Quality Control for the Foreman*) magazine, Dr. Ishikawa built upon quality control articles and exercises written by the editorial committee of the magazine to produce "nonsophisticated" quality analysis textbooks for quality circle members. His book *Guide to Quality Control, Quality Resource*[48] was subsequently translated into English in 1971; the Asian Productivity Organization published a 2nd edition in 1986. Among other books, he published *What is Total Quality Control? The Japanese Way*, also translated into English.[49] As with other Japanese quality experts, such as Genichi

Taguchi, Kaoru Ishikawa paid particular attention to making technical statistical techniques used in quality attainment accessible to those in industry.

Turning to organizational rather than technical contributions to quality as mentioned earlier, Ishikawa is associated with the company-wide quality control movement that started in Japan in the years 1955 to 1960, following the visits of W. Edwards Deming and Joseph Juran.

Under this concept, quality control in Japan is characterized by company-wide participation from top management to the lower-ranking employees; all study statistical methods. As well as participation by the engineering, design, research, and manufacturing departments, also involved are sales, materials, and clerical or management departments (planning, accounting, business, and personnel).

Quality control concepts and methods are used for problem solving in the production process, for incoming material control, and new product design control, as well as for analysis to help top management decide policies, to verify that policies are being carried out, and for solving problems in sales, personnel, labor management, and in clerical departments. Quality control audits, internal as well as external, form part of this activity. Ishikawa reported: "The results of these company-wide quality control activities are remarkable, not only in ensuring the quality of industrial products but also in their great contribution to the company's overall business."[49] Ishikawa saw the company-wide quality control movement as implying that quality does not only mean the quality of product, but also of sales service, quality of management, the company itself, and the human being, resulting in:

1. Improved and uniform product quality. Defects are reduced.
2. Improved reliability of goods.
3. Reduction in costs.
4. Increased quantity of production. It becomes possible to make rational production schedules.
5. Reduction in wasteful work and rework.
6. Established and improved techniques.
7. Reduction in expenses for inspection and testing.
8. Contracts between vendor and vendee are rationalized.
9. Enlarged sales market.
10. Better relationships between departments.
11. Reduction in false data and reports.
12. Discussions carried out more freely and democratically.
13. Meetings operated more smoothly.
14. Repairs and installation of equipment and facilities done more rationally.
15. Improved human relations.

Dr. Ishikawa died in April 1989 as consequence of a cerebral hemorrhage. In 1993 the ASQ established the Ishikawa Medal to recognize leadership in the human aspects of quality. The medal is awarded annually in honor of Dr. Ishikawa to an individual or team for outstanding leadership in improving the human aspects of quality.

Genichi Taguchi

Dr. Genichi Taguchi was born in 1924. After service in the Astronomical Department of the Navigation Institute of the Imperial Japanese Navy during 1942 to 1945, he worked at the Ministry of Public Health and Welfare — where he learned experimental design techniques and the use of orthogonal arrays from the prize-winning Japanese statistician Matosaburo Masuyama — and the Institute of Statistical Mathematics, Ministry of Education. In 1950 he joined the newly founded Electrical Communications Laboratory of the Nippon Telephone and Telegraph Company with the purpose of increasing the productivity of its research and development activities by training engineers in effective techniques. He stayed for more than 12 years, during which period he began to develop his methods.

Japanese companies including Toyota and its subsidiaries began applying Taguchi methods extensively from the early 1950s. His first book, in which he introduced orthogonal arrays, was published in 1951. In 1958 he published the first version of his two-volume book on design of experiments. In 1962 he earned his Ph.D. from Kyushu University. His first visit to the U.S. was in 1962 as a visiting research associate at Princeton University. In 1964 Taguchi became a professor at Aoyama Gakuin University in Tokyo, a position he held until 1982. At this stage, Taguchi's methods were still essentially unknown in the West, although applications were taking place in Taiwan and India. In the early 1970s Taguchi developed the concept of the quality loss function, publishing two other books in the 1970s. By the late 1970s he had an impressive record in Japan, having won the Deming awards for literature on quality in 1951 and 1953 and the Deming application prize in 1960.

In 1980, Yuin Wu, who had immigrated to the United States and was an executive director for the American Supplier Institute (ASI), invited Taguchi — at the time director of the Japanese Academy of Quality — to give a presentation at his company. Mr. Wu had become acquainted with Dr. Taguchi in 1966 while in Japan on a study sponsored by the Taiwan government. During his visit, Taguchi arranged to revisit AT&T Bell Laboratories, which he had previously visited in 1962. Despite communication problems, successful experiments were run that established Taguchi's methods within Bell Laboratories.

Despite an adverse reaction among American statisticians to the methods, and possibly to the way they were being marketed, more and more American manufacturers implemented Taguchi's methodology including Xerox, Ford, and ITT.

Taguchi's methods are systems of cost-driven quality engineering that emphasize the application of engineering strategies rather than advanced statistical techniques. They can be classified as upstream methods and shopfloor methods.

Upstream methods use small-scale experiments to reduce variability and find cost-effective, robust designs for large-scale production and the marketplace. Shopfloor methods provide cost-based, real-time methods for monitoring and maintaining quality in production. Taguchi's upstream methods, better known as robust design, are concerned with optimization of product and process prior to manufacture, rather than emphasizing the achievement of quality through inspection. The concepts of quality and reliability are pushed back to the design stage where he considers they really belong. A robust design method provides an efficient technique to develop product tests prior to entering the manufacturing phase. This method can be defined as a process that results in consistent, high-level performance products despite being subjected to a wide range of changing customer and manufacturing conditions. The method can also be used as a trouble-shooting tool to sort out pressing manufacturing problems.

Taguchi works in terms of quality loss rather than quality. This loss includes not only the loss to the company through costs of reworking or scrapping, maintenance, downtime due to equipment failure and warranty claims, but also costs to the customer through poor product performance and reliability, leading to further losses to the manufacturer as his market share falls.

To solve the situation a company has several choices:

- Compensate the customers for their losses.
- Institute tighter tolerances through process control on the manufacturing line.
- Change the nominal values of critical design parameters (inputs) such that the product performance (output) becomes insensitive to manufacturing variation (Figure 2.17). This approach is the robustness strategy and can be evaluated by experimental design.

Taking a target value for the quality characteristics under consideration as the best possible value of these characteristics, Taguchi associates a quadratic loss function with deviations from this target. The loss function shows that a reduction in variability about the target leads to a decrease in loss and a subsequent increase in quality (Figure 2.18).

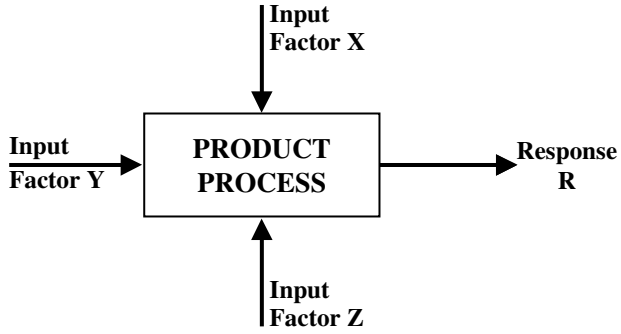
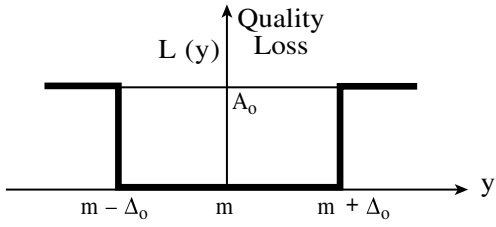
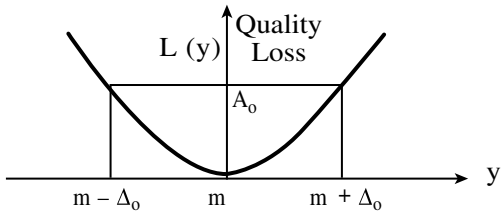


Figure 2.17 Product process parameter diagram.

Quality Loss Function



(a) Step Function



(b) Quadratic Loss Function
$L(y) = k(y - m)^2$
where $k = A_o / \Delta_o^2$

Products that meet tolerances also inflict quality loss

Figure 2.18 Quadratic loss function.

The loss function may be used to evaluate design decisions on a financial basis to decide whether additional costs in production will actually prove to be worthwhile in the marketplace.

m = Target value for a critical product characteristic

+/– Δ_0 = Allowed deviation from the target

A_0 = Loss due to defective product

The quality loss, L, suffered by an average customer due to a product with y as value of the characteristic is given by the following equation:[50]

$$L = k^*(y - m)^2$$

where $k = (A_0/\Delta_0^2)$.

If the output of the factory has distribution of the critical characteristic with mean μ and variance σ^2, the average quality loss per unit of the product is given by:[50]

$$Q = k\{(\mu - m)^2 + \sigma^2\}$$

Taguchi breaks down off-line quality control into three stages:

1. System design. Creation of a design concept prototype.
2. Parameter design. The step of achieving high-quality levels without an increase in cost. The nominal design features or process factor levels selected are tested and the combination of product parameter levels or process operating levels least sensitive to changes in environmental conditions and other uncontrollable factors are determined.
3. Tolerance design. Employed to reduce variation further if required, by tightening the tolerance on those factors shown to have a large impact on variation. In this stage, by utilizing the loss function, it is decided if more money should be spent buying better materials or equipment. This emphasizes the Japanese philosophy of invest last, not first.

Taguchi's robust design methodology is fundamentally a prototyping method that enables the engineer or designer to identify the optimal settings to produce a robust product that can survive manufacturing time after time, piece after piece, in order to provide the functionality required by the customer.

There are perhaps two major features of advantage in Taguchi's robust design methodology. First, it was developed by, and is largely used by, engineers rather than statisticians. This removes most of the communication gap and the problems of language traditionally associated with many statistical methodologies. In addition, it is tailored directly to the engineering context. The consequence of this is that the importance of "noise" variables (factors beyond the control of the designer) that disrupt production must be considered in addition to "control" variables (factors that can be specified by the designer). Optimizing a product corresponds not only to getting its quality characteristics on target but also to minimizing variability away from that target on a piece-to-piece or time-to-time basis. This is the connection of robust design with statistical process control (SPC).

Taguchi's robust methodology may be used to narrow the quality characteristics' distribution and to identify variables to build control on. SPC may then be used to keep quality characteristics on target by making use of the known spread about the target value. Essentially, this is the other novel feature of Taguchi's methodology. One other major feature is the codifying by Taguchi of the so-called orthogonal arrays. These are designs for experiments which were largely previously identified by others but were codified by Taguchi in such a way that an engineer automatically has a route to the minimum number of prototypes necessary for experimentation (the confirmatory trial).

Quality Circles

One major characteristic of Japanese company-wide quality control is the quality control circle (also called quality improvement team) concept originated in Japan and introduced in 1962 by Dr. Kaoru Ishikawa in the inaugural issue of the Union of Japanese Scientists and Engineers journal *Genba-to-QC*. The first quality control circle was registered with the Nippon Telegraph and Telephone Public Corporation. In the last 40 years, the quality circle concept has spread to banks and retailing, and it has been exported worldwide to as many as 130 countries; regardless of this, the concept is well established only in Asian countries like Japan, South Korea, People's Republic of China, and Taiwan. Success in the West has not been so extensive.

By the late 1970s, American companies had begun to take notice of the rapidly improving competitive position of Japanese manufacturing, and the quality circles concept started to be promoted as a means of improving quality.[51] Some companies, such as Hewlett Packard and Xerox, that already had business relationships with Japanese firms imported the movement into the U.S., but most companies were looking for a quick turnaround approach to replicate the Japanese quality success without altering the structure of American management. Adaptations were of varying effectiveness; in some companies circles were successful, or regarded as such; in most they failed.

Experts such as Philip Crosby had warned against the fashion for quality circles as a cure-all for poor employee motivation or inadequate quality and productivity in the U.S. Joseph Juran, in particular, expressed doubts about the effectiveness of quality circles in the West at all, where few company hierarchies have executives trained in quality management.

Model Japanese companies, they asserted, had 75% or more of their workforce in quality circles; many workers participated in several quality circles. Every worker and supervisor already had extensive training in quality measurement concepts, and trust between management and

employees was high. Most Japanese labor unions were company unions that supported different categories of employees meeting and discussing work process changes; few of these conditions existed in American corporations and government. Even those experimenting with quality circles with the best intentions simply faced too many obstacles. After a few successes, most organizations were willing to declare victory, abandon the circles, and then wait for the next stage of development; an organizationally comprehensive approach to quality, under the banner of total quality management.

The nature and role of quality circles vary between companies. In general, it consists of a team of 6 to 10 people participating freely in challenging assumptions and existing methods, examining data and exploring possibilities, calling in expertise and asking for training. The quality circle needs a skilled team leader to work as a facilitator of the team efforts, and a budget so that members can be responsible for tests and possible pilots. The aims of the quality circle activities are:

1. To develop the capability and make possible self-actualization for quality circle members
2. To contribute to the improvement and development of the company
3. To analyze the context of a problem and its nature
4. To define what the problem is and the relationship between its components
5. To identify and verify that the causes are indeed the causes
6. To evaluate and recommend possible solutions and the resources needed
7. To fully understand the problem and its solution to prevent recurrence; otherwise solutions as developed may fail to address the real problem
8. To respect human relations and build a happy workshop offering job satisfaction
9. To deploy human capabilities fully and draw out infinite potential

The members of the circle master statistical quality control and related methods, and utilize them to achieve significant results in quality improvement, cost reduction, productivity, and safety. All members of the circle are continuously engaged in self- and mutual development, control, and improvement whenever possible; the circles implement solutions themselves, otherwise they put strong pressure on management to introduce them. Since management is already committed, it is ready to listen or act.

More important, greater worker involvement and motivation is created through:

- An atmosphere where employees are continuously looking to resolve problems
- Greater commercial awareness
- A change of shopfloor attitude aimed at increasing goals

Although even in Japan many quality circles have collapsed, usually because of management's lack of interest or excessive intervention, many have worked. There are now more than 10 million circle members there. The benefits are typically seen as being minor from any one improvement introduced by a quality circle, but when added together they represent substantial improvements to the company. In summary, it is possible to say that quality circles, when well established with members contributing as expected, constitute the heart of a TQM program.[52]

PRESENT UTILIZATION OF TQM PROGRAMS

The increased acceptance and use of TQM in the U.S. are the result of four major trends:

1. Reaction to increasing domestic and global competition. In order to keep up with the most important international companies, domestic companies must improve all aspects of their businesses and their processes on a continual basis.
2. The acceptance of TQM in a variety of service industries.
3. The demands from customers, continuously higher, as a result of the availability in the market of products of high quality manufactured by quality leading companies.
4. The publicity surrounding the quality awards for which companies compete, including the Malcolm Baldrige National Quality Award, the Deming Prize in Japan, and the European Quality Award.

Aside from the existing competitive pressures from Japan and the Pacific Rim countries, American firms are also faced with increasing competition from members of the European Union (EU).* This concern is

* The European Union (EU) is an economic and political confederation of European nations, providing for a central banking system, a common currency (the euro) to replace the national currencies and a legal definition of the EU. It was created by the Treaty of the European Union, or Maastricht Treaty, signed in Maastricht, The Netherlands in 1992 and ratified in November 1993. The name replaced European Community, which was created in 1967 from the original European Economic Community (EEC), an organization established in 1958 by a treaty between Belgium, France, Italy, Luxembourg, The Netherlands, and West Germany (now Germany), known informally as the Common Market.

justified by the nature of manufacturing strategy among European firms, where quality has replaced technology as the primary consideration.

ISO 9000 system of standards is another factor propelling companies into the direction of quality. These standards emphasize processes, and the system of certification and registration of companies guarantees that goods are produced according to documented standards.

Basic to the concept of TQM is the notion that quality is essential in all functions of the business, not just manufacturing. Companies that commit to the concept of TQM apply quality improvement techniques in almost every area of product development, manufacturing, distribution, administration, and customer service. The paradigm of TQM applies to all enterprises, both manufacturing and service. Industries as diverse as telecommunications, public utilities, and health care have applied the principles of TQM.

The widespread adoption of one or more approaches or principles of TQM does not mean that results have met expectations. According to a 1992 General Accounting Office (GAO) survey, 13% of government agency employees actively participate in the TQM efforts.[53] Human resource professionals report a strong interest in TQM issues, ranking employee involvement, customer service, and TQM as the top three key issues, yet initiatives taken by organizations are not receiving as much praise now as they did a few years ago.

Quality and Business Performance

The relationship between quality, profitability, and market share has been studied in depth by the Strategic Planning Institute of Cambridge, MA. The conclusion, based on performance data of about 3000 strategic business units, is unequivocal: one factor above all others — quality — drives market share, and when superior quality and large market share are both present, profitability is virtually guaranteed.

There is no doubt that relative perceived quality and profitability are strongly related. Whether the profit measure is return-on-sales or return-on-investment, businesses with a superior product or service offering clearly outperform those with inferior quality. In addition to profitability and market share, quality drives growth. The linkages between these correlates of quality are shown in Figure 2.19.

Quality also reduces costs. This reduction, in turn, provides an additional competitive edge. Figure 2.19 includes two types of quality: customer-driven quality and conformance or internal specification quality. The latter relates to appropriate product specifications and service standards that lead to cost reduction.

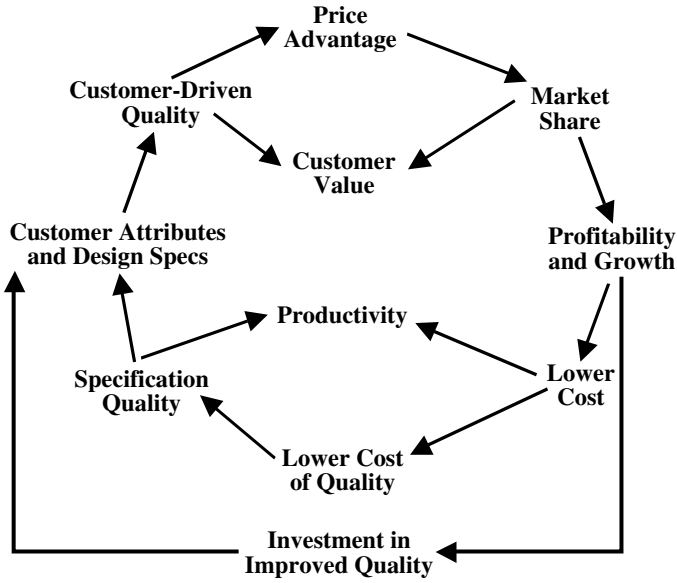


Figure 2.19 The quality circle.

There is an inverse relationship between internal or conformance quality and costs, and thus the phrase coined by Crosby: "Quality is Free." As quality improves, so does cost, resulting in improved market share and hence profitability and growth. This in turn provides a means for further investment in such quality improvement areas as research and development. And the cycle goes on. In summary, improving both internal (conformance) quality and external (customer perceived) quality not only lowers the cost of poor quality or "nonquality" but also serves as a driver for growth, market share, and profitability. Attainment of quality superiority produces the following organizational benefits:

1. Greater customer loyalty
2. Market share improvements
3. Higher stock prices
4. Reduced service calls
5. Higher prices
6. Greater productivity

Service Quality vs. Product Quality

In the U.S. there is more concern for product quality than there is for quality of services and service industries. Despite the rather obvious need for quality service, people directly employed in manufacturing functions

tend to focus on production first and quality second. "Get out the production" and "meet the schedule" are common cries on many shopfloors.[54] A study conducted by David Garvin of Harvard Business School revealed that U.S. supervisors believe that a deep concern for quality was lacking among workers and that quality as an objective in manufacturing was secondary to the primary goal of meeting production schedules.[54] The same conclusion is suggested in more than 100 companies. Supervisors almost invariably set targets related to productivity and cost reduction rather than quality improvement.

As a strategic issue, customer service can be considered a major dimension of competitiveness. In the most exhaustive study in its history, the American Management Association surveyed over 3000 international respondents:[55] 78% of these identified improving quality and service to customers as the key to competitive success; 92% indicated that providing superior service is one of their key responsibilities, regardless of position.

After being viewed as a manufacturing problem for most of the past decade, quality has now become a service issue as well. TQM relates not only to the product, but to all the services that accompany it as well. Among the distinguishing characteristics of TQM are:

1. Behavior of the salesperson
2. Image of the organization
3. Quality management during the production process
4. Quality certification of the finished product
5. Appropriate variance and acceptance of quality ranges
6. Dynamic state of the quality management program

THE MALCOLM BALDRIGE NATIONAL QUALITY AWARD

The Malcolm Baldrige National Quality Award was established by Congress as Public Law 100-107 and signed into law by President Reagan on August 20, 1987. It is one of the most important factors for the transformation of American business; the award criteria have evolved to become a national standard, providing a framework any organization can use to achieve superior competitiveness. The Baldrige Award's success is a stimulus for change, in part due to the great publicity it generates, with the awards being presented by the President of the United States.[17]

Principal support for the program comes from the Foundation for the Malcolm Baldrige National Quality Award established in 1987. The Baldrige program is managed by the National Institute of Standards and Technology (NIST) in conjunction with the private sector. As a nonregulatory agency of the U.S. Department of Commerce's Technology Administration, NIST develops and promotes measurements, standards, and technology to enhance productivity, facilitate trade, and improve the quality of life.[56]

The award is named for Malcolm Baldrige, who served as Secretary of Commerce from 1981 until his tragic death in 1987.[57] His managerial excellence contributed to long-term improvement in efficiency and effectiveness of government. The Findings and Purposes Section of Public Law 100-107 states:

1. The leadership of the United States in product and process quality has been challenged strongly by foreign competition, and our Nation's productivity growth has improved less than our competitors' over the last two decades.
2. American business and industry are beginning to understand that poor quality costs companies as much as 20 percent of sales revenues nationally and that improved quality of goods and services goes hand in hand with improved productivity, lower costs, and increased profitability.
3. Strategic planning for quality and quality improvement programs, through a commitment to excellence in manufacturing and services, are becoming more and more essential to the well being of our Nation's economy and our ability to compete effectively in the global marketplace.
4. Improved management understanding of the factory floor, worker involvement in quality, and greater emphasis on statistical process control can lead to dramatic improvements in the cost and quality of manufactured products.
5. The concept of quality improvement is directly applicable to small companies as well as large, to service industries as well as manufacturing, and to the public sector as well as private enterprise.
6. In order to be successful, quality improvement programs must be management-led and customer-oriented, and this may require fundamental changes in the way companies and agencies do business.
7. Several major industrial nations have successfully coupled rigorous private-sector quality audits with national awards giving special recognition to those enterprises the audits identify as the very best; and
8. A national quality award program of this kind in the United States would help improve quality and productivity by:
   a. Helping to stimulate American companies to improve quality and productivity for the pride of recognition while obtaining a competitive edge through increased profits;
   b. Recognizing the achievements of those companies that improve the quality of their goods and services and providing an example to others;

c. Establishing guidelines and criteria that can be used by business, industrial, governmental, and other organizations in evaluating their own quality improvement efforts; and
d. Providing specific guidance for other American organizations that wish to learn how to manage for high quality by making available detailed information on how winning organizations were able to change their cultures and achieve eminence.[56]

Background information on the law mentions foreign competition as the major rationale. No other business prize or development in management theory can match its impact.[58] The award has set a national standard for quality, and hundreds of major corporations use the criteria in the application form as a basic management guide for quality improvement programs. Although the award has its detractors,[59] it has effectively created a new set of standards — a benchmark for quality in U.S. industry.

The Malcolm Baldrige Award Criteria

The Baldrige Award is based on an analysis of what makes for an effective organization. Included are: leadership; a people focus, a customer focus, and a supplier focus; planning for improvement; process optimization; and organizational performance.[60]

Applicants for the Baldrige Award need to submit an application summary addressing the topics in the examination categories, documenting the company's practices and results. All applicants for the Baldrige Award undergo a rigorous examination process that involves a minimum of 300 hours of review by an independent board of examiners primarily from the private sector. Final-stage applicants receive about 1000 hours of review and are visited by teams of examiners to clarify questions and verify information. The Baldrige Award Board of Examiners examines the quality of an organization's activities in seven categories:[61]

1. Leadership
2. Strategic Planning
3. Customer and Market Focus
4. Measurement, Analysis, and Knowledge Management
5. Human Resource Focus
6. Process Management
7. Business Results

These seven criteria categories include Examination Items and Areas to Address. There are 24 Examination Items (Table 2.1).

Table 2.1 The Malcolm Baldrige Award Criteria for Performance Excellence. 2003 Categories and Items Point Values

Examination Categories/Items		*Point Values*
1.	**Leadership**	**120**
	1.1 Organizational Leadership	70
	1.2 Social Responsibility	50
2.	**Strategic Planning**	**85**
	2.1 Strategy Development	40
	2.2 Strategy Deployment	45
3.	**Customer and Market Focus**	**85**
	3.1 Customer and Market Knowledge	40
	3.2 Customer Relationships and Satisfaction	45
4.	**Measurement, Analysis, and Knowledge Management**	**90**
	4.1 Measurement and Analysis of Organizational Performance	45
	4.2 Information and Knowledge Management	45
5.	**Human Resource Focus**	**85**
	5.1 Work Systems	35
	5.2 Employee Learning and Motivation	25
	5.3 Employee Well-Being and Satisfaction	25
6.	**Process Management**	**85**
	6.1 Value Creation Processes	50
	6.2 Support Processes	35
7.	**Business Results**	**450**
	7.1 Customer-Focused Results	75
	7.2 Product and Service Results	75
	7.3 Financial and Market Results	75
	7.4 Human Resource Results	75
	7.5 Organizational Effectiveness Results	75
	7.6 Governance and Social Responsibility Results	75
	TOTAL POINTS	**1000**

Source: Malcolm Baldrige National Quality Award, 2000. http://www.quality.nist.gov/Business_Criteria.htm

Although developed with the private sector in mind, the approach of the Baldrige Award is applicable to the public sector.

The first-stage review by the Board of Examiners consists of independent, detailed reviews carried out by at least five examiners. A perfect score is 1000. The top applications are forwarded to a second consensus stage to review and refine the first-stage evaluations. In the third stage, top contenders (two to five) are site-visited by teams of six to eight examiners. Finally, a panel of nine judges reviews the site-visit reports

and recommends award recipients. All applicants receive comprehensive feedback reports.

An indication of the interest in the Baldrige Award is the number of application guidelines (167,000 in 1990) requested. In the first 3 years, 203 companies applied and 9 won: 6 manufacturers, 2 small companies, and 1 service company (Federal Express). Since 1988, 51 organizations have received the Baldrige Award. The winners in 2002 were Motorola Commercial, Government & Industrial Solutions Sector, of Schaumburg, IL; Branch-Smith Printing Division, of Fort Worth, TX; and SSM Health Care, of St. Louis, MO.

Winners of the award are required to share their successful strategies with other companies. IBM's Rochester, MN site, home of the Applications System/400 and a 1990 winner, attributed the success of the division to the way in which it appropriated the ideas of Motorola, Xerox, and Milliken, winners in prior years. This sharing of ideas is a central purpose of the National Institute of Standards and Technology (NIST), the administering agency. The sharing policy by winners ensures a multiplier effect. Award recipients have been very generous in their commitment to improving U.S. competitiveness, sharing information with hundreds of companies, educational institutions, health care organizations, government agencies, and others.

Another indication of the award's leverage is the stringent criteria related to quality assurance for products and services purchased by external providers (suppliers) of goods and services. It is clear that suppliers are a critical link in the chain of processes that constitute TQM. As a result, many companies require their suppliers to apply for the Baldrige Award. For example, Motorola, a winner in 1988 and in 2002, will not do business with a supplier that has not applied for the award and does not use its criteria. Another winner, Globe Metallurgical, is certified as a supplier by Ford. Globe in turn requires certification by its suppliers. Thus, the number of firms using the Baldrige criteria may grow geometrically as first-tier suppliers certify second-tier suppliers and so on.

REFERENCES

1. Juran, J.M., 1990. *Made in the USA: A Break in the Clouds,* Juran Institute, Wilton, CT.
2. Juran, J.M., 1991. World War II and the quality movement, *Quality Progress*, December, 24(12), 19–24.
3. Integrated Quality Dynamics, Inc., 2001. TQM: Definition of Total Quality Management. http:/www.iqd.com/hoshin_def.htm
4. Feingenbaum, A.V., 1991. Quality. An international imperative, *J. Quality and Particip.*, March, 16.

5. Fortuna, R.M., 1990. The quality imperative, *Executive Excellence*, March, 1.
6. American Society for Quality Control (ASQC), 1989. Quality: Executive priority or afterthought? *Am. Soc. Qual. Control*, Milwaukee, WI.
7. American Society for Quality Control (ASQC), 1988. 1988 Gallup Survey. Consumer's Perception Concerning the Quality of American Products and Services, *Am. Soc. Qual. Control*, Milwaukee, WI.
8. American Society for Quality Control (ASQC), 1990. Quality: Everyone's job. Many vacancies, *Am. Soc. Qual. Control*, Milwaukee, WI.
9. Hansen, D.A., Total Quality Management (TQM) Tutorial. TQM Compared to ISO 9001, http://home.att.net/~iso9k1/tqm/tqm.html
10. Hubbard, M.R., 1996. *Statistical Quality Control for the Food Industry*, 2nd ed., Chapman & Hall, New York, NY.
11. Mizuno, S., Ed., 1988. *Management for Quality Improvement: The 7 New QC Tools,* Productivity Press, Cambridge MA.
12. Pinchback, R.M., 2003. Entiry-Relationship Diagram. A Quick Summary in Two Pages, Reviewed January 30,2003. http://web.mit.edu/afs/athena/user/r/e/reidmp/www/old/framed/work/ERDsummary.pdf
13. Mercer, D., 1991. Total Quality Management: Key Quality Issues, in Global Perspectives on Total Quality, Conference Board, New York, NY, p. 11.
14. Breisch, W.E., 1990. Employee involvement, *Quality*, May, pp. 49–51.
15. Hauser, J., 1988. The house of quality, *Harvard Business Review*, May/June, 63–73.
16. George, C.S., 1972. *The History of Management Thought*, Prentice-Hall, Englewood Cliffs, NJ.
17. McLaughin, G.C., 1995. *Total Quality in Research and Development*, St. Lucie Press, Delray Beach, FL.
18. Burrill, C.W. and Ledolter, J., 1999. *Achieving Quality through Continual Improvement*, John Wiley & Sons, New York, NY.
19. Ishikawa, K., 1985. *What is Total Quality Control? The Japanese Way*, Prentice Hall, Englewood Cliffs, NJ.
20. Mazur, G.H., Takasu, H., and Ono, M., 1998. *Policy Management. Quality Approach to Strategic Planning*, Integrated Quality Dynamics, Torrance, CA.
21. Juran, J.M., 1999. *Juran's Quality Handbook*, 5th ed., McGraw-Hill, New York, NY.
22. Garvin, D.A., 1987. Competing on the eight dimensions of quality, *Harvard Bus. Rev.*, November/December, 101–109.
23. Halsall, P., 1998. Modern History Sourcebook: Frederick W. Taylor: The Principles of Scientific Management, 1911. http://www.fordham.edu/halsall/mod/1911taylor.html
24. Drucker, P.F., 1993. *Management: Tasks Responsibilities Practices*, Harper Business, New York, NY.
25. Weisbord, M.R., 1987. *Productive Workplaces*, Jossey-Bass, San Francisco, CA.
26. Shewhart, W.A., 1931. *Economic Control of Quality of Manufactured Product*, Van Nostrand, New York, NY.
27. Pande, P.S. and Holpp, L., 2001. *What Is Six Sigma?* McGraw-Hill, New York, NY.
28. Pizdek, T., 2000. *The Six Sigma Handbook*, Quality America, Tucson, AZ.
29. American Society for Quality, 2003. Walter A. Shewhart. Father of statistical quality control. http://www.asq.org/join/about/history/shewhart.html

30. Katawala, Y., 1989. A comparative analysis of selected approaches to quality, *Int. J. Qual. Reliab. Manag.*, 6(5), 7–17.
31. Deming, W.E., 1982. *Quality, Productivity and Competitive Position*, Cambridge University Press, Cambridge, MA.
32. Voehl, F.W., 1990. The Deming Prize, *South Carolina Bus. J.*, 33–38.
33. Juran, J.M., 1951. *Quality Control Handbook*, McGraw-Hill, New York, NY.
34. Juran, J.M., 1986. The quality trilogy. *Qual. Prog.*, August, 19, 8, 19–24.
35. Juran, J.M., 1989. Universal approach to managing quality, *Exec. Excell.*, 6(5), 15–17.
36. Juran, J.M., 1991. Made in USA – A quality resurgence, *J. Qual. Particip.*, March, 6–8.
37. Juran, J.M., 1991. Strategies for world-class quality progress, *Qual. Prog.* March, 24(3), 81–85.
38. *Business Week*, 1991. Dueling pioneers, in The Quality Imperative, *Business Week*, October 25.
39. Feigenbaum, A.V., 1986. *Total Quality Control: Engineering and Management*, McGraw-Hill, New York, NY.
40. Feigenbaum. A.V., 1991. *Total Quality Control*, 3rd ed., McGraw-Hill, New York, NY.
41. Feigenbaum, A.V., 1986. Quality. The strategic business imperative, *Quality Progress*, 19(2), 27.
42. Feingenbaum, A.V., 1990. America on the threshold of quality, *Quality*, January, 16.
43. Crosby, P.B., 1979. *Quality Is Free: The Art of Making Quality Certain*, McGraw-Hill, New York, NY.
44. Crosby, P.B., 1984. *Quality without Tears. The Art of Hassle-Free Management*, McGraw-Hill, New York, NY.
45. Crosby, P.B., 1986. *Running Things. The Art of Making Things Happen*, McGraw-Hill, New York, NY.
46. Crosby, P.B., 1993. *The Eternally Successful Organization: The Art of Corporate Wellness*, Mentor Publishers, Dublin, Ireland.
47. Crosby, P.B., 1999. *Leading. The Art of Becoming an Executive*, Diane Publishing, Collingdale, PA.
48. Ishikawa, K., 1989. *Guide to Quality Control, Quality Resource*, Prentice Hall, White Plains, NY.
49. Ishikawa, K., 1985. *What is Total Quality Control? The Japanese Way*, Prentice Hall, Englewood Cliffs, NJ.
50. Phadke, M.S., Introduction to Robust Design — Robustness Strategy. Rev. Jan. 31, 2003. http://www.isixsigma.com/library/content/c020311b.asp
51. Harrington, H.J. and Rieker, W.S., 1988. Quality control circles, *J. Qual. Particip.* (March), 12–14.
52. Vasconcellos, J.A., 2002. Quality Assurance for the Food Industry. A Practical Approach. Personal Notes.
53. Jordan, J., 1993. Everything you wanted to know about TQM, *Public Manager*, Winter 1992–1993, 45–48.
54. Garvin, D.A., 1987. Competing on the eight dimensions of quality, *Harvard Bus. Rev.*, November/December, 101–109.
55. Greenberg, E.R., 1990. Customer service: The key to competitiveness, *Manage. Rev.*, December, 29.

56. Baldrige National Quality Program, 2001. http://www.quality.nist.gov/Improvement_Act.htm
57. DeCarlo, N.J. and Sterett, W.K., 1990. History of the Malcolm Baldrige National Quality Award. *Quality Progress*, March, 23(3), 21–27.
58. Reimann, C.W., 1990. America unites behind the Baldrige quality crusade, *Electron. Bus.*, October 15, 63.
59. Main, J., 1991. Is the Baldrige overblown? *Fortune*, July 1, 62–65.
60. Innovation Journal, 1998. http://www.innovation.cc/inno1/bald.html
61. Malcolm Baldrige National Quality Award, 2003. The 2003 Baldrige Criteria for Performance Excellence, http://www.quality.nist.gov/Business_Criteria.htm Accessed September 20, 2003.

Chapter 3

QUALITY ASSURANCE

THEORIES AND APPLICATIONS

Many well-established companies give product quality a primary role in the organization. This effort requires a special group of professionals that the companies include under a vice president of quality assurance who reports directly to the president. Quality assurance (QA) describes and manages the activities of control, evaluation, audits, and regulatory aspects of a food processing system. A QA program consists of an in-house consulting organization; it evaluates the quality program and gives advice, suggestions, and instructions for its improvement.

The QA department should report directly to top management in order to have independence in serving the organization. If quality is to be the primary goal of a food manufacturing company, the head of quality assurance should have the title of vice president and report directly to the president of the enterprise. In headquarters, there should be a staff to assist the vice president, with quality professionals reporting to a director of QA and supporting quality efforts in each corporate division.

QA is an advisory function, not a police function. It is not responsible for the quality program, it does not operate the system, and it does not do quality control. QA may audit the system and provide assistance in making improvements, but the planning, organizing, staffing, directing, and controlling of the quality program are in the hands of upper and production management. A divisional quality control (QC) staff promotes quality in the division and assists and consults with production as required; the responsibility for the quality of divisional products rests directly with production. In particular, QA is not responsible for the quality of the products the organization provides to its customers.

The QC professionals of the company are staff personnel with responsibility for assisting production in quality-related matters. They should

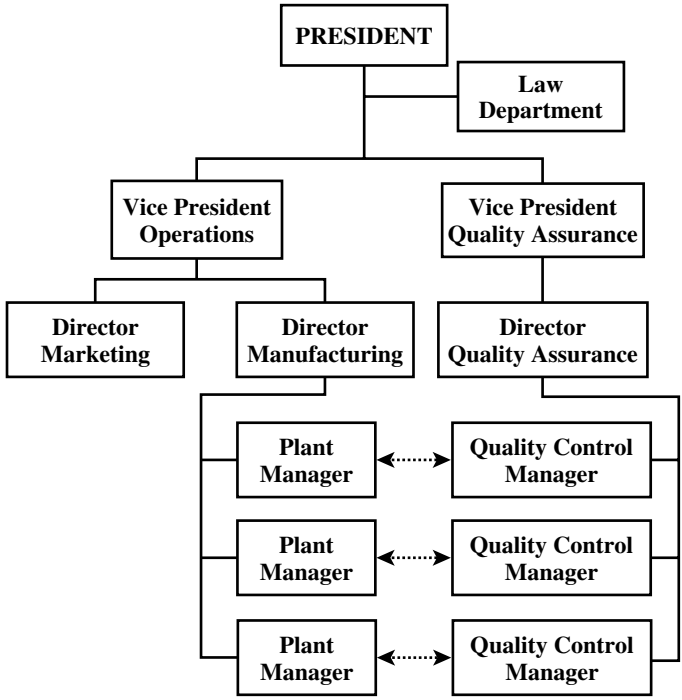


Figure 3.1 Delegation of responsibilities and operational interactions in a food company.

report to the division director of QA, with a strong link ("dotted line" relationship) to plant management (Figure 3.1). The divisional QC personnel look to the vice president of QA for direction and assistance, and support his programs.

According to Burrill and Ledolter,[1] a vice president for QA is charged with specific responsibilities that include:

- Serving as a focal point for quality matters, including corrective action and continual improvement activities
- Formulating and recommending company policies, strategies, tactics, and goals and objectives relating to quality
- Reviewing and helping to coordinate quality aspects of design of line plans
- Assisting and counseling top managers on quality matters
- Exercising authority over QA groups in different plants
- Concurring with the appointment of QA directors for different plants
- Serving as a resource for information in the quality area, including regulatory and competitive information

- Coordinating the efforts of standards committees, quality improvement teams, and other groups whose activities touch on the quality area
- Monitoring quality and reporting to top managers on the status of quality in the enterprise
- Providing leadership for the quality function as necessary
- Fostering awareness of quality and helping to gain credibility for the quality improvement effort
- Interacting on quality matters with external organizations, e.g., government agencies, professional associations, etc.

QA is a relatively new area of activity in the food industry, beginning in the late 1950s to early 1960s with the advent of concepts such as Hazard Analysis and Critical Control Points (HACCP) as a means of preventing, rather than correcting, the occurrence of defects and contamination or the presence of foreign substances during product manufacture. Although more than 40 years have passed since then, the concept of a QA program is still not well understood by many and is confused with QC. Unfortunately, these two terms have been used indiscriminately and the difference between them is blurred. Many companies refer to their QA program, but when discussing it, or through inspection, what it comes out is that it is a QC program. This occurs particularly with mid- and small-size food manufacturing plants and with many companies in the dietary supplements industry. QC constitutes a fundamental part of a QA program, but is normally associated with the production line to regulate it to some standard.[2]

So, a distinction needs to be drawn between QA and QC. According to the International Standards Organization (ISO 8402 – Terminology), QA is "all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality." In other words, QA is a strategic management function that establishes policies, adapts programs to meet established goals, and provides confidence that these measures are being effectively applied. QC, on the other hand, is "the operational techniques and activities that are used to fulfill requirements for quality" (ISO 8402 — Terminology), i.e., a tactical function that carries out the programs established by the QA.

During the last 2 decades, further changes have been taking place in the area of QA, particularly with the development of the concepts and applications of Total Quality Management (TQM), the empowerment and training of the line operator, and the practices for the control of quality on the production line, reducing the work of the QC laboratory.

By empowering the line operator to control his unit operation to given specifications — as part of this process — the quality of the product can be more uniform and consistent. The work of QC, a fundamental part of

a QA program, in all manufacturing unit operation steps of a process, and the evaluation of the final product at the end of the line, or in the market, together with human management, and management of regulatory aspects of the food industry are what in modern terms constitute the QA field.

FUNCTIONS OF A QUALITY ASSURANCE PROGRAM

Information on food quality and food manufacturing is currently more readily available to consumers through the mass media. In many countries, the safety and quality of foods are becoming a matter of increasing concern and consumers are considerably more aware of existing and potential risks in their food from various sources: pesticides, food poisoning, and a poor diet. Demonstrating the impact of this greater awareness, consumers often prefer to buy foods that are made by larger, more recognizable manufacturers, because larger companies are supposed to have better quality products or manufacture their products under optimum conditions of quality, although many mid-size and small companies produce equally excellent quality foods.

Irrespective of the specific nature of the food-processing unit, food processors are responsible for the quality and safety of the food they produce. This obliges corporations to emphasize quality as the most important factor in their business, something they can only obtain through a well-established QA program.

What then are the functions of a QA department? QA functions involve establishing and managing the company's quality organizations, designing operating procedures, discussing the quality direction with top management, introducing them to the fundamentals of quality, and making certain there is consistency in management pronouncements.

The minimum requirement is for food processors to apply good sanitation practices, which include the design and layout of the premises, provision of adequate facilities, and programs for cleaning and sanitation (pest control), as set out in the Code of Federal Regulations 21 CFR Part 110 of the United States and in Codex General Principles of Food Hygiene of the United Nations. Additional QA programs, such as Hazard Analysis and Critical Control Point (HACCP), audits of several areas of manufacturing, of sanitation, and of the product in the market are also the responsibilities of a QA department. QA programs enable the application and verification of control measures intended to assure the quality and safety of food. They are required at each step in the food production chain to ensure safe food and to show compliance with regulatory and customer requirements.

The programs are a set of controls implemented and verified by the responsible person(s) at each step in the chain (e.g., producers, farmers,

fishermen, food processors, retailers, distributors, storage and transport personnel, etc.). Governments have an important role in providing policy guidance on the most appropriate QA programs and verifying and auditing their implementation as a means of regulatory compliance. Selection and application of QA programs can vary depending on the step in the food production chain, size of the food business, type of product produced, etc., and may include Good Manufacturing Practices (GMPs), Good Agricultural Practices (GAPs), Good Laboratory Practices (GLPs), HACCP systems, and HACCP-based systems.

Regulatory agencies and food companies are improving QA programs to meet the demands for safe, high-quality foods. Successful management programs that enable food processors to address global marketplace opportunities while maintaining high quality and safety are more common.

The primary function of a QA department is to provide confidence for management and the consumer — the person a company must satisfy and who actually establishes the level of quality of the products a company manufactures. The function of QA in this sense is never ending. A company builds its product specifications and legal requirements around consumer preferences, and only by having an integrated and well-planned quality program can a food company succeed in supplying the customer with the desired products. The role of the QA department and the professional in this area is to guarantee that the consumer receives what he desires and that the company makes the profit it deserves. The QA department must also maintain monitoring activities on the available growing literature on concepts, techniques, and programs related to quality issues, to select the best ideas and bring them to management's attention.

Some companies assign the QA department additional functions in product development, plant sanitation, waste disposal, and research on processes, equipment, ingredients, etc. These are all specialized areas and require expertise for success.

Perhaps the most significant aspect of a QA program is the fact that through its functions, upper management is able to monitor, at all times and through all stages of manufacturing, the level of quality of its product, as well as keeping in line with industry trends.

By reporting directly to upper management, the QA professional is provided with the necessary independence to be effective in his or her functions. In turn, the QA professional needs to be competent and knowledgeable in the various aspects of the food industry, including regulatory, processing, sanitation, safety, and human relations. Thus, the selection, training, and respect given to QA professionals are very important factors of the company's quality program. The QA department's personnel should be considered as in-house consultants, advisors, and trainers for the company, to help the production of quality products through audits,

to make recommendations for improvements, and to provide assistance in making such improvements.[3]

To reach and maintain these goals, a QA program is built around three fundamental functions:

Quality Control

A program established around a processing operation to regulate a resulting product by some standard, the function of QC is associated with the production line, i.e., with specific processes and unit operations. QC activities are the operator's tools that help him to maintain a production line in accordance with predetermined parameters for a given quality level.

Quality Evaluation

Describing or appraising the worth of a product, quality evaluation generally means taking a measurement of the product to the QC laboratory to evaluate the performance of incoming materials, products in process, or finished products. The finished product can be evaluated as offered in the market, ready for the consumer. This is carried out by product quality audits.

Quality Audits

Quality audits are programs designed to verify or examine a product or manufacturing process over time. These can be classified as manufacturing quality audits, sanitation/GMPs audits, HACCP audits, product quality audits, and other special types of audits. A quality audit is a fundamental part of a QA program. It allows for quality verification of a product during manufacture, in the warehouse, in the distribution system, and in the market to assess performance over time or for comparison to competitor brands.

Each person with responsibility for a portion of the program should conduct regular assessments or reviews of the effectiveness of the quality program and its operation. Such assessments are a normal part of good process management. In addition, there should be a systematic review of the quality program by an authority that is not directly responsible for the process or its operations; such a review is a quality audit.

A quality audit is a planned, systematic examination of a manufacturing program and its implementation to determine its adequacy and the degree of conformance to it. It concentrates on quality-related aspects of production.

A quality audit consists in examining a representative portion of the manufacturing program and drawing an inference about the total system based on this sample.

There are two types of quality audits: internal audits and third-party audits. An internal quality audit is a review conducted by employees of the organization. A third-party audit is conducted by an outside organization.

In its role within the company, the activities of the QA department include the responsibility to build these types of programs, to ensure that proper controls exist not only in communication, but also in the transfer of responsibility between departments and, most importantly, between individuals, both at the operational and at the managerial level. A QA program in this context becomes a key element for a responsible and quality-oriented operation; by reporting errors in the manufacturing system so that these can be corrected and by identifying and suggesting process modifications, the QA department contributes to a higher operation efficiency and thus higher productivity.

According to IFT experts,[4] specific major functions of the QA department include monitoring of:

Compliance with specifications. Legal requirements, industry standards, internal company standards, shelf-life tests, customers' specifications.

Test procedures. Testing of raw materials, finished products, in-process tests.

Sampling procedures and schedules. Suitable sampling schedules should be used to maximize the probability of detection while minimizing workload.

Record-keeping and reporting procedures. Maintenance of all QA records so that customer complaints and legal problems can be dealt with.

Troubleshooting. Solution of problems caused by poor quality raw materials, erratic supplies, malfunctioning process equipment; investigation of reasons for poor quality product to avoid repetition.

Special problems. Customer complaints, production problems, personnel training, short courses, etc.

A typical QA department may include a chemistry lab, a raw materials inspection lab, a sensory lab, and a microbiology lab. All these disciplines serve to assure that the food produced is of the highest quality, and will bring customers back.

Other functions of the QA department include the following.

Education and Training

Much of this effort focuses on conducting classes and meeting the organization's needs. In a manufacturing company, more than half the education takes place on the job, not in the classroom. Because of this, one task of QA is to encourage supervisors and management to include quality concepts in their training efforts.

Education and training should focus on the culture and traditions of the organization, fundamentals of quality, quality improvement, concepts of processes, technical topics, statistical concepts, management and supervisory practices, and quality leadership. A company must have a mechanism for providing this required education and training. It must also have a mechanism for keeping personnel informed about quality developments that are pertinent to their work and to the organization. QA management and education concepts constitute a massive effort and might require temporary assistance from outside consultants to cope with the workload.

Process Improvement

An important aspect of the work in manufacturing is to promote the interest of the workers in their jobs. They should be encouraged to observe the operation and to look for information and learn from technical magazines about important process developments that the enterprise could use and may eventually depend upon for success.

Standards

A company should develop, review, and implement internal standards and keep track of external standards with which it must comply. This is one of the areas in which the QA department may contribute considerably, helping standards committees with their work.

Special Projects

QA responsibility also includes collecting and analyzing data related to quality, and assisting other inside organizations to implement their own procedures. Examples are:

- Forming and leading corrective-action teams to make specific improvements.
- Facilitating quality actions of others.
- Evaluating tools, techniques, procedures, standards, etc.

Consulting

QA can serve the company by assessing a process and recommending improvements; by helping to improve a co-packer's quality performance, evaluating and recommending changes in a division or plant quality program, etc.

Auditing the Quality Program

Each person with responsibility for a portion of the quality program should conduct regular assessments of the QA and its operation. In addition, there should be a systematic review of the quality program by an authority that is not directly responsible for the process or its operations; such a review is a quality audit.

A quality audit is a planned, systematic examination of a representative portion of the manufacturing program and its implementation to determine its adequacy and the degree of conformance to it. It concentrates on quality-related aspects of production.

There are two types of quality audits: internal audits and third-party audits. An internal quality audit is a review conducted by employees of the organization. A third-party audit is conducted by an outside organization.

CAREERS IN QUALITY ASSURANCE

The professionals in QA become involved in the development of systems for continuous process improvement and reliable QC tests, inspection, management, and testing aspects of the manufacturing processes. Requirements to enter the QA field in the food industry include technical aptitude, effective decision-making skills, strong verbal and written skills, and leadership potential. QA personnel continually monitor incoming raw materials and ingredients as well as finished products to ensure compliance with compositional standards, microbiological standards, and various government regulations. A QA manager can halt production, refuse acceptance of raw material, or stop the shipment if specifications for a product or process are not met. Thus, he or she also needs knowledge of the regulatory and safety aspects of food manufacturing.

A QA professional must have a solid background in mathematics, English and composition, general sciences (chemistry, physics, biology, sanitation), and information technology, which is becoming more and more important.

At present, the food industry is one of the most competitive industries and is constantly changing to react to consumer demands and technological

innovations. Recent examples are the areas of nutraceutics and functional foods, which have grown very rapidly in the last few years and demand far more regulatory definitions and QA application. Another is the very recent area of concern regarding food terrorism, which, as a result of the tragic events of September 11, 2001, equally demands very strict regulatory implementation. These events, as well as the anthrax incidents, have reemphasized food safety concerns and the priorities of regulatory agencies. The threat of terrorism aimed at the food supply and assuring biosecurity to the food industry have become priority concerns.[5]

Recently, the World Health Organization (WHO) cautioned about the possibility of food terrorism using chemical, biological, or radioactive agents and urged countries to tighten their defenses. Should the regulatory agencies supply biosecurity or will responsibility largely fall on the growers, packers, shippers, and processors of our food? The question almost answers itself: the burden falls on the regulated industry to assure the safety of its products. How will they do this? The industry needs to adopt preventative measures to deal with food quality issues. Included in these steps are such obvious ones as updating and maintaining inspection practices, tightening security in ports, making sure that chemicals and explosives are kept under lock and key, implementing a tight qualification of ingredients, raw material, etc., and closer control on the manufacturing lines. In addition, it is vital that food processing facilities be able to assure restricted access to computer control systems, laboratory facilities, and other sensitive plant areas. Security guidelines for food facilities are published in the Federal Register. All of these activities are the responsibility of the QA department through the various quality evaluation programs in place.

Even if relatively little harm to human health results from an incident, the economic consequences could be great and consumer confidence in the food supply and the regulatory agencies shaken. The Tylenol tampering episode of 1982 launched a legion of "copycat" offenders. Thousands of product tampering threats and hoaxes and dozens of genuine cases of product contamination swept the nation, reaching a peak in 1986. These cases cost pharmaceutical companies, food processors, grocers, and retailers hundreds of millions of dollars.[6,7]

As the world population increases, food technologists are challenged with developing innovative applications in biotechnology and the processing of foods, and the role of QA professionals will acquire unprecedented importance in the years to come. There will be a great need for graduates to work in this area of the food manufacturing industry.

A Bachelor of Science degree in food science with an option in QA will give graduates an advantage in securing positions in the constantly

changing environment of the food industry. Other college degrees that lead to careers in QA include those in chemistry, microbiology, and nutritional sciences. Persons can also qualify for QA positions through many combinations of work experience and training, but more and more, employers prefer applicants with a formal technical education. However, given the present situation, this might not be enough and higher degrees may be needed. Some institutions already realize that and are offering areas of specialization for graduate students. The University of Guelph, Canada, for example, offers a collaborative Master of Science degree program in food safety/quality assurance. The program, which includes participation by the departments of biomedical sciences, consumer studies, environmental biology, food science, pathobiology, and population medicine, and the School of Engineering, is intended to prepare food scientists, food engineers, veterinarians, and others with appropriate scientific backgrounds for participation in food safety monitoring and QA maintenance in the food industry and in government.

Usually, graduates of university food science programs hold these positions. In a typical hierarchy, technicians report to a laboratory supervisor who in turn reports to the QA manager.

In some food companies, the technicians do not necessarily have college degrees. With the widespread use of more specific, high-tech analytical techniques, however, it is becoming more important for a QA technician to at least have a 2-year college degree emphasizing the sciences. Examples of QA careers at the technician level are:[4]

Microbiology lab technician. Responsible for the day-to-day activities in the microbiology lab. Must be knowledgeable of sterile techniques, mathematics, and accurate reporting of data.

Chemistry lab technician. Responsible for the day-to-day chemical analysis of food in the chemistry lab. Must have knowledge in basic chemistry, physics, mathematics, and accurate reporting of data.

Inspection lab technician. Knowledge of the sanitary handling of food samples, mathematics, and record-keeping.

Customer service. Responsible for handling customer complaints and tracking down test results and product. Must be knowledgeable of specifications and broad legal responsibilities. Helps to be people oriented.

Specifications. Responsible for accurate, organized record-keeping so that, if needed, product can be traced and verified.

Laboratory supervisor. In charge of the lab personnel and their daily activities. Responsible for scheduling both personnel and testing.

QA RESPONSIBILITIES AND OPERATIONAL INTERACTIONS

One way to visualize the delegation of responsibilities within the food industry is to again examine the organizational plan of a typical food company (Figure 3.1) describing the level of responsibilities and interaction between operations personnel. The figure shows the primary functions of marketing, manufacturing, and QA. While some variations are possible, several key features should be noted:

- The senior person responsible for QA reports directly to upper management, with the same status as the heads of marketing and manufacturing.
- The plant QC managers should report to the director of QA, although dotted lines on the organizational chart indicate close functional ties with plant managers.

  QA experts recommend that plant laboratories report directly to QA rather than to production. The argument used is that if quality control is allowed to slip into the manufacturing organization, there may be a tendency to overlook danger signals and to delay corrective actions. For the QC manager to discharge his duties effectively, he must be given wide latitude without fear of reprisals.
- The cornerstones of any QA program are the food scientists in the plant QC laboratories. They bear the responsibility of maintaining a steady output of quality products. In keeping with the principle of decentralization, as much responsibility as possible should be delegated to the laboratories. Not only are these groups closer to the quality problems, but they are also far more efficient than corporate staffs in handling the numerous requests from customers.
- The director of QA is charged with exercising tight control over all aspects of quality. His or her accepted duties include the approval of all product labels, packaging, product specifications, special releases of products, and data sheets. The organization depends more on the director of QA than any other person for implementing the necessary programs and procedures.

If no decisive measures are taken to enforce specific objectives of manufacturing and their control, a QA program will remain a well-meaning but ineffective body of rhetoric.

Procedures should be stated in a concise form, pinpointing job assignments and with the means for communication within the organization. In the preparation of such directives, a realistic appraisal should be made of business needs and the resources and manpower available for meeting these demands. A valuable tool would be a QA manual, comprising these procedures, to be distributed to all supervisory personnel.

No other component in a QA program is more important than developing a strong organization in terms of both ability and mission. Corporations are not the only principals concerned with organization and management. Industry's counterparts, the government regulatory agencies, manage staffs that outnumber the employees of most food processors and are involved with the same food-related issues, although from a different reference point. What government regulators say and do have as great a bearing on product planning as any decisions made by industry personnel.

The basic responsibilities of a QA department are recording and reporting the results from:

1. Line inspection and control of:
   a. Supplies, ingredient materials, and raw products
   b. Operating procedures
   c. Finished products
2. Physical evaluation and qualification of raw and processed products, and ingredients
3. Chemical evaluation of raw and processed products, and ingredients
4. Microbiological evaluation of raw and processed products, and ingredients
5. Warehousing conditions for shelf-life time, temperature control, and handling procedures
6. Sanitation control of products, processes, and storage
7. Waste disposal control
8. Compliance with Federal, State, and Municipal requirements and standards
9. Specification compliance during marketing and distribution for consumer confidence and assurance of the integrity of the product and company

Additional responsibilities include training, problem solving, development of test and operational procedures, occupational safety and health regulations, and special research and development projects. The most important responsibility of the QA professional is that of a team player as well as being a leader in the efficient production of a quality product.

THE NEED FOR AND ROLES OF QA

QA may be thought of as the scientific control of production.

The primary objective of a QA program is to ensure the safety and quality of products. This objective is carried out by obtaining adequate information on all factors of the processing system that affect the quality of the product and integrating them, taking into consideration product

composition, specifications, processing, packaging, storage, distribution, microbiological safety, plant equipment, sanitation, pest and rodent control, and hazard analysis and critical control points.

The QA technologist's information serves as a constant guide for management as to the exact quality of the product being manufactured from a given quality of raw stocks, or it may provide management with the information needed in the processing to obtain a product of a given quality.

ORGANIZATION OF A QA PROGRAM

The organization of a QA program is the first step that must be carefully considered. Upper management must support the program and the QA department should be directly responsible to upper management. Obviously, it is necessary for the QA professional to provide each of the other departments with specific information regarding quality at the receiving platform, or on the line, or even in the warehouse; but he should not be responsible to these groups as such.

Management — rather than any of the departments within the company — must make the decision between quality and quantity. The QA professional should, however, have the authority from management to work closely with production to maintain operations so that the product being packed at all times meets the desired standards.

QA PERSONNEL

The number of personnel in the QA department varies depending upon the products being packed, the size of the operation, and the amount of control desired by management. Besides his or her technical qualifications, the QA technologist must have other qualifications to fulfill the responsibilities necessary for a successful program. Some of these qualifications are:

1. Honesty. Truthfulness in reports, in decisions, and above all, in analysis
2. Salesmanship
3. Ability to speak the industry's language and write intelligently
4. Cooperative spirit (a team player)
5. Alertness and responsiveness to necessary changes
6. Courteous and neat in appearance
7. Reliable
8. Adequately trained
9. Ability to instruct production employees as to:
   a. What is to be done
   b. How it is to be done
   c. Why it must be done

Among the most critical decisions in a quality program is the choice of QA personnel, particularly the person to head the program.

Valued employees should be chosen; one fundamental reason for having the best qualified people in QA is that the staff can mean the failure or success in making a company a first-class competitor. A well-done QA job will have a significant impact on profitability and survival. Top management must support a well-qualified QA program or it will not be successful. If top management doesn't believe in it, no one else will, and the program will be a failure.

The Vice President of QA

The vice president of QA should report to the president and should have a strong voice in selecting the QC staffs. This will prevent the problem of plant managers making QC appointments, often before they themselves are thoroughly familiar with the QA program.

The vice president of Q.A is charged with specific responsibilities; some of these are:

- To serve as a key guidance for quality matters, corrective actions, and continual improvement activities
- To formulate and recommend the company's policies, strategies, tactics, and goals relating to quality
- To review and help coordinate quality aspects of production plans
- To assist and counsel division managers on quality matters
- To exercise authority over QC groups in the divisions
- To concur with the appointment of the division QA directors
- To serve as a resource for information on quality issues, including competitive information
- To foster awareness of quality and help to gain credibility for quality improvement efforts
- To monitor quality and report to top management
- To coordinate efforts of standards committees, quality improvement teams, and other groups whose activities touch on quality matters
- To interface on quality matters with external organizations, including government agencies and professional organizations
- To provide leadership for the company's quality effort as necessary

This list of responsibilities clearly describes QA as a support function, leaving the responsibility for quality to production. Organization charts should be adjusted to make quality responsibility within the company explicit. Most QA organizations choose process improvement as their basic tactic, and support it by interpreting their mandate to include further responsibilities:

- Maintain high professional standards for managing quality organizations or groups
- Provide education and training relating to quality
- Implement quality programs, projects, procedures, and information systems
- Recommend employee recognition programs
- Foster development and use of standards
- Promote and conduct special studies of tools, techniques, and procedures that might improve quality
- Promote appropriate and effective quality audits
- Assess the enterprise's quality relative to competitors
- Recommend appropriate corrective actions

QA Professionals

QA professionals should be familiar with the technical aspects of the organization with which they work and understand basic quality concepts; ASQ certification (such as CQA, CQE, etc.) is often a good indicator of engagement in the field. For the most part, QA professionals are people oriented, able to establish rapport with all levels of the organization, and they should be viewed as consultants and facilitators. The skills QA professionals are most likely to use are the abilities to organize, teach, counsel, and communicate. They should understand organizational and team dynamics and behavior.

QA AUDITS

Typically two classes of audits exist: the internal quality audits carried out by the company's QA department on its own plants, and external or third-party audits, usually carried out by clients, to certify the manufacturing quality of their products, if these are manufactured in the plant. One example of this class of audits is that carried out by rabbis to certify the kosher status of products. Among the internal quality audits, the QA department carries out several types (manufacturing, sanitation, finished product quality, etc.), which allow the identification of problems existing in the manufacturing process.

The most common types of audits carried out in the food industry include the following:

1. Product manufacturing
2. Plant sanitation/GMP
3. Product quality
4. HACCP

This does not mean that specific audits cannot be carried out at the discretion of management or of the director of QA. At a given point, a special audit on QC programs (including methodology performance in all shifts), on temperature controls, on ingredient qualification programs, or on batching and formulation practices could very well be advisable in order to specifically determine actual practices and controls in these important areas of manufacturing operations.

An internal quality audit usually is referred to simply as a quality audit, or an audit. Internal audits focus on quality and are the eyes and ears of top management; their task is to make an independent assessment of compliance to standards and procedures and evaluate whether those standards and procedures are adequate, effective, and efficient. This helps management to obtain factual information about the status of the quality program and identify opportunities for improvement. Internal audits also help to improve communications and can be used as tools for training personnel who participate as observers.

Top management should commit the organization to conducting quality audits on a regular, scheduled basis, report the results, and follow up with corrective actions as appropriate. Audit findings are an important input to adjusting and improving the quality program and to management's review of the quality program. The quality manual should contain this policy statement.

The members of an audit team are trained and qualified employees in the QA department. They are independent of the process being audited, but at the same time, they are familiar with the process. One way to gain familiarity is to study the process documentation. This study should include the trainee in an audit team as an observer, giving the trainee an opportunity to learn about both the process being audited and the auditing process. Being an auditor is an excellent way for a person to understand the requirements for a quality program and the objective evidence that must be collected to demonstrate the effectiveness of the system.

Auditors should examine the quality program documentation for the area being audited, and they should prepare a schedule for the audit. They should examine the overall system as well as the individual elements (processes) of the system, and document objective evidence that can be used to assess the effectiveness of the program. Observed nonconformances should be reported, and corrective actions should be taken.

An organization should plan and schedule internal audits periodically for every element of the quality program. For a mature system, it might be sufficient to audit each element once a year, but newly implemented elements should be audited more often.

Conducting an Audit

A unit being audited should be notified of a planned audit well in advance of the scheduled date; the audit should not be a surprise visit to catch wrongdoing. If the audited plant gets everything in shape and passes the audit with flying colors, that's fine. Audits are a tool to help the organization, not to "catch" people.

Every manufacturing process is accomplished through an interconnected number of procedures described in different types of documents, as explained later. A manufacturing process is audited by auditing the procedures that accomplish the process. This is done because a procedure is detailed in a corresponding document, specifying not only what work is to be accomplished but also where and who will do it.

The auditor will observe the procedures and ask specific questions concerning the quality program; he will require revision of records for specific procedures and for instrument calibrations. His task is to gather objective evidence concerning the implementation of the quality program and the degree of conformance to it. If the auditor finds a problem with the quality program, he will usually report it to the plant management, which should take appropriate action to correct the problem and to improve the quality program and report this correction back to the auditor.

Purposes

A well-documented, planned program for process control serves as the basis for development of the QC procedures to be performed. The exact control procedures developed depend on the nature of the process and the type of product being manufactured or formulated. For most food processing operations, the developed control procedures should include HACCP techniques, in-process inspection, testing and monitoring, and the use of appropriate statistical procedures. The purposes of an audit are to confirm that procedures are being carried out — under normal conditions of operation — as prescribed in the manufacturing documents, and to report deviations from the procedures to promote their correction or implementation.

Procedures

In-Process Monitoring

An important aspect of process control is the surveillance, or monitoring, of the process during operation to determine if the established controls are effective, and to ensure that there is adherence to regulatory policies and procedures.

In-process inspection and tests must be developed to provide information relating to the performance of the process and to the quality of

the product obtained at the various stages of the process. The inspection should include testing and analysis using well-documented, appropriate procedures. For variable measurement, the methods used must provide reliable data and should be continuously checked using standards or by checking samples.

In addition, there must be frequent calibration of equipment and of the instruments used in the testing or analysis. Any factor that affects the reliability of the measurements taken must be considered so that results from the analysis are meaningful. In practice, this type of audit is known as a "manufacturing quality audit."

Statistical Procedures

Monitoring during processing generates data that are used to evaluate the process during operation. These data can be used to determine whether the process is under control, results in an acceptable product, and meets specifications. The proper use of statistical process control (SPC) leads to an understanding and control of the variables affecting the process while in operation.

Some fundamental objectives of SPC procedures include:

1. Studying process behavior along with its variability
2. Taking the necessary corrective action to eliminate causes of unnatural behavior
3. Identifying the causes of problems while the process is operating
4. Establishing and maintaining stability in the process
5. Identifying process characteristics that may influence other operations

Statistical procedures can also be used to determine the capability of the process in relation to the specifications established for that process.

SPC can be applied to any process from which an attribute or variable measurement can be taken, regardless of the complexity of the process. The important point in this regard is that the appropriate statistical procedure must be selected for the particular process.

The efforts devoted to the development of process control procedures must be made meaningful by having the procedures documented in a concise and clearly understood manner. A well-conceived program for process control is of little value if it is not completely understood by the personnel directly responsible for carrying out the control activities.

The Audit Report

The audit report should describe any nonconformities that were observed. It should also report any observations of potential nonconformities, lack

of effectiveness, or lack of relevance of process steps. The report should also detail the corrective action taken by plant management, but should not make suggestions or recommendations for solving a problem; that should be left to management.

Thus, the QA technologist constitutes the "nerve center" for management and each of the separate departments. Some of the reasons for a QA program include:

1. Control over raw materials through set specifications
2. Improvement of product quality
3. Improvement of processing methods to reduce production costs and promote greater profits
4. Standardization of the finished product according to label specifications
5. Increased order and better housekeeping in a sanitary plant
6. Greater consumer confidence in the uniform high quality of the product

Types of Audits

Product Manufacturing Audits

In addition to having an effective process, it is necessary to operate it properly. Some assurance that production will result in quality products can be obtained by conducting manufacturing quality audits, in which operation and control of the process should show that manufacturing is carried out in a suitable environment, under accepted manufacturing and sanitary conditions as designed and described in the corresponding manufacturing documents. These include documented work instructions, suitable equipment, samples or criteria for workmanship, and compliance with relevant standards and quality plans. Process and product characteristics should be monitored during production, warehousing, distribution, and sales at the consumer level.

Quality production also depends on the quality of raw materials, on acquiring suitable ingredients from suppliers, and on effective management of the product being manufactured through all stages of production and delivery. Control of purchasing ingredients and properly identifying and tracing raw materials provide extra assurance that the quality of the products being manufactured is not compromised.

A product manufacturing audit is a planned, systematic, and comprehensive inspection of a manufacturing process (process instructions, quality control activities, sanitation/good manufacturing practices, safety process points) and its implementation to determine whether it is performing satisfactorily and at the level of conformance to documented

requirements. The audit describes any observed deviation from prescribed manufacturing instructions, any potential situation for a deviation, and lack of effectiveness or relevance of any processing steps. The report should not, however, recommend or make suggestions for solving a nonconformance situation; this is the function of the plant manager.

A product manufacturing audit is usually limited to a small portion of the units produced, but the manufacturing processes involved are reviewed thoroughly. An audit does not replace normal QC efforts, but supplements them.

In summary, the reasons for conducting a manufacturing audit include:

- Assurance that actual practices reflect required procedures
- Uncovering deviations, so that they can be quickly corrected
- Confirming consistency of a process (from shift to shift or day to day, independent of the operator)
- Demonstrating a proactive approach to process improvement

Control of Nonconforming Products

The company must have established procedures (Product Hold) to ensure that nonconforming products are prevented from inadvertent use or release to the market. In accordance with these procedures, nonconforming products should be reworked, accepted by concession, regraded for alternative application, or scrapped. An authority should be designated for dealing with such products.

Corrective Action

The company should establish documented procedures for taking corrective action to eliminate potential causes of nonconforming products. These corrective action procedures must include error–cause investigation, error–cause removal, controls to ensure that corrective actions are effective, and the authority to document procedures to implement corrective actions.

Plant Sanitation/GMP Audits

All functions and operations of a food manufacturing facility must be included in a sanitation program on an ongoing basis. The federal regulations contained in 21 CFR Part 110, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, provides important guidelines for the production of safe and quality foods. A plant sanitation audit focuses on the following areas:

Plant Facilities

A detailed review is conducted to determine acceptability of the building and facilities, including the areas of warehousing and storage (storage conditions, code dating, separation of allergen-containing ingredients, proper label declarations, specifications and Certificate of Analysis (CoA) on file). Buildings and facilities construction, plant and grounds maintenance, walls, floors, and ceilings are closely scrutinized. Utilities and support services, including sanitary operations, sanitary facilities, and maintenance are evaluated to determine if measures need to be taken to provide an effective food safety environment.

Employee Hygiene

Procedures and practices are inspected and evaluated. Control and enforcement of personal hygienic practices, control of employee health conditions, proper use of gloves and outer garments are reviewed in detail. Evaluations are made regarding the appropriateness of plant practices relative to food risks associated with the products manufactured.

In-Process Control

Plant operating conditions are observed in detail. This includes review of sanitation standard-operating procedures and sanitation control records for adherence to food safety and plant policies and procedures. Quality of the water that comes into contact with the food or food surfaces is determined and conditions and cleanliness of food contact surfaces, equipment and utensils maintenance, and prevention of cross-contamination are reviewed.

Contamination and Adulteration

Appropriate programs must exist for the protection of food ingredients, raw materials, food products, packaging materials, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, etc. Proper labeling of cans, boxes, bags, etc. for identification of contents, as well as the proper storage and use of toxic compounds are reviewed.

Pest Control

A food plant's records of pest control are examined as part of an audit. A food company should not attempt to perform its own pest control but rather should rely on a dependable outside firm. Still, it is important for the sanitation manager or someone in QA to be trained in the area of pest

control. QA should be aware of the warning signs of potential problems or infestations. It is necessary to review the credentials and references provided by the pest control firm and to verify that it maintains continuing education in the regulations and newest methods of pest control. When reviewing a pest control program, it is proper to look for a written pest control policy and to check the location maps of traps, records of pest inspections, and the condition and location of electronic exterminators. Also, outside doors and windows of a facility should be sealed.

Auditors evaluate the ability of plant sanitation to adequately clean and sanitize food facilities before plant production begins. These services are coordinated with food safety controls to provide a more complete set of precautions, especially suited to high-risk, ready-to-eat products.

Pre-operational sanitation audits assess a plant's standard sanitation operating procedures for compliance to regulatory requirements. Actual plant performance is reviewed against written sanitation procedures. It evaluates chemical handling and sign-off documents to confirm that proper and regularly scheduled cleaning and sanitation have taken place.

In addition to observations made before production begins, audits review the ongoing sanitation program after production commences, evaluating details and documents that confirm that the impact of proper sanitation continues throughout the manufacturing of the food products.

The management staff should work closely with the auditor to define needed improvements as a means of aiding plant management decision making. This approach provides an independent review, helping organizations in food safety and sanitation operations.

Product Quality Audits

A product audit involves inspecting a product that has previously been inspected and accepted by normal inspection methods and that has been qualified for release into the market, or already is in the market.

The immediate goal of a product audit is to determine the degree of compliance to established QC specification and to evaluate its performance over time, when available to the consumer at the retail level.

Other objectives include:

- To compare the results of the audit to the limits of the company's QC specifications
- To compare the quality of the company's product to the quality of competitive brands
- To compare the quality of the company's product to that of the same product in previous years
- To compare the quality of the product as manufactured by the company's different plants

HACCP Audits

HACCP is an internationally recognized means of assuring food safety from harvest to consumption. Recognized by "Codex Alimentarius" of the United Nations and other leading international food safety agencies, HACCP has become the market standard for food safety worldwide. Currently, food manufacturers and private label retailers insist that their suppliers and co-packers implement HACCP in their own facilities.

The purpose of an HACCP audit is to verify that the HACCP plan complies with its seven principles. Auditing an HACCP program offers the opportunity to reinforce strengths while detecting weaknesses.

The audit includes a detailed observation of a manufacturing process to ensure that the appropriate significant hazards have been identified, that hazards are being effectively controlled, and the appropriate critical limits have been specifically validated or proven effective. Monitoring records are evaluated, concentrating on the critical control points (CCPs) in the process to ensure appropriate maintenance of the program and that corrective actions are taken when critical limits are exceeded. Verification activities will be evaluated to ensure they verify the overall HACCP plan.

Special Audits

On given occasions, the QA department can decide that other types of audits be carried out in a food plant to complement the audits described above. Such audits are relatively limited in scope but are helpful in evaluating a specific area of the quality program and the managing of the manufacturing process. Among the special audits are:

Document Control Audits

This type of audit provides valuable support in the setting up or refining of the plant document control system; the status and issue of forms, procedures, and work instructions; controlled copies of documentation (in electronic or hard copy format); maintaining records of changes and backups; and removing obsolete documentation.

Supplier Audits

With the almost universal implementation of the HACCP program, and the application of the concepts of TQM, it has become increasingly common in the food manufacturing industry that a company requires the practice of these programs and philosophies by their suppliers and other business associates. In other words, suppliers are certified, which means that they agree to a set of specifications and that they will deliver what

they are contracted for. In turn, when establishing a business relationship, a manufacturing company includes the right to carry out ingredient or raw material quality audits at their supplier's site. Such instances may include manufacturing, sanitation, and HACCP audits to ensure that a supplier's quality system has been applied to a specific product of interest. Audits can also be initiated by a customer experiencing quality, compositional, or food safety problems, whereby a specific issue needs to be investigated and resolved.

QC/Instrument Calibration and Maintenance Audits

This type of audit helps to track correct application of methods, method steps, and of measuring and testing instruments. It includes review of individual records maintained for each piece of equipment or instrument; calibration frequency, checkpoints, and tolerances; program for next calibration schedule; calibration data and maintenance of historical records.

Product Batch Preparation/Formulation Audits

The objective of this type of audit is to evaluate the operator's performance in preparing a product formula. The operator's care and control of equipment and instruments, the proper maintenance of batching records, and his or her accuracy in inspecting ingredient specifications, ingredient weights, and when necessary, ingredient sequence of addition.

This audit also requires revising batch records, equipment sanitation procedures, and instrument calibration records.

QUALITY PROGRAM REVIEW

At appropriate intervals, management should conduct reviews of the QA program to ensure its continuing suitability and effectiveness. These reviews typically include the assessment of conducted internal audits. Records of these management reviews should be maintained; results of audits and management reviews are an important input to process improvements activities.

QA DOCUMENTATION SYSTEM

To provide quality products, a company requires an effective production system. Documenting it, maintaining control over the documents describing the system, maintaining records to establish that the documented system is followed, and auditing periodically to verify that plans are followed provide assurance that a system is effective. The documents used for these purposes should describe the processes for product manufacturing and the

various controls, inspections, measurements, reviews, and standards to be applied. They also document the effective implementation of those processes. In addition, the QA program requires the preparation of QC methods, quality measurement systems, standards used, and performance records.

Commonly, documents are referred to as standard operating procedures (SOPs) related to manufacturing procedures[9] and sanitary standard operating procedures (SSOPs).

An SOP is a set of written instructions that provides a step-by-step process documenting a routine or repetitive activity conducted or followed by an organization. SOPs document the way activities are to be performed to facilitate consistent conformance to safety and quality system requirements. SOPs are intended to be specific to the organization or facility whose activities are described. They assist that organization in maintaining their safety and QC and in ensuring compliance with regulations.

In practice, the documentation of a quality program is arranged into four levels ranging from general policies and procedures to records of performance. These four levels cover:

1. Why the organization has a quality program
2. The what, when, where, and who aspects of quality-related tasks
3. How these tasks are to be performed
4. Records of what actually was done

"What" describes what to do and what was done. This hierarchy of documentation gives increasing detail about the organization, its operations, its methods, and its accomplishments.

Specifically, the levels of documentation include the following.

Quality Manual

The company's quality policy and the descriptions of its processes must be contained in a corporate quality manual. It should express the organization's total commitment to quality, how it is organized to fulfill that commitment, and its approach to fulfilling it. The purpose of the manual is to outline the quality program, including procedures and detailed instructions, and to serve as a reference.

The composition of the manual varies from organization to organization, but usually includes:

- The quality policy of the organization
- Documented organizational processes, procedures, instructions, and standards

- Controls, such as inspection equipment, checkpoints, measurements required, and reviews
- Identification of required measurements
- Identification and preparation of quality records

All documents included in the quality manual and describing the company's quality program must be properly controlled. Prior to use, documents should be reviewed and approved by authorized personnel; changes to documents should be made following an established document control procedure. Appropriate documents should be available at all work locations where required; obsolete documents should be removed to prevent their inadvertent use.

In general, the term *document* is used for items that describe a quality program; *record* is used for evidence to demonstrate effective operation of the program. Thus, description of a process is a document; a test report is a record.

SOP (Manufacturing and Quality) Documents

The second level of the quality program is a collection of procedures that specifies the major activities of an organization and the way they are to be performed. A procedure is "a specified way to perform an activity" according to an ISO definition.[8] Procedures describe what is to be done and why, who (by organizational title) is responsible for doing it, where it is to be done, and when (that is, the order in which procedures are to be accomplished). Procedures reflect the principles and practices expressed in the quality manual; they detail how those principles and practices are to be fulfilled. This family of documents includes: product-specific manufacturing (PSM) documents, general manufacturing operation (GMO) documents, quality control analytical methods (QCA) documents, good manufacturing practices/sanitation (GMP) documents, equipment-specific sanitation documents, and preoperation sanitation documents.

PSM Documents

This type of document belongs to level 2, as described above. They describe in detail the procedures for manufacturing a specific product, including batching and formulation, processing, packaging, coding, and storage requirements. GMO documents, ingredient specification documents, sanitation documents, HACCP documents, and QC method documents are referred to in this document, as needed, and contribute to the number of requirements for the quality manufacturing process of the product. Figure 3.2 shows an example of a PSM document.

Eureka Foods, Inc.
Quality Assurance/Quality Control
MANUFACTURING STANDARD PRACTICE

Product: SAUCE, SOUTH AMERICAN STYLE — Product Code: SS001
Manuf. Plant: NAMPAHC — Location: Orange, CA
Revision: 1st Issue — Issue Date: 09/17/00
V. P. Operations. Approval: _____ V. P. QA. Approval: _____

I. General Requirements. Per General Maintenance Requirements (GM001).

II. Clean per Sanitation Standard Operation Procedures (SS001).

III. Manufacturing Procedures

A. Seasoning Mix Vessel: Combine chili spice, cayenne pepper, and ginger with 40 lbs of water. Let stand a minimum of 10 min.
B. Add tomato puree to processing tank.
C. While agitating, add salt, starch, remaining water, sugar, and the seasoning mix from **A**.
D. Heat product to a minimum of 195°F.
E. Add vinegar and mix well.
F. Fill containers to 175°F minimum, MT001.
G. Check net weights per GN010, MN001.
H. Cool product to 120°F maximum center jar temperature per MT001, MC010, GC010, MS020, GI020.
I. Code per GC030.
J. Case per GC050, GS020.

IV. Product Quality Characteristics

Characteristic	*Limit*	*Frequency*	*Method*
Acid	1.20	1/hour	MA001
Brix	46.5	1/hour	MB001
Bostwick	TBD	1/hour	MC001
Flavor/Odor	Typical	1/hour	Organoleptic
Appearance	Typical	1/hour	Visual
pH	3.6–3.7	1/hour	MP001
Torque	TBD	1/hour	MT010
Headspace	TBD	1/hour	MH001
Vacuum (min.) @ 70°F	5″	1/hour	MV001

Figure 3.2 Example of a product-specific manufacturing (PSM) document.

V. Operating Formula

Ingredients	*(lbs.)*	*Formula %*
Tomato puree (IT049)	673.20	67.320
Sugar (IS025)	120.00	12.000
Vinegar (120 gr) (IV002)	100.00	10.000
Water	80.00	8.000
Salt (IS004)	8.38	0.838
Starch (IS092)	7.50	0.750
Chili spice (IC319)	7.20	0.720
Pepper, cayenne (IP011)	2.75	0.275
Ginger (IG044)	0.97	0.097
		100.000

Figure 3.2 (Continued)

GMO Documents

This type of document describes a certain activity related to the manufacturing process of a specific product; it is used in conjunction with the prescribed PSM document. For example:

The can/glass container packaging document addresses the procedure by which a product is canned, labeled, coded and the container handled, to the warehouse, so as to preserve the container intact.
The weight control document addresses the procedure for determining the net weight of a product during manufacture.

Figure 3.3 shows an example of this type of document. The following is a list of the most common GMO documents used in food manufacturing plants.

Document	*ID Code*
Cans Receiving Inspection	GC001
Cans Packaging, QC	GC005
Case Packaging, QC	GC010

Document	*ID Code*
Chlorination and pH, Water	GC020
Collaborative Cross-Check Samples	GC030
Coding System	GC040
Container Cleaning	GC050
Container Specification	GC060
Disposition, Product	GD001
Fill Weight Control	GF001
Hold, Product	GH001
Ingredient Qualification Program	GI001
Ingredient Analysis	GI005
Inspection of Carriers	GI010
Line Start-Up and Shut-Down	GL001
Net Weight Control	GN001
Nutritional Labeling	GN005
Nutritional Testing	GN010
Packaging, Container Defects	GP001
Range Chart Principles	GR001
Seam Inspection	GS001
Seaming, Metal Cans	GS002
Shipping Case, Warehouse Stacking	GS005
Shipping Case, Receiving Inspection	GS010
Thermometer, Calibration and Records	GT001
Water Quality	GW001

QCA Methods Documents

These documents basically consist of the official methods published by organizations such as the American Oil Chemists' Society, The American Cereal Chemists' Society, or the Organization of Official Analytical Chemists, which are recognized as the official standards for the analysis of food products and their ingredients.

These methods can be used as such or adapted to the company's needs, as long as the variations do not affect their accuracy and replication when used against the official version, and have been tested and checked by collaborative studies with other laboratories.

The company can then create its own test methods bank, in which it collects the methods which are directly used in the analysis of its products. Figure 3.4 shows an example of an analytical method used for determination of ascorbic acid (vitamin C).

Eureka Foods, Inc.
Quality Assurance/Quality Control
INGREDIENT QUALIFICATION PROGRAM

ID Code: GI01 page # 1 of 2
Revision #: 00 Issue Date: 07/18/00
Nature of Revision: Effective Date: 01/09/00
Location: Orange, CA
V. P. Operations. Approval: _____ V. P. QA. Approval: _____

I. DESCRIPTION

This document describes the procedures to be followed by Eureka Foods, Inc. personnel in the Research and Development, Purchasing, and Marketing Departments to ensure that the ingredients used in the formulation and manufacture of all products meet the quality standards and specifications established for each and every product distributed and sold by Eureka Foods, Inc.

II. QUALITY SPECIFICATION

An individual ingredient used in the manufacture of Eureka Foods, Inc. products must comply with the quality specification limits established by R&D-PD for use in each specific product.

Such quality specifications must be certified by the ingredient vendor (supplier) in their Certificate of Analysis and should be subjected to a confirmatory analysis by an independent laboratory, specified and to the discretion of Eureka Foods, Inc.

The cost of the analysis carried out by an independent laboratory, chosen by Eureka Foods, Inc. will be incurred by the vendor as part of the contract to supply Eureka Foods, Inc. with the desired ingredient.

"Quality specifications" means that an ingredient must be characterized by its chemical/biochemical components, and microbiological count as necessary, depending upon the nature of the ingredient and as specified and required in its corresponding "Ingredient Specification" document.

An ingredient that does not meet the quality specifications established in its corresponding "Ingredient Specification" document will be immediately rejected by the Purchasing Department and returned to the vendor (supplier), as reported and requested by R&D-QA/QC Department.

III. APPROVED VENDOR (SUPPLIERS)

Eureka Foods, Inc. establishes a List of Approved Vendors (Suppliers) for each of the ingredients it purchases, on the basis of the quality of the ingredients provided.

Such list must be maintained by the Purchasing Department and the R&D-QA/QC Department and updated as necessary on the basis of the recommendations made to the Purchasing Department by the R&D-QA/QC Department.

On the basis of periodical assessments and random sampling of the ingredients provided by a vendor (supplier), Eureka Foods, Inc. will include in the List of Approved Vendors (Suppliers) those that offer the desired quality of ingredients and will remove from such list those vendors (suppliers) that do not conform to the quality standards established.

Figure 3.3 Example of a general manufacturing operation (GMO) document.

Eureka Foods, Inc.
Quality Assurance/Quality Control
QUALITY CONTROL ANALYTICAL METHOD

Document: HPLC Method for Ascorbic Acid — Code: QA001
Manuf. Plant: NAMPAHC — Location: Orange, CA
Revision: 1st Issue — Issue Date: 09/17/00
V. P. Operations. Approval: _____ — V. P. QA. Approval: _____

Mobile Phase Preparation

A. Mobile Phase A: 0.002 M tetrahexylammonium chloride. Adjust pH to 5.0 with 1% formic acid and NaOH.
B. Mobile Phase B: Methanol
C. Instrument: Waters HPLC system with a 600 pump, a 600 controller, and 490E programmable multiwavelength detector
   Column: Supelcosil ABZ Plus. 15 cm x 4.6 mm. Particle size 3 μm
   HPLC Condition: Flow rate: 1.3 ml/min
   Detector wave length: 269 nm
   Mobile phase A: 55%,
   Mobile phase B: 45%
D. Standard Preparation
   1. Accurately weigh about 0.025 g ascorbic acid.
   2. Transfer to a 100 ml volumetric flask; add about 40 ml water to dissolve the ascorbic acid.
   3. Dilute to volume with ethyl alcohol, mix and filter.
   4. Inject this solution within one half hour (keep it in the dark until injection).
E. Sample Preparation
   1. Weigh and finely powder the sample A.
   2. Transfer an accurately weighed portion of sample A (sample a) (equivalent to 25 mg of ascorbic acid) to a 100 ml volumetric flask.
   3. Add 40 ml of water, shake for 5 min.
   4. Dilute to volume with ethyl alcohol, mix and filter.
   5. Inject this solution within 1 hour.
F. Calculation
   mg of vitamin C in Sample A

$$\frac{\text{Area of sample a}}{\text{Area of Standard}} \times \frac{\text{Weight of Standard}}{\text{Weight of sample a}} \times \text{Weight of Sample A}$$

Figure 3.4 Example of a quality control analytical method (QCA) document.

Other examples of this type of document are:

Document	*ID Code*
Total Acidity	MA001
Brix/Refractive Index	MB001
Consistency Bostwick	MB005
Consistency Brookfield	MB010
Chlorine Analysis, Water	MC001
Color, Agtron	MC005
Color, Hunter	MC010
Headspace	MH001
Net Weight Determination	MN001
pH Determination	MP001
Salt Determination	MS001
Seam Teardown Evaluation	MS005
Temperature, Center Can	MT001
Vacuum, Cans	MV001
Viscosity Determination	MV005
Water Quality	MW010

SSOP Documents

Regulations 21 CFR Part 110 pertain to direct product contamination or adulteration, contamination of product contact surfaces, or the creation of unsanitary conditions likely to result in contamination or adulteration of a food product. To control sanitation hazards that cause direct product contamination, every federally inspected food processing plant is required to develop, maintain, and implement a written SSOP or similar document to monitor sanitary practices in its manufacturing locations. Such a document should be specific to each plant and should specify how the processor will meet their requirements. Detailed SSOPs should be developed and documented for every sanitary procedure in the plant. It is plant management's responsibility to adhere to the SSOP.

SSOP documents describe the procedures that must be followed in order to make sure that cleaning and sanitation activities are performed correctly. This involves the development of detailed descriptions of the cleaning procedures and sanitation operations that must be performed prior to initiating the food manufacturing process to prevent contamination or adulteration of the product. SSOPs also describe the frequency with which each sanitation procedure is to be conducted, and identify the employee(s) responsible for the implementation and maintenance of each procedure.

The establishment of standardized procedures for each sanitation activity helps assure that the activities are being performed properly.

An SSOP usually includes:

- Activity name
- Place where it is performed
- List of equipment and material necessary to perform activity
- Frequency of performance
- Approximate time of performance
- Responsible individual(s)
- Description of each performance step

GMP Documents

Each manager and supervisor must assume responsibility for the safety, cleanliness, and wholesomeness of the environment in which food products are produced. Cleaning and sanitizing procedures, appropriate chemicals and concentrations, surfaces, cleaning frequencies, and instructions for workers should be written down and filed so that every employee can be properly trained in what to do and why he or she is doing it. Sanitation employees must be instructed on how to clean individual pieces of equipment; also, employees should be responsible for monitoring the condition of their own personal protective equipment.

The SSOP written for a food processing plant should be a comprehensive document and must include the following areas for monitoring:

Hygiene and personnel practices. Regardless of the type of processing or food handling operation, the first consideration in food sanitation is people. People set, follow, and break the rules of sanitation.

Sanitation principles and food handling practices. Personnel training should nurture an understanding of processes and technologies involved in manufacturing and handling food products.

Manufacturing controls of operations. Production personnel must be trained in the critical elements of the operations for which they are responsible.

Communicable diseases/injuries. Persons known to be suffering from, or known to be carriers of, a disease likely to be transmitted through food must be restricted from any food-handling area.

Handwashing. Facilities with hot water for handwashing must be provided and must be conveniently located in food handling areas.

Personal cleanliness and conduct. Personal cleanliness must be maintained while involved in food handling operations.

Traffic control/controlled access. Personnel and visitor access to specific food-product handling areas must be restricted.

Outside surroundings. Outside surroundings to a manufacturing plant should be evaluated for sources of contamination such as vermin, bird harborage areas, drainage problems, odor problems, debris, refuse, smoke, dust, and other contaminants.

Buildings and facilities. Food processing and handling areas should be cleanable, and so designed and constructed.

Building construction. Floors, walls, and ceilings must be constructed of suitable, approved materials that are durable, smooth, and easy to clean.

Overhead structures and lighting. Should be situated and constructed so as to prevent contamination of food products; lighting must be protected with properly sealed, safety-type overhead fixtures.

Heating, ventilation, air conditioning. Must be designed and installed to prevent buildup of heat, steam, condensation, or dust, and to remove contaminated air. Positive air pressure is required in microbiologically sensitive areas.

Drainage and sewage systems. Appropriate traps and vents are to be used throughout.

Waste facilities. Facilities should be designed so as to prevent contamination and for the sanitary storage of waste and inedible materials prior to their removal from the plant or its surroundings.

General protection from contamination. The facilities and nonproduct contact surfaces and equipment must be evaluated to assess potential for food product contamination.

Flow-through pathways. A well-designed food processing or handling facility should be constructed to minimize traffic and to prevent cross-contamination from raw product to finished product.

Washrooms, lunchrooms, changing rooms. Self-closing doors must be provided for these rooms. The areas must be separate from and not directly entered from food processing and handling areas.

Water quality program. Potable water, steam, and ice supply is imperative for sanitary food processing and handling facilities.

Raw material receiving. All operations involved with receiving and storage of ingredients, packaging, and other incoming materials must be monitored to prevent potential contamination of the food product manufactured. Incoming materials must be received into an area that is separated from the processing areas.

Temperature and humidity control. The primary rule of sanitation is to pay strict attention to food temperatures. The temperature and humidity of storage rooms for raw materials, ingredients, packaging materials, and food should be maintained and monitored.

Returned foods. Foods returned from retail outlets must be clearly identified and stored in a designated area for appropriate disposition.

Nonfood chemicals. Detergents, sanitizers, and other chemicals must be properly labeled, stored, and used in a manner that prevents contamination of food, packaging materials, and food contact surfaces.

General cleanliness and housekeeping. All food processing, food handling, and other rooms must be maintained in a clean, sanitary manner.

Equipment construction and maintenance. Equipment for food processing and food handling operations must be designed and constructed in a manner that makes them cleanable and maintained in such a manner as to prevent contamination.

Equipment-Specific Sanitation Documents

In certain situations, the characteristics of the processing equipment are such that the general cleaning procedures for equipment sanitation cannot be applied. In that event, it is necessary to apply procedures specific to that equipment. The equipment vendor, together with the technical and sanitation personnel of the plant, should develop a custom-designed sanitation document that takes into consideration the installation characteristic of the system in the particular plant, as well as the recommended sanitation procedure.[9]

Examples of a custom-designed sanitation document are the cleaning-in-place (CIP) systems used in dairy plants and breweries. Figure 3.5 shows a simplified diagram of a CIP system.[10,11]

Pre-Operation Sanitation Documents

The SSOPs for an operation should detail the sanitation procedures to be used before processing can begin (pre-operational sanitation). A pre-operation (Pre-Op) document detailing the procedure to be followed should be written, noting that all equipment to be used must be checked and approved for cleanliness and sanitation. The following sanitation conditions must be monitored and reported:

- Safety of water
- Condition and cleanliness of food contact surfaces
- Use of acceptable chemicals and cleaning techniques
- Prevention of cross-contamination
- Proper labeling of toxic compounds
- Employees' health conditions
- Exclusion of pests

Also, the following information might be included in Pre-Op SSOPs:

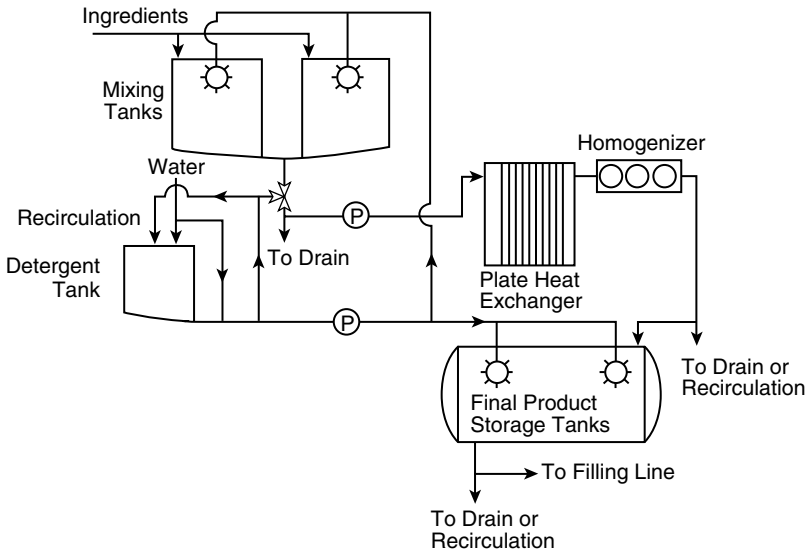


Figure 3.5 Simplified diagram of a CIP system. (From Marriott, N.G., 1997. *Essentials of Food Sanitation*, Chapman & Hall, New York, NY. With permission.)

- Descriptions of equipment disassembly and reassembly after cleaning
- The application of sanitizers to product contact surfaces after cleaning

Established procedures for operational SSOPs vary with the operations, the plant design, and the location of the equipment, but Pre-Op sanitation will result in clean facilities, equipment, and utensils prior to starting the operation. Figure 3.6 shows a generic form for checking equipment sanitation before and during a manufacturing process.

WORK INSTRUCTIONS

Instructions detailing how work is to be accomplished might be known as operating instructions, service instructions, flow diagrams, process charts, activity charts, review or inspection instructions, etc.; they should be written and readily available.

RECORDS

Procedures and work instructions describe what is to be done and how; records describe what was done. Records document the output from a procedure, and may reference other documents such as inspections, test

Eureka Foods Company DAILY SANITATION REPORT			Date:
	Approval/Initials		
Condition	Pre-Op Sanitation	Midday Cleanup	End of Shift Cleanup
Plant grounds do not cause food contamination.			
Waste properly stored.			
Equipment and utensils adequately cleanable.			
Food contact surfaces and utensils clean and sanitized.			
Food, food-contact surfaces, packaging materials protected from adulteration/contaminants.			
Non-food-contact surfaces clean.			
Hoses have antisiphoning devices. Floors have adequate drainage.			
Coolers and evaporators clean.			
Cooked and raw products physically separated in coolers.			
Toilets facilities clean, sanitary, and in good repair.			
Toxic compounds identified and stored properly.			
Employee health conditions acceptable.			
Gloves/garments contacting food clean and sanitary.			
Employee practices do not result in food contamination (hair restraints, glove use, hand washing, personal belonging storage, eating and drinking, boot sanitizing).			
Proper color-coded sanitation equipment is used.			
Hand and boot sanitizer strength adequate.			
No pests in the plant.			
Deviations from SSOP and corrective actions:			
Reviewed by QC Manager:		Date:	

Figure 3.6 Example of a sanitation report in a food manufacturing plant.

records, audit results, and design charts. Records are an objective evidence of the achievement of quality, of conformance to specified requirements, and a demonstration of the effective operation of the quality program. Rules must be established for the maintenance and storage of records so that they can be retrieved to demonstrate compliance. Quality auditors can use records to confirm that the organization is in compliance with its quality program. The purchasing department might use quality records to verify conformance of the company's product ingredients to requirements.

HACCP PROGRAM DOCUMENTS

Food manufacturing plants must have written procedures to comply with HACCP programs for their products, particularly if their products contain meat or fish.

HACCP is a science-based process of QC management for food safety, designed to reduce the occurrence and numbers of pathogenic microorganisms on food products. HACCP places total responsibility for the results on the manufacturers and handlers of the products. The actual system can be described as a "care, custody, and control" process over raw materials, work in progress, or completed products, at each step of manufacture.

HACCP is being adopted worldwide on recommendation of the United Nations' Codex Alimentarius Committee. It is already mandated in many countries. The European Union (EU) is establishing an HACCP-inclusive food regulatory system to govern all EU members.

FDA HACCP for fish and fishery products is mandated by the "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products: Final Rule," published in the Federal Register.[12] It specified a 2-year wait to become effective; December 18, 1997 was the effective date. Meat and poultry regulated by the United States Department of Agriculture's (USDA) Food Safety Inspection Service (FSIS) went "on" the SSOP January 27, 1997. Mandatory local *E. coli* testing also began at the time.

The latest effective HACCP date was January 25, 2000 for the smallest of firms. Mandatory local salmonella testing commenced at that time. CGMP, SSOP, and *E. coli* testing are now in effect for all USDA-regulated firms.

Other firms, from seed suppliers to common carriers, are not yet specifically mandated to operate under HACCP rules. Yet their customers' HACCP demands will require that unregulated companies voluntarily adopt full HACCP for the food-product handling of their operations. Not to do so would require HACCP-mandated customers to perform additional testing to acquire adequate traceability. In short, every commercial food

processor, regardless of size, must be on the cGMP/SSOP/HACCP QA program. This includes any new "startup" commercial food preservation processing/distribution operations.

REFERENCES

1. Burrill, C.W. and Ledolter, J., 1999. *Achieving Quality through Continual Improvement,* John Wiley & Sons, Inc., New York, NY.
2. Gould, W.A. and Gould, R.W., 2001. *Total Quality Assurance for the Food Industry*, 3rd ed., CTI Publications, Timonium, MD.
3. McLaughin, G.C., 1995. *Total Quality in Research and Development*, St. Lucie Press, Delray Beach, FL.
4. IFT, 2003. Continuing Education and Professional Development. Introduction to the Food Industry. Lesson 1: Food Safety and Quality Assurance. Reviewed February 1, 2003. http://www.ift.org/education/food_industry/lesson1.shtml
5. World Health Organization (WHO)/UN, 2003. Warning on food terrorism issued. January 31, 2003. Geneva, Switzerland. http://www.msnbc.com/news/866909.asp?0si=-#BODY. Reviewed February 6, 2003.
6. Dietz, P., 2003. The media and weapons of mass hysteria. FACSNET. The War on Terrorism. February 3, 2003. Reviewed February 6, 2003. http://www.facsnet.org/issues/specials/terrorism/dietz.php3
7. Lowe, D., Ramsey, D., and Warner, J., 2000. Product tampering. FACSNET. The War on Terrorism. February 14, 2000. Reviewed February 6, 2003. http://www.facsnet.org/tools/ref_tutor/tampering/forward.php3
8. ISO 9000:2000. Quality management systems — fundamentals and vocabulary. http://www.qualitydigest.com/html/iso9000.html Accessed July 2003.
9. Marriott, N.G., 1999. *Principles of Food Sanitation*, 4th ed., Aspen Publishers, Gaithersburg, MD.
10. Marriott, N.G., 1997. *Essentials of Food Sanitation*, Chapman & Hall, New York, NY.
11. Jowitt, R., 1980. *Hygienic Design and Operation of Food Plant,* AVI Publishing, Westport, CT.
12. FDA, 1995. Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products: Final Rule. Federal Register 60(242):65095–65202. December 18.

Chapter 4

INGREDIENT SPECIFICATIONS AND SUPPLIER CERTIFICATION PROGRAM

Present-day consumers demand consistent, defect-free, high-quality products. One of the key areas for production of high-quality foods is the quality of the raw materials and ingredients used. With the variability of many of the raw materials used in foods, increased pressure has been put on food manufacturers to provide higher-quality foods.

Raw and packaging materials should be purchased to agreed-upon specifications from suppliers capable of achieving those specifications. Inspection of the materials should complement the suppliers' quality systems, and be stored under hygienic conditions to prevent contamination by microorganisms, insects, and other pests. Their control and release should be done under the responsibility of a competent technical person. The suppliers must be audited for quality and safety, under the purchasing company's quality assurance (QA) program. Nonconforming raw materials should be recorded and investigated to identify and rectify problems.

Product contamination by microbiological, chemical, and physical hazards — such as pathogens, pesticides, herbicides, antibiotics, naturally occurring toxins, and metal fragments — is present in raw materials. When a processor has control measures in place to prevent contaminated raw materials from entering the plant, these materials and the act of their receipt can be critical control points (CCPs) under the Hazard Analysis and Critical Control Points (HACCP) program for the product being manufactured.[1] This is especially true if no step exists in the process to eliminate or reduce the hazard; for example, no thermal processing step exists to eliminate a microbiological hazard. If a significant hazard is

associated with a raw material, then a supplier QA program should be in place to control the hazard to the best of the supplier's ability.

The improper storage of some dry ingredients can result in aflatoxin production or insect infestation. If control measures are not in place under the prerequisite programs to reduce or eliminate these hazards, then these steps can be considered CCPs under the HACCP program. Control measures for this type of CCP include sifters, magnets, temperature and humidity control, and regular chemical treatment to avoid infestation.

Poor appearance, odor, or taste of raw materials will result in end products with poor appearance, smell, or taste, as processing often magnifies the defects of raw materials. Unfortunately, many U.S. companies modify processes to deal with poor quality raw materials, but the quality of the finished product usually does not exceed the quality of the raw materials used to produce it. To overcome these challenges, many food producers are in the process of establishing quality partnerships with their suppliers, through programs of total quality management (TQM).

The quality and safety of these materials are also key factors in an HACCP program. According to a Washington, D.C. law firm, the majority of food product quality issues can be traced back to a supplier's inappropriate qualification.[2] Thus, it is important to know that a supplier is controlling hazards if they cannot be controlled in the process or by consumer action; it is also important for a company to have a long-term quality relation with qualified suppliers, for the benefit of both organizations.

While the U.S. food system is extremely safe, with an enviable track record, manufacturers are aware of the need to address contamination problems when they occur. In contamination crises, having rapid access to important information is critical in defining the problem's scope and reassuring the public and responsible governmental agencies. Otherwise, brand equity built over many years, and at great expense, can be ruined with one significant contamination problem that is not dealt with quickly, accurately, and effectively.

RAW MATERIAL/INGREDIENT CERTIFICATION PROGRAMS

There are two major criteria for testing raw materials: health and safety, and functionality. The first criterion involves microbiological tests and analysis for carcinogenic substances such as pesticides. Testing for functionality encompasses a number of considerations, such as desired shelf life of the final product, possible rancidity problems, usage level needed to get the desired functionality vs. cost, and how the final product will be marketed.

Approving vendors under these programs is a major undertaking. Once an ingredient and vendor are approved by a company's QA, it is necessary to assure consistent quality of that ingredient. All incoming ingredient lots must be held until the laboratory tests of samples selected through a statistical sampling procedure are approved. Samples are analyzed for chemical and microbiological characteristics. After a lot is approved, it is released to prime stock, whereby production can use it. Statistical sampling procedure has been instituted for ingredients and for packaging materials in many companies.

Degree of Variability

Raw ingredients can be affected by a large number of factors during processing. Dealing with imported ingredients from third-world countries can also present special challenges. Statistical process control is used to correlate customers' specifications, thereby assuring consistency.

As food designers establish ingredient-testing programs, a variety of factors need to be considered in developing specifications. These include what marketing claims will be made, shelf life, functionality, and quality. With this in place, assurance that the finished product will be consistently on target is virtually assured.

Flavor Considerations

If a food doesn't taste right, consumers won't eat it. This, and the demand for higher quality foods, have resulted in more sophisticated flavors. Much of the testing to assure high quality flavors is undertaken by the flavor supplier — both on raw ingredients for the flavors and on the finished flavor. Certification of these tests is a must.

With any natural component, a company is faced with ascertaining that it is indeed natural. A certification may be sufficient with a trusted supplier, but with an unknown company or a shockingly low-priced material, testing is recommended.

Analyses to test for natural flavor ingredients include gas chromatography (GC), where the chromatograph of the material being tested is compared with the chromatograph of a known natural. More sophisticated tests involve stable isotope ratio analysis (SIRA). Camouflaging a synthetic substance by adding a commercial source of C_{14} can be done in efforts to hide the truth. Thus, the measurement of C_{14}/C_{12} ratio often reveals if a synthetic flavor component has been substituted for a natural component. It is very difficult, though, to adulterate a natural flavor in a way that cannot be detected by deuterium stable isotope measurements. Most

companies send material out for SIRA, because very few laboratories are set up to run the test due to the expense of the equipment.

THE SUPPLIER QUALITY PROGRAM (SQP)

Generally, raw material/ingredient quality programs are driven by the customer requiring reassurance that a product meets a given quality standard or was produced according to some other criteria or protocol. An effective supplier quality program (SQP) is also fundamental to an HACCP program. In fact, SQP has to apply before the HACCP plan is developed. There are a number of different elements in an effective SQP, including agreed-upon specifications, auditing suppliers, and certificates of analysis. Whenever possible, supplies are purchased from suppliers who have registered HACCP programs and provide HACCP-based certification of all supplies and materials.[3] If not, suppliers must provide information on probable levels of pathogen contamination. Suppliers of food containers must provide information on leaching of substances from the containers or show proof that the food container surfaces are constructed of materials approved by the Food and Drug Administration (FDA). Equipment suppliers must provide simple cleaning and maintenance instructions as well as how the equipment must be used to meet FDA safety standards.[3] Suppliers of chemical products must furnish Material Safety Data Sheets (MSDSs).

A supplier's approval depends on the customer having confidence in the supplier's operation and in the supplier's competence at managing presented hazards.

For the company's benefit, it is important to develop good customer–supplier relationships as partners in the management of safe raw materials and products. There are a number of stages to go through in achieving this objective. It should be noted that all purchased materials that can affect product or service quality should be included in this program.

Raw material conformance. Sources of information here include the vendor's own inspection records and incoming inspection records.

Raw material unfit for use. This is the worst scenario: a nonconformance is not detected until it fails on the production line, in distribution, or in use (complaints). The impact is usually severe, affecting ability to sell the final product. Despite the severity of the problem, it is often difficult to gather sufficient evidence to inform the vendor of the fault.

Feedback should be given on a regular basis so that the vendor does not see nonconformance as "complaints." The main message is to transmit good as well as bad news. Where possible, evidence should be incontrovertible. The best evidence is records and samples. Regular meetings with suppliers will ensure that positive feedback is given. This helps to support the partnership when exceptional communication of nonconformances is necessary.

Therefore, an SQP is a vital activity of quality assurance/quality control (QA/QC), as qualified suppliers are able to use their experience to help their food-manufacturing customers in research, development, testing, and production. An SQP is also a key factor in keeping the management of suppliers under control. Figure 4.1 shows an example of an ingredient qualification document that delineates the program for supplier qualification.

Evaluating and qualifying a supplier are important functions of the QA/QC department, and great care must be taken in doing so; the supplier's evaluation and qualification procedures should be documented and filed. The supplier should know the reasons and possible challenges for outsourcing the product of interest, as the costs for outsourcing are significant for its food-manufacturing customer, and it would not be appropriate for the supplier or the customer to discover obvious problems after a short relationship.

Supplier Qualification

The purchasing company should have a team, formed by a coordinator from the purchasing department, the technologist, responsible for the product, a representative from QC, and a representative from QA, should be in charge of interviewing and reviewing the prospective suppliers and presenting their report for acceptance or rejection.

A Supplier Qualification form (Figure 4.2), consisting of a short questionnaire that addresses the supplier's history, compliance record, financial stability, and the qualification of its staff should be completed by the supplier in a prequalification process.[4] This would allow selection of a supplier as a first stage of the qualification process and would reduce later costs. Prior to signing a contract, a confidentiality agreement between the parties must be established, with any exchanged data remaining confidential even if a further relationship does not happen or the collaboration ends. After a contract is established and responsibilities defined, information and follow-up activities are maintained.

Based on the information provided, an audit of the supplier may be carried out as the next step of the qualification process. The inspection should consider the requirements of the product to be manufactured as

Eureka Foods, Inc.
Quality Assurance/Quality Control
INGREDIENT QUALIFICATION PROGRAM

ID Code: GI001 page # 1 of 2
Revision #: 00 Issue Date: 07/18/00
Nature of Revision: Effective Date: 01/09/00
Location: Orange, CA
Approval:_____
Director of R & D

I. DESCRIPTION

This document describes the procedures to be followed by Eureka Foods, Inc. personnel in the Research and Development, Purchasing and Marketing Departments to ensure that the ingredients used in the formulation and manufacture of all products meet the quality standards and specifications established for each and every product distributed and sold by Eureka Foods, Inc.

II. QUALITY SPECIFICATION

An individual ingredient used in the manufacture of Eureka Foods, Inc. products must comply with the quality specification limits established by R&D-PD for use in each specific product.

Such quality specifications must be certified by the ingredient vendor (supplier) in their Certificate of Analysis and should be subjected to a confirmatory analysis by an independent laboratory, specified and to the discretion of Eureka Foods, Inc.

The cost of the analysis carried out by an independent laboratory, chosen by Eureka Foods, Inc. will be incurred by the vendor as part of the contract to supply Eureka Foods, Inc. with the desired ingredient.

"Quality specifications" means that an ingredient must be characterized by its chemical/biochemical components, and microbiological count as necessary, depending upon the nature of the ingredient and as specified and required in its corresponding "Ingredient Specification" document.

An ingredient that does not meet the quality specifications established in its corresponding "Ingredient Specification" document will be immediately rejected by the Purchasing Department and returned to the supplier (vendor), as reported and requested by R&D-QA/QC Department.

III. APPROVED SUPPLIERS (VENDORS)

Eureka Foods, Inc. establishes a List of Approved Suppliers (Vendors) for each of the ingredients it purchases, on the basis of the quality of the ingredients provided.

Such list must be maintained by the Purchasing Department and the R&D-QA/QC Department and updated as necessary on the basis of the recommendations made to the Purchasing Department by the R&D-QA/QC Department.

Figure 4.1 Ingredient qualification program, general manufacturing operation document.

On the basis of periodic assessments and random sampling of the ingredients provided by a supplier (vendor), Eureka Foods, Inc. will include in the List of Approved Suppliers (Vendors) those that offer the desired quality of ingredients and will remove from such list, those suppliers (vendors) that do not conform to the quality standards established.

Figure 4.1 (Continued)

well as the appropriate product and raw material/ingredient specifications. These should include specifications for packaging, shipment documentation, process information, etc., and both parties should agree on such specifications. It is essential to exchange and update information with the supplier; it should be clear, for a regulatory review, what has been expected from a supplier, what has been supplied, and what has been established in-house. There is little point in trying to develop a partnership with a supplier unless both parties have a clear understanding of the objectives to be achieved. This usually takes the form of a contract covering, for example, material specifications, delivery parameters, responsibilities for quality including those for verification, access to supplier, and procedures for settling disputes. It is important that all these parameters are agreed upon and verified prior to signing the contract and entering a supplier onto an approved vendor list.

Approved Vendors List

There are two main criteria to be considered here:

1. Financial capability and stability
2. Ability to meet specification. This can be assessed in a number of ways:
   - Auditing supplier's quality system
   - Vendor's previous performance
   - Vendor's reputation
   - Tests on representative samples

After the QA/QC team has accepted a supplier and the recommendation has been submitted to the vice president/director of QA, the supplier's name should be entered in the list of approved vendors for the company. The list should be maintained by the QA department and show the supplier's name, items supplied, and evidence of an HACCP certification program. The following forms can be used for supplier certification records.

Eureka Foods, Inc.
Quality Assurance/Quality Control Department
INGREDIENT SUPPLIER QUALIFICATION PROGRAM

COMPANY:_____	**Eureka Foods Supplier Qualification Program**
CONTACT:_____	**DATE:**_____

Thank you for participating in Eureka Foods supplier qualification review process. We believe that this is important in establishing mutually satisfying and profitable supplier/customer relationships. Please answer each question completely and provide additional information if you feel clarification is required. Additional questions may be attached to this questionnaire that pertain to your specific products or services. If you have questions regarding items contained within, please contact our QA/Supplier Qualification Department, Eureka Foods, phone number: 000-000-0000.

Part I - General Information:

Company Name: _____

Corporate Headquarters Address: _____

City: _____ State: _____ ZIP CODE: _____ Country: _____

Telephone: _____ Fax: _____ Telex: _____

□ Attached is a list of all branch offices and sales offices as requested.

Type of company: ☐ Manufacturer ☐ Distributor ☐ Packager ☐ Marketer ☐ Wholesaler

Start of Business Date: _____ Years in present location: _____

Business Classifications (If a Public Company, Please Enter Stock Symbol: _____)

☐ Corporation	☐ Privately Held	☐ Large Business	☐ Minority Owned
☐ Partnership	☐ Non-Profit	☐ Small Business	☐ Woman Owned
☐ Publicly held	☐ Government	☐ Veteran Owned	☐ Blind/Severely Disabled

Executive Personnel

President/CEO _____	Phone _____
Vice President _____	Phone _____
Vice President/Finance _____	Phone _____
Vice President/Manufacturing _____	Phone _____
Vice President/Marketing _____	Phone _____
Vice President/Customer Service_____	Phone _____
Vice President/QA_____	Phone _____
Legal Counsel _____	Phone _____
Sales Manager _____	Phone _____
Customer Service_____	Phone _____
Traffic/Shipping Manager _____	Phone _____

Figure 4.2 Example of a supplier qualification form.

Financial Information

Dun and Bradstreet Number _____

Company's current financial report attached. Y/N

□ *(Form 10K or latest annual report and quarterly report)*

_____ Past year's revenue _____ Current year's project revenue (approximate)

_____ Next year's revenue (anticipated)

Number of employees — total _____ Number of shifts being worked _____

Union shop? Y/N _____ Contract expiration date(s) _____

Name of union(s) and union numbers

Vacation/holiday shutdown schedule

Products or product lines (identify all that you desire to be included as a bidder in the RFP issued by Premier)

Please list at least three customer references that are either multi-facility systems or GPOs.

Please provide your North American Industrial Classification System Code formerly Standard Industrial Classification Code: _____

If in health care and you have a Health Industry Number (HIN), please provide: _____

If a large business, do you currently have any contracts with the federal government? Y/N ___.

If "Yes" above, do you have an approved "Small and Small Disadvantaged Business Plan" with the contracting office? Y/N _____. Please provide a copy of your approved plan with this submission.

By signing below I am certifying that the information provided in response to this survey is current, complete, and accurate to the best of my knowledge and may be relied upon by Premier Group Purchasing Services in any contract negotiations or supplier validation as of the date entered below. (Signature must be that of an individual authorized to commit the supplier to binding agreements or certify representations of the company)

Completed by (Signature) _____ Date _____

Printed Name _____ Title _____

Figure 4.2 (Continued)

Code of Conduct: Please note the attached Premier Code of Conduct. It is Purchasing Partner's expectation that Supplier, in its dealings with Purchasing Paterners, will respect Purchasing Partner's commitment to comply with Eureka Foods, Inc. Ethical Standards.

Supplier also agrees to provide a copy of its Code of Conduct and/or Ethics Policy to Eureka Foods, Inc.

_____ _____

(Signature and Title) (Date)

Attachment: Premier Code of Conduct*

***Until available please refer to www. premier.com public site, Hanson Report for details.**

Code of Conduct: Please note the attached Eureka Foods, Inc. Code of Conduct. By signing below in this section, the supplier represents that it accepts this Code of Conduct and ethical behavior in principle related to any contract relationship that should exist presently or in the future with Eureka Foods, Inc. Purchasing Services.

[ ] Agree [ ] Do not agree _____ _____

(Signature and Title) (Date)

Attachment: Eureka Foods, Inc. Code of Conduct

Please send your completed form(s) to:
Eureka Foods, Inc.
ATTN: QA (Supplier Qualification)
1000 N. Anystreet
Bigcity, CA 90000

If you have any questions please call or write:

Mark Anybody
QA Supplier Qualification Manager
Eureka Foods, Inc.
1000 N. Anystreet
Bigcity, CA 90000
Ph.: 000-000-0000

Figure 4.2 (Continued)

Supplier HACCP Qualification Standards

This form requires the supplier to provide information about the company's HACCP-TQM program. The supplier's information should be kept on hand to verify performance when periodically visiting the supplier. A model form is shown in Figure 4.3.[3]

Supplier _____ Date

Address

Since you are one of our current/potential vendors, we would like to know about your quality assurance program. If you have a HACCP program, we consider this to be part of your QA program. It is very costly for us to receive a product or service from a vendor that does not meet our expectations. Please answer the following questions and provide the material as appropriate concerning your quality assurance plan and program to achieve each requirement. When we visit with you, we will expect that you be able to demonstrate that you do each item effectively and are continually improving.

1. Who developed your HACCP/Quality Assurance program?
   Who validated your program as effective?
   Who are the members of your HACCP/QA team?
   How often do they meet? Describe your pre-ship verification program.
2. Have you taught each employee who works with food the hazards associated with the task he/she performs and how to perform the necessary controls?
3. What do you require of your suppliers in terms of ingredient HACCP controls?
4. Please tell us about your recall and emergency action program.
5. Describe the responsibilities of your Quality Assurance/Quality Control department.
   What ingredient testing do you do?
   What product testing do you do?
6. What are the critical limits, if you have them, for the biological, chemical, and physical hazards that are reasonably likely to be in the products you provide to use?

In addition to the above, please provide specifications to us for the products we purchase from you.

We will appreciate your prompt response.

Sincerely,

_____

(Adapted from Hospitality Institute of Technology and Management, 2003.)

Figure 4.3 Supplier HACCP qualification standard.

Supplier HACCP/QA Qualification List by Ingredients Purchased

This form provides a summary list of the suppliers that have provided HACCP-TQM information. Each year, when the supplier HACCP forms are updated, it is appropriate to check for improvements, and if the hazard levels have been reduced. Figure 4.4 is a model for this form.[3]

SUPPLIER HACCP QUALIFICATION LIST BY INGREDIENTS PURCHASED			
Supplier	*Food Item(s)*	*HACCP Yes/No*	*Date Expected Hazards and Levels*

Figure 4.4 Example of a supplier HACCP qualification list by ingredients purchased.

Ingredient Specification/Certification

It is vital that all raw materials and ingredients are purchased from approved suppliers in the company's list of approved vendors, to an up-to-date agreed-upon specification. The specification is the cornerstone of the company's SQP, detailing all the accepted criteria against which raw material and ingredient quality and safety are measured. The specification should define clearly all the factors considered important, including limits of tolerance or acceptability. Figure 4.5 shows a specification document with the complete characteristics of the ingredient, as required by the buyer and by the regulations.[5] Compliance of purchased raw materials and ingredients can be achieved by means of a certificate of guarantee from the supplier or by analyzing these materials and ingredients for microorganisms, natural toxins, or contamination. Figure 4.6 shows a specification document including the characteristics of the raw material, as required by the buyer and by the regulations.[6]

The specification document can be lengthy or concise, but should always include the minimum acceptance criteria. A typical specification document should be supplied for each raw material or ingredient by the supplier and would include the following:

- Details of supplier and manufacturing or supply site
- Description of the raw material and its functionality
- Ingredients breakdown
- Details of all intrinsic factors with tolerance limits, e.g., a_w, pH, salt, alcohol, etc.
- Microbiological acceptance criteria, e.g., absence of identified hazard organisms
- Analytical and microbiological limits and sampling plans
- Labeling requirements
- Storage and distribution conditions
- Safe handling and use instructions
- Description of pack type, size, and quality

Furthermore, the document also must assert that:

- Raw materials and ingredients do not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing so that they no longer contain levels that could cause the product to be adulterated.
- Raw materials and ingredients susceptible to contamination with aflatoxin or other natural toxins do comply with current FDA regulations, guidelines, and action levels for poisonous or deleterious

WHOLE MILK POWDER (WMP)

Physical Characteristics

Natural fresh milk, sweet pleasant light cream flavor, without any rancid or foreign taste or odor
Cream color
Homogenous appearance, without lumps and colored particles
Shelf life: About 6 months

Chemical Characteristics

Butterfat content: 26–28.5%
Moisture: 2–4.5%
Proteins (N X 6.38): 24.5–27%
Lactose: 36–38.5%
Ash: 5.5–6.5%
Titrable acidity: 0.15% maximum
Solubility: 99% minimum
Filtration test: Disc A, tolerance disc B
Antiseptics: Absent
Additives: Absent
Vitamins A and D may be added
The emulsifying agent lecithin may also be added in an amount not exceeding 0.5%

Microbiological Characteristics

Standard plate count: 10,000/g
Coliforms: Absent
Staphylococcus aureus: Absent
Pathogenic or toxicogenic microorganisms: Absent
Yeasts and molds: 50/g maximum
Antibiotics: Absent

Packaging and Storage

Heavy-duty 25 kg net 4-ply paper bags plus inner polyethylene bag stitched separately.
WMP should be kept in a cool, dry storage room and should not be exposed to direct sunlight or strong odors.

Utilization

The food industry in general and, in particular, ice cream, biscuit, confectionery, chocolate, yogurt, dessert products.

Figure 4.5 Example of an ingredient specification document.

MANGO CONCENTRATE AND PULP

Varieties: Totapuri and Alphonso
Specifications: As per international standards

PRODUCT	*MANGO CONCENTRATE*	*MANGO PULP*	*ALPHONSO MANGO PULP*
Variety	*Totapuri*	*Totapuri*	*Alphonso*
Physical Characteristics			
Color	Golden yellow	Golden yellow	Bright orange/yellow
Flavor and taste	Typical of fresh mangoes	Typical of fresh mangoes	Typical of fresh mangoes
Texture	Smooth	Homogenous and free flowing	Homogenous and free flowing
Shelf life	About 18 months	About 18 months	About 18 months
Chemical Characteristics			
Total solids	28–30°Brix	14–16°Brix	16–18°Brix
Acidity % (as citric acid)	0.6–1.1	0.4–0.8	0.5–1.0
pH	3.4–4.0	3.8–4.5	3.6–4.0
Crude fiber	0.2%	0.4%	0.2%
Microbiological Characteristics			
Total plate count	50 CFU/g Max	<50 CFU/g	<50 CFU/g
Yeast and mold	Absent	Absent	Absent
E. coli	Absent	Absent	Absent
S. auereus	Absent	Absent	Absent
Packaging and Storage			
	Aseptic bag in barrel	Aseptic bag in barrel	Aseptic bag in barrel

Figure 4.6 Example of a raw material specification document.

substances, before they are incorporated into the finished food. Suppliers shall provide certifications.

- Raw materials, ingredients, and rework products susceptible to contamination with pests, undesirable microorganisms, or extraneous materials comply with applicable FDA regulations, guidelines, and defect action levels for natural or unavoidable defects.

A description of how the raw material is processed, or a process flow diagram, and a site plan are helpful to the HACCP team in ensuring that they have fully identified all hazards of concern in the raw material. This information can be supplied as a separate document and is essential when evaluating high-risk raw materials; therefore, it should be built into the specifications. These documents can also be used to draw up a checklist of questions before the supplier audit. If a supplier is unwilling to provide processing information for reasons of confidentiality, then the purchasing company could assure itself that the raw material is safe by some other means. This may be through an understanding of the raw material's critical intrinsic factors along with the structured audit of the supplier's operation.

Supplier Auditing

A supplier audit is one of the key functions in SQP, as it is through audits that confidence can be gained in the supplier's operation. The objective here is to establish the supplier's ability to meet agreed-upon requirements; auditors should be trained to conduct this activity promptly and efficiently. The auditors observe the manufacturing facilities, the building's environment, the plant, and quality procedures and implementation of such procedures. Other evidence to collect includes information about management and workforce attitudes, and QC records, and so on. Often auditors will also look at financial and technological aspects.

Before auditing a supplier there are a number of questions that must be asked:

1. General information: company name, address, contacts and ownership details, organizational structure, and number of personnel.
2. Where is the production site for the product?
3. How long has the factory been in operation?
4. Was the building purposely built for this operation?
5. Are any other types of product manufactured at the facility (are any known allergens present on the site)?
6. Does the company operate a food safety management system based on the principles of HACCP?
7. Does the manufacturing site operate within a formal quality system such as ISO 9000, and is it certified?
8. Is microbiological testing carried out on-site? If so, does this include pathogen testing?
9. Are any contract laboratories used?
10. Have on-site and contract laboratories been accredited to an independent laboratory quality standard?

11. Is the manufacturing site covered by a pest control contract? If not, what pest control procedures are in place?
12. Where is protective clothing laundered? If a contract laundry is used, has it been audited?
13. Who is responsible for plant sanitation? If contract cleaners are used, how often do they visit?
14. Are raw materials, or intermediate or finished products stored off-site? If so, who is responsible for the condition of these facilities?
15. Are specifications held for all raw materials and finished products?
16. Are written work procedures available on-site?
17. Are there written personal hygiene standards?
18. What training do food handlers receive?
19. What vehicles are used for distribution (own/contract)? Who monitors their condition?
20. What legislation is considered applicable to the company's operations?

The above information has to be sent to suppliers. The information will also be important for low-risk raw materials. Additionally, supervising suppliers requires being aware of possible outsourcing issues.

When organizing an auditing program, it is important to think about how the audit will be carried out. An SQP audit is important to the safety and quality of the products being manufactured, so it is vital that it is carried out effectively, while maintaining a good relationship with the supplier. This can only be secured with properly trained personnel carrying out the audits.

Certificate of Analysis

Certificates of Analysis can be obtained for batches of raw materials to confirm that these have been sampled for certain criteria, and to provide the analytical results. It is necessary to check that they comply with the specification for these criteria. A Certificate of Analysis forms a useful part of the SQP program; consequently, it is necessary to make sure that only competent laboratories carry out the tests, so as to provide accurate results. This is best attained through certificates of independent laboratory accreditation and good laboratory practices.[5]

Third-Party Inspections

If there is no trained and experienced staff available to carry out a program of audits, then third-party inspections are needed. In such a situation, it is advisable to use experts from a food research association, or to look for commercial food-auditing organizations. In choosing third-party inspectors, it is important to check whether a higher-level board has accredited

their inspections, and the expertise and experience of the auditors at the third-party inspection organization need to be considered. It is vital that the inspectors have sufficient experience both in the technology concerned and in auditing practices. It must be ensured that they will highlight potential food safety problems and help the company to maintain good relationships with the suppliers.

BUYING FROM AGENTS AND BROKERS

When the raw materials are obtained through agents or brokers, the company loses out on direct contact with the supplier. This practice can have drawbacks if the agent has little or no technical knowledge of the raw material, but it can work if the situation is managed effectively.

It is necessary to know how the raw materials have been processed and handled at every stage, in order to establish whether likely hazards are present at expected or increased levels, and whether any new unexpected hazards have crept in. It is important to obtain the appropriate assurances from the agent and, possibly, a form from the processor via the agents, but the most important factor is to ensure that appropriate control is built into the company's operation to cope with the worst-case scenario.

Even with a carefully planned SQP program, it is difficult to be absolutely sure that raw materials always meet the required standards for safety and quality. To be effective, it is best to pass on to the suppliers the requirements to operate an effective HACCP program for food safety hazards. These requirements can be passed up the supply chain so that growers, processors, agents, and the final manufacturer have the same level of confidence in the material at their stage in the chain, in the same way that a consumer can have confidence in a finished product manufactured through an effective HACCP program.[5]

IDENTITY-PRESERVED PRODUCTS: A NEW FOOD PRODUCTION SCENARIO

Identity-preserved (IP) ingredients and finished products for the consumer, which recently have gained currency with leading global food-manufacturing firms, are raw materials coordinated through several food-chain segments.

Defining IP Products

IP production involves a fully traceable system detailing the history of a crop, from the sowing of the seed to the resulting end product. Simply stated, IP products are raw materials — either plant or animal products — that are coordinated through several segments of the food chain and are

not mingled with somewhat similar raw materials that have different specifications. The IP scheme is documented in order to provide confidence to the customer; documented production systems, open to audit and scrutiny by the end user, can have a significant effect on the end product's characteristics. According to Senechal,[6] IP products have the following typical characteristics:

- Carefully defined contractual relationships between agricultural producer and next-stage handler(s)
- Specification of product to be grown, e.g., corn hybrid, cattle of certain bloodlines, etc.
- Specification of a method of agricultural production, e.g., organic production practices, specific animal health regimen, usage of or absence of a specified production technique
- Exacting quality standards
- Specification of harvest, transportation, storage, and other logistics to minimize contamination by similar but inferior products
- Processing standards to maintain identity, e.g., equipment clean-out, segregated storage, separation during transportation
- A system to monitor the IP system's integrity from farm to end-use
- A method to trace a contamination source or system compromise, should any occur
- Agreed-upon fees and premium charges for production, handling, and processing

IP products will become more and more important, particularly following the reported recent food scares. The use of genetically modified crops (GMOs), the incidence of bovine spongiform encephalopathy (BSE) or "mad cow" disease, *E. coli* and the environmental pollution with dioxins have made consumers far more aware of what they are eating.[7] As manufacturers strive to differentiate their products from their competitors, companies dealing with the concept and production of IP crops are rapidly appearing in the market.

As early as 2000, *IdentityPreserved.com* announced its formation,[8] and Cargill Foods, among other companies, offered IP products such as whole corn, Yellow Goods (the brand of products for use in breakfast cereals, snack foods, etc.), and masa flours under the brand name of InnovaSure.[9] Customers wish to express a choice in what they and their families consume and, regardless of whether their worries are scientifically justified, their perception can have a significant effect on a company's profits.

For pharmaceutical markets an IP system is essential, as the research and development investment in a project can be very significant. Plants

are a natural product and cannot be as easily controlled as the manufacture of nuts and bolts in a factory, for example. Things can go wrong and the whole point of having an IP system is to try and control the uncontrollable.

The recent interest in GMOs not only puts an enormous emphasis on having an IP system when growing these type of products but also, customers need to be guaranteed that their non-GMO crops are free from this new technology. IP products typically cost 5 to 10% above comparable raw materials. Premiums also may be charged for yield reductions that may be inherent with a specific desired variety of raw material.

Firms are establishing IP relationships for key ingredients and exploring expanded arrangements because participants believe these products are worth the overall cost and effort when competitive and economic advantages can be gained through their use. Firms are using IP products for several reasons:

Consumer Desire

Important and growing consumer segments attribute premium value to products of known origins and specific qualities.

Processing Improvements

The neverending drive for cost position has led the food industry toward improved process monitoring and evaluation technology to judge performance of raw materials of differing specifications.

Product Attributes

Certain IP product attributes provide a sustainable product advantage to processors, such as Frito-Lay's system of procuring specific types of food-grade corn to manufacture unique tortilla chips.

Some firms are exploring the possibilities for expanding their use of IP products to enhance their ability to trace contaminated product. Tainted product can be traced from the retail outlet all the way to the exact field or farm building where the initial raw material was produced. While a full-fledged system of traceability is not without cost, manufacturers are exploring the practicality and cost-effectiveness of cutting-edge information technology to reduce risk to the firm's reputation and value of its brands.

Required Resources

How does a firm cost-effectively explore and implement an IP initiative? The good news is that an infrastructure is well into development for

assisting food-industry participants in the exploitation of proprietary IP opportunities.

This new infrastructure includes agricultural product promotion organizations that can assist in the research, product-development, and process-development process. Established commercial organizations can handle virtually all production, contracting, and logistics functions for IP products.

Food companies have demonstrated that significant competitive and economic advantages can be gained by using IP products in specific applications; however, IP use will add complexity and cost to the traditional food system. Firms considering IP-product economics are wise to undertake a comprehensive value-chain analysis to understand the benefits, costs, and risks associated with such a program.

REFERENCES

1. ASQ Food, Drug, and Cosmetic Division, 2002. *The Certified Quality Auditor's HACCP Handbook*, ASQ Quality Press, Milwaukee, WI.
2. Scheidegger, G., 2002. World Drug Manufacturing Summit. http://www.worldtradeco.com/summitclub/resources/dmm_transcript_scheidegger.html. Accessed February 8, 2003.
3. Hospitality Institute of Technology and Management, 2003. Section V. Supplier Policies, Procedures, and Standards. Last modified January 13, 2003. http://www.hi-tm.com/PDG/Retail-V.html#2. Accessed February 8, 2003.
4. L-3 Communications, Link Simulation & Training. 2002. Available from: http://www.link.com/pdfs/supplier.form.pdf. Accessed February 8, 2003.
5. Mortimer, S. and Wallace, C., 1998. *HACCP: A Practical Approach*, 2nd ed., Aspen Publ., Frederick, MD.
6. Senechal, D.M., 2002. Identity-preserved ingredients. A competitive weapon?, *Food Prod. Design*, April.
7. Green, S., 2002. Identity Preserved Production and the Commercial Development of Novel Medicinal and Cosmetic Plants. Interactive European Network for Industrial Crops and their Applications (IENICA). September 23–27, 2002. Available from: http://www.ienica.net/specchemseminar/green.pdf. Accessed February 11, 2003.
8. IdentityPreserved.com, 2000. Identity Preserved Crop Production Gets Boost from New Company, Products. September 14, 2000. Available from: http://www.identitypreserved.com/news/pr-new-feature.htm. Accessed February 13, 2003.
9. Cargill Dry Corn Ingredients, 2003. Available from: www.cargilldci.com/products/yellow.htm. Accessed September 22, 2003.

Chapter 5

STATISTICAL METHODS OF QUALITY CONTROL IN THE FOOD INDUSTRY

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INTRODUCTION

Statistical studies can be classified into two types: enumerative and analytic.[1] The objective of the enumerative study is to describe a population in a static sense; an analytic study considers the population in a dynamic sense, and its objective is to predict or improve a process or product in the future.

STATISTICAL TOOLS AND STRATEGIES FOR PROCESS CONTROL IMPROVEMENT

In statistical quality control and statistical process control, in order to perform an analytical study or experiment, it is important to consider observations under time or production sequence. There is another approach in which time sequence is not important in the analysis itself. This is considered off-line experimentation and is known as experimental design. Through this kind of experimentation, it is possible to discover

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or confirm cause-and-effect relationships. Experimental design is a better alternative to trial and error methods[2] because it provides an efficient and effective means of knowledge acquisition and a higher level of formality.

There are statistical methods that support the usefulness of this kind of study. Flowcharts and cause-and-effect diagrams, mentioned in Chapter 2, are examples of necessary tools to study the cause-and-effect system inherent in the analytic study.

DESIGN AND ANALYSIS OF ANALYTIC STUDIES

Moen, Nolan, and Provost[2] offer a detailed description of the elements to be considered in the design of analytic studies. However, the most relevant guidelines are:

- Knowledge should be built in a sequential and iterative fashion
- Experiments must be developed over a wide range of conditions
- Selection of units for the study must be thoughtful

In conjunction with the design concepts, and according to the aforementioned authors, the analysis of these studies is generated by three basic principles:

1. There is a close relationship among the analysis of data, the interpretation of results, and the actions that are taken based on those results and the current knowledge of experts on the subject matter.
2. Given that the conditions of the experiment will be different from the conditions under which the results will be used, a consideration of the magnitude of this difference and its impact by experts is part of the interpretation of results of the study.
3. Methods for the analysis of data will be almost exclusively graphic, with minimum aggregation of the data before graphic display. The aim of the graphic display will be to visually partition the data among the sources of variation present in the study.

DEFINITIONS OF TERMS AND CONCEPTS

Before we proceed with the experimental design approach, a set of definitions of terms and concepts is given in order to follow the discussion in this chapter.

Experiment. For the purpose of this section, an analytic study to provide an action to be taken on a cause-and-effect system.

Response Variable. Observed or measured variable under given circumstances in the experiment. It is often the measure of performance

or a quality characteristic of the process or product. It is also called the dependent variable.

Factor. Independent, causal, or controllable variable. A variable intentionally changed in the experiment so as to observe its influence on the response variable. Factors can be quantitative, for example, a cooking time of 30 or 60 min; or qualitative, for example, method X, Y, or Z. Sometimes, qualitative factors are called class or classification variables.

Experimental Unit. The smallest division of material in an experiment such that any two units may receive different combinations of factors.

Block. Groups of experimental units treated similarly during a designed experiment.

Background Variable. Blocking or noise variable; a variable that might affect a response variable in the experiment but is not of interest as a controllable variable. Examples include: operator, shift, day, or supplier. Background variables can be controlled during the experiment by holding them constant or by the use of blocks.

Level. A specific setting or value of a factor included in the experiment. The levels may be fixed at certain values of interest, or they may consist of a random sample from a set of many possible values. The levels of a factor are sometimes called treatments.

Effect. The change in the response variable caused when a factor is changed from one level to another.

SINGLE FACTOR EXPERIMENTS

The *completely randomized design* is the simplest of the single factor experiments. Only one factor is manipulated during the experiment. It is assumed that other factors are held constant or controlled at some level. Randomization plays a critical role in experimental designs. There are always a number of uncontrolled variables; to average out their effect, it is necessary to randomize the order of experimentation in the corresponding design.

The following example is used to present a graphic method of analysis for this kind of experiment.

Example 5.1

A manufacturer of sausages is interested in comparing the smoke intensity obtained by three different smoking methods: M1, M2, and M3. Fourteen samples of *smoke intensity* are obtained for each method. A 7-point evaluation scale is used where 1 denotes “not noticeable amount of smoking” and 7

Table 5.1 Smoke Intensity (SI) of Sausages

Smoking Method	M1	7	6	4	3	5	6	6	5	3	4	5	4	6	6
	M2	5	4	3	6	5	4	6	5	4	3	5	7	5	6
	M3	4	5	4	3	6	6	3	5	2	4	6	4	4	3

denotes "extremely strong amount of smoking." Table 5.1 shows the collected data.

In this case, the factor, or controllable variable, is the smoking method. It has three levels or treatments: M1, M2, and M3. The response variable is smoking intensity. Each treatment has 14 observations, or replicates, randomly assigned to the treatments.

As suggested previously, it is important to make a graphic analysis of the data from an experiment. Although there are several options to do this, Figure 5.1 shows the box plots of the smoking intensity for three different methods generated by Minitab®. A box plot displays important descriptive statistics (central tendency and dispersion) from a dataset simultaneously. The dot inside the box represents the mean of the dataset. The box encompasses the interquartile range, the first quartile or q_1 is the lower edge, and the third quartile or q_3 is the upper edge. The line across the box is the second quartile, q_2, or median of the data. A line is drawn from each extreme of the box. The lower line grows from the q_1 to the smallest data within 1.5 interquartile ranges from q_1. The upper line departs from q_3 and grows up to the largest data point within 1.5 interquartile ranges.

Figure 5.1 shows that methods 1 and 2 lead to practically the same smoking intensity level while method 3 provides a lower level of that

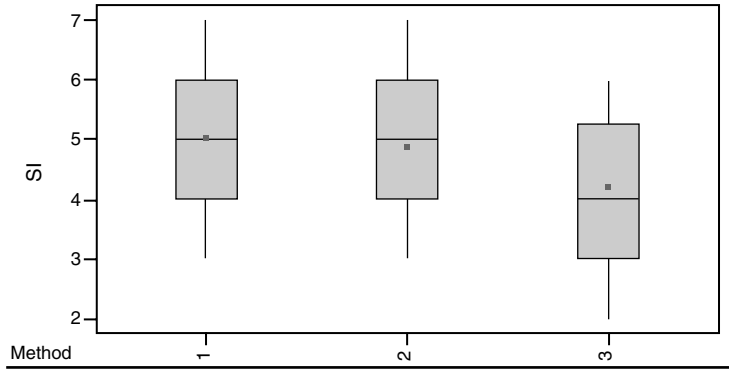


Figure 5.1 Box plots to compare three different smoking methods.

measured quality characteristic. However, from a statistical point of view, there is no difference among the three methods. We will discuss this result in the context of the analysis of variance (ANOVA), to be presented in detail.

THE ANOVA METHOD

Although this method is used in a wide variety of situations, it is used here as an extension of the experiments designed to study two populations (methods, treatments, levels, brands, etc.).

The computational procedure to develop the ANOVA for the single factor experiment is based on the variance decomposition principle that, in this first case, states:

$$\begin{matrix}\text{Total Variation} = \text{Variation between treatments} \\ \text{Variation within treatments}\end{matrix} \tag{5.1}$$

To understand this decomposition into its sources of variation, consider the typical data layout used for a single factor experiment. It is assumed that the number of observations per treatment is the same.

Consider that each observation in the previous table is represented by the linear mathematical model

$$y_{ij} = \mu + \tau_i + \varepsilon_{ij} \qquad \begin{cases} i = 1, 2, \cdots a \\ j = 1, 2, \cdots n \end{cases} \tag{5.2}$$

where: y_{ij} is the jth observation under the ith treatment or factor level; μ, the overall mean that is a parameter common to all treatments; τ_i, a parameter that describes the ith treatment effect; and ε_{ij} the corresponding random error component.

The mathematical model in Equation 5.2 is appropriate for the single factor experiment. Actually, two statistical models, the fixed effects model and the random effects model, could be derived from it, depending on the way the a treatments are selected. The following material is devoted to the fixed effects model in which the a treatments are specifically chosen. Consequently, the conclusions will be valid only for those treatments considered in the experiment. In the fixed effects model, the treatment effects τ_i are defined as deviations from the overall μ, then

$$\sum_{i=1}^{a} \tau_i = 0 \tag{5.3}$$

Table 5.2 Data Layout for a Single Factor Experiment

Treatment	*Observations*				*Totals*	*Averages*
1	y_{11}	y_{12}	⋯	y_{1n}	$y_{1\bullet}$	$\bar{y}_{1\bullet}$
2	y_{21}	y_{22}		y_{2n}	$y_{2\bullet}$	$\bar{y}_{2\bullet}$
⋮	*Variation between treatments*					
a	y_{a1}	y_{a1}		y_{an}	$y_{a\bullet}$	$\bar{y}_{a\bullet}$
	Variation within treatments				$y_{\bullet\bullet}$	$\bar{y}_{\bullet\bullet}$

The ANOVA procedure is then used to test the equality of a treatment means $\mu_1, \mu_2, \cdots, \mu_a$ and then the underlying hypotheses under consideration are:

$$H_0: \tau_1 = \tau_2 = \cdots = \tau_a = 0$$
$$H_1: \tau_i \neq 0 \quad \textit{for at least one } i \tag{5.4}$$

When the null hypothesis is true, Equation 5.2 reduces to $y_{ij} = \mu + \varepsilon_{ij}$. This means that under these circumstances, the variation we observe in the data is due only to the random error component. In other words, under H_0 true, Equation 5.1 would read as *Total Variation = Variation within Treatments*.

Again, from Table 5.2, $y_{i\bullet}$ is the total of observations under treatment i and $\bar{y}_{i\bullet}$ is the corresponding average. Using the summation notation,

$$y_{i\bullet} = \sum_{j=1}^{n} y_{ij} \qquad \bar{y}_{i\bullet} = \frac{y_{i\bullet}}{n} \qquad i = 1, 2 \cdots a$$
$$y_{\bullet\bullet} = \sum_{i=1}^{a}\sum_{j=1}^{n} y_{ij} \quad \bar{y}_{\bullet\bullet} = \frac{y_{\bullet\bullet}}{N} \qquad N = an \tag{5.5}$$

Note that N is the total number of observations in the experiment.

Given that the total variability in data can be equivalently described in terms of the sum of squares (SS) of the corresponding deviations as

$$SS_T = \sum\sum \left(y_{ij} - \bar{y}_{\bullet\bullet}\right)^2$$

Equation 5.1 may be rewritten in terms of the SS identity as follows:

$$\sum_{i=1}^{a}\sum_{j=1}^{n}\left(y_{ij}-\bar{y}_{\bullet\bullet}\right)^2 = n\sum_{i=1}^{a}\left(\bar{y}_{i\bullet}-\bar{y}_{\bullet\bullet}\right)^2 + \sum_{i=1}^{a}\sum_{j=1}^{n}\left(y_{ij}-\bar{y}_{i\bullet}\right)^2 \qquad (5.6)$$

that is equivalent to

$$SS_T = SS_{Treatments} + SS_{Error} \qquad (5.7)$$

where:

$SS_{Treatments}$ is the variation between treatments and
SS_{Error} is the variation within treatments or random error.

With a little algebraic effort, it can be shown that the formulas for $SS_{Treatments}$ and SS_{Error} have equivalent expressions using totals instead of averages. These expressions are computationally simpler to use:

$$SS_T = \sum_{i=1}^{a}\sum_{j=1}^{n} y_{ij}^2 - \frac{y_{\bullet\bullet}^2}{N} \qquad (5.8)$$

$$SS_{Treatments} = \sum_{i=1}^{a}\frac{y_{i\bullet}^2}{n} - \frac{y_{\bullet\bullet}^2}{N} \qquad (5.9)$$

by subtraction

$$SS_E = SS_T - SS_{Treatments} \qquad (5.10)$$

As will be seen, the outputs provided by available statistical software to report the results of the ANOVA use a table similar to the one shown in Table 5.3.

The use of statistical software is becoming progressively familiar in industrial environments. The next example illustrates the use of these computing formulas and compares the results, in this case, with those provided by a statistical module that is part of Microsoft Excel®.

Example 5.2[3]

To study the effect of nozzle width on the weight of the chewing gum tablet, five different nozzle widths were studied. Eight sam-

Table 5.3 ANOVA Table for the Single Factor Experiments, Fixed Effects Model

Source of Variation	*Sum of Squares*	*Degrees of Freedom*	*Mean Square*	F_0
Treatments	$SS_{Treatments}$	$a - 1$	$MS_{Treatments}$	$\frac{MS_{Treatments}}{MS_E}$
Error	SS_E	$a(n - 1)$	MS_E	
Total	SS_T	$an - 1$		

Table 5.4 Tablet Weights under Different Nozzle Widths

Nozzle Width (mm)	*Weight (g)*								*Totals ($y_{i\bullet}$)*
13.5	1.60	1.57	1.58	1.43	1.55	1.61	1.63	1.64	12.61
14.0	1.64	1.69	1.73	1.65	1.71	1.72	1.68	1.69	13.51
14.5	1.79	1.75	1.76	1.75	1.78	1.76	1.78	1.79	14.16
15.0	1.74	1.73	1.69	1.76	1.75	1.72	1.75	1.79	13.93
15.5	1.82	1.79	1.81	1.80	1.79	1.80	1.83	1.81	14.45

ples of the tablet weight were recorded under each factor level. The tablets were taken from the production line in random order. Table 5.4 summarizes the data for this single factor experiment.

From the data table we compute $y_{\bullet\bullet} = 68.66$. Manual computations can be done by applying Equation 5.8 through Equation 5.10.

$$SS_T = \sum_{i=1}^{5}\sum_{j=1}^{8} y_{ij}^2 - \frac{y_{\bullet\bullet}^2}{N}$$

$$SS_T = 1.60^2 + 1.57^2 + \cdots\cdots + 1.83^2 + 1.81^2 - \frac{68.66^2}{40} = 0.3031$$

$$SS_{Treatments} = \sum_{i=1}^{5} \frac{y_{i\bullet}^2}{n} - \frac{y_{\bullet\bullet}^2}{N}$$

$$SS_{Treatments} = \frac{12.61^2 + 13.51^2 + 14.16^2 + 13.93^2 + 14.45^2}{8} - \frac{68.66^2}{40} = 0.2558$$

Table 5.5 ANOVA Table for the Nozzle Widths Experiment

Source of Variation	*Sum of Squares*	*Degrees of Freedom*	*Mean Square*	F_0
Nozzle widths	0.2558	4	0.0639	47.26
Error	0.0474	35	0.0014	
Total	0.3031	39		

$$SS_E = SS_T - SS_{Treatments}$$

$$SS_E = 0.0474$$

Table 5.5 summarizes these results.

Table 5.6 shows the output of the ANOVA single factor analysis tool in the Analysis Toolpak add-in from Microsoft Excel. When comparing those results with the manual computations in Table 5.5, two additional columns appear in the Excel software output: *P-value and F crit*. These two values are closely related to the controversial significance issue.[1,4-5] Given that the F value in Table 5.5 (47.26) or the F_0 value in Table 5.6 (47.2629356) is larger than the F_{crit} value (2.64146394), H_0 is rejected and it is said that nozzle width affects the weight of the chewing gum tablet. The P-value in Table 5.6 means that because 1.2241×10^{-13} is notably smaller than $\alpha = 0.05$, the significance level employed during the test, there is strong evidence to conclude that H_0 is not true.

If you wish to refer to the catalog of available analysis procedures in Excel, click Data Analysis on the Tools menu. If Data Analysis does not appear on that menu, it will be necessary to install the Analysis Toolpak.

THE RANDOMIZED COMPLETE BLOCK DESIGN: TWO-WAY ANOVA

The randomized complete block design leads to the two-way ANOVA procedure in which the response variable is classified as two variables, one of them describing the factor to be studied, and the other acting as a background variable. In this type of procedure, each factor level or treatment must appear at least once in every block. The treatments, or factor levels, are assigned in random order within each block. Table 5.7 shows the typical data layout for this design, containing *a* treatments and *b* blocks.

Table 5.6 ANOVA Table from Microsoft Excel Analysis Toolpak

ANOVA: Single Factor

Summary

Groups	*Count*	*Sum*	*Average*	*Variance*
13.5	8	12.61	1.57625	0.00439821
14.0	8	13.51	1.68875	0.0010125
14.5	8	14.16	1.77	0.00028571
15.0	8	13.93	1.74125	0.00086964
15.5	8	14.45	1.80625	0.00019821

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Between Groups	0.25576	4	0.06394	47.2629356	1.2241E-13	2.64146394
Within Groups	0.04735	35	0.00135286			
Total	0.30311	39				

Table 5.7 Randomized Complete Block Design

	Blocks					
Treatment	*1*	*2*		*b*	*Totals*	*Averages*
1	y_{11}	y_{12}	$\cdots$	y_{1n}	$y_{1\bullet}$	$\bar{y}_{1\bullet}$
2	y_{21}	y_{22}		y_{2n}	$y_{2\bullet}$	$\bar{y}_{2\bullet}$
:						
a	y_{a1}	y_{a2}	$\cdots$	y_{an}	$y_{a\bullet}$	$\bar{y}_{a\bullet}$
Totals	$y_{\bullet 1}$	$y_{\bullet 2}$	$\cdots$	$y_{\bullet b}$	$y_{\bullet\bullet}$	
Averages	$\bar{y}_{\bullet 1}$	$\bar{y}_{\bullet 1}$	$\cdots$	$\bar{y}_{\bullet b}$		$\bar{y}_{\bullet\bullet}$

In this case, the statistical linear model is represented by

$$y_{ij} = \mu + \tau_i + \beta_j + \varepsilon_{ij} \quad \begin{cases} i = 1, 2, \cdots a \\ j = 1, 2, \cdots b \end{cases} \tag{5.11}$$

The difference among the right-hand side of Equation 5.2 and Equation 5.11 is β_j, the effect of the *j*th block. The other elements were already defined.

The interest, however, remains focused on the treatment effects from a single factor in the experiment, thus the associated hypotheses are the same from the previous design, namely:

$$\begin{aligned} &H_0: \tau_1 = \tau_2 = \cdots = \tau_a = 0 \\ &H_1: \tau_i \neq 0 \quad for \quad at \quad least \quad one \quad i \end{aligned} \tag{5.12}$$

The computing formulas for the Randomized Complete Block Design emerge from the fact that total variation is now:

$$\begin{aligned} \text{Total variation} = {} & \text{Variation between treatments} + \\ & \text{Variation between blocks} + \\ & \text{Variation within treatments} \end{aligned} \tag{5.13}$$

Or, in terms of an equivalent expression using sum of squares,

$$SS_T = SS_{Treatments} + SS_{Blocks} + SS_{Error} \tag{5.14}$$

Using the summation notation, this equation is equivalent to:

$$\begin{aligned} \sum_{i=1}^{a}\sum_{j=1}^{b}\left(y_{ij} - \bar{y}_{\bullet\bullet}\right)^2 = {} & b\sum_{i=1}^{a}\left(\bar{y}_{i\bullet} - \bar{y}_{\bullet\bullet}\right)^2 + a\sum_{j=1}^{b}\left(\bar{y}_{\bullet j} - \bar{y}_{\bullet\bullet}\right)^2 + \\ & \sum_{i=1}^{a}\sum_{j=1}^{b}\left(y_{ij} - \bar{y}_{\bullet j} - \bar{y}_{i\bullet} + \bar{y}_{\bullet\bullet}\right)^2 \end{aligned} \tag{5.15}$$

From Equation 5.15, the corresponding computational formulas for the randomized complete block design can be obtained:

$$SS_T = \sum_{i=1}^{a}\sum_{j=1}^{b} y_{ij}^2 - \frac{y_{\bullet\bullet}^2}{N} \tag{5.16}$$

$$SS_{Treatments} = \sum_{i=1}^{a}\frac{y_{i\bullet}^2}{n} - \frac{y_{\bullet\bullet}^2}{N} \tag{5.17}$$

$$SS_{Blocks} = \frac{1}{a}\sum_{j=1}^{b}\frac{y_{\bullet j}^2}{n} - \frac{y_{\bullet\bullet}^2}{N} \tag{5.18}$$

where N is the total number of observations in the experiment, and

$$SS_E = SS_T - SS_{Treatments} - SS_{Blocks} \tag{5.19}$$

The following example illustrates the application of the two-way ANOVA procedure; it is solved using Minitab®, another excellent statistical software. You are encouraged to apply Equation 5.16 through Equation 5.19 to complete the corresponding ANOVA table and compare the results in Figure 5.2 with your own answers.

Analysis of Variance for Volume

Source	DF	SS	MS	F	P
Formula	3	3176.5	1058.8	15.79	0.001
Oven	3	1130.0	376.7	5.62	0.019
Error	9	603.5	67.1		
Total	15	4910.0			

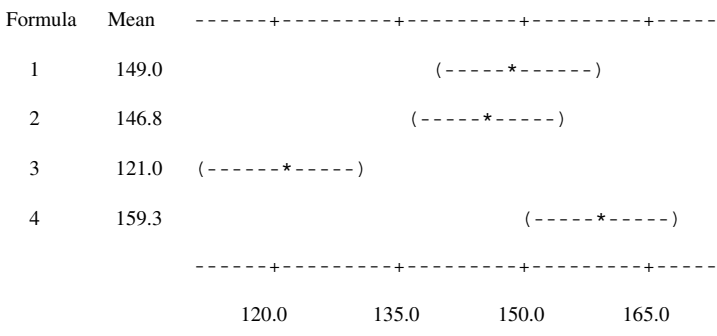


Figure 5.2 Output from Minitab for randomized complete block design in Example 5.3.

Table 5.8 Loaf Volume (cu. in.) Data for the Randomized Complete Block Design

Formula (Treatment)	*Oven*				*Treatment Totals* $y_{i\bullet}$	*Treatment Averages* $y_{i\bullet}$
	1	*2*	*3*	*4*		
1	156	143	160	137	149.0	37.250
2	150	151	157	129	146.8	36.700
3	112	137	126	109	121.0	30.250
4	162	151	175	149	159.3	39.825
Block Totals $y_{\bullet j}$	145.0	145.5	154.5	131.0	$y_{\bullet\bullet} = 576.1$	
Block Averages $\bar{y}_{\bullet j}$	36.250	36.375	38.625	32.750		

Example 5.3

The data shown in Table 5.8 are taken from an example presented by Merton R. Hubbard.[6] In the example, four bread formulas and treatments are compared for loaf volume when baked in a microwave oven. The single factor is bread formula; four treatments or factor levels are tested. In order to have a complete design, four ovens (blocks) will be necessary so that each bread formula appears at least once in each oven. Remember, however, that the interest is focused on only one of them, namely, the formula used to bake the loaves of bread. Figure 5.2 is the output for the two-way ANOVA from Minitab, for the loaves volume vs. formula data.

	Ovens			
Formula	*GE*	*TA*	*SA*	*AM*
1	156	143	160	137
2	150	151	157	129
3	112	137	126	109
4	162	151	175	149

From this output, we can say that given that F value = 15.79 > $F_{0.05,3,9}$ = 3.86, the formula employed to bake the loaves of bread affects its volume. Note that Minitab output includes an F value for the oven that acted as a block. A word of caution is in order here: remember that we are still

working with a single factor, experiment (formula). The blocks, in this case the ovens, represent a restriction on randomization, and this F ratio could lead to a misinterpretation. When a background variable is considered important, it should be taken into account in the design as another controllable factor, in this case a factorial design, which is designed to handle two or more factors simultaneously.

In Example 5.2, it was found that nozzle width affected the weight of the chewing gum tablet, and in Example 5.3, the formula affected the volume of the loaves of bread. In both cases, there are differences among the treatments means. ANOVA does not specify which means are different. There are procedures to compare individual treatment means; these methods are known as multiple comparison methods. Although simple, multiple comparison methods are imprecise. For a further discussion and alternative approaches see Burguete-Hernandez, Tamborero-Arnal, and Morales-Cruz.[5] A wide variety of experimental designs are available to support industrial experimentation. The previous illustrations in this chapter cover just a very small part of them; the three examples in this section involve just a single factor; there are other models called factorial experiments, which handle two or more factors simultaneously. One of the main advantages of this latter type of experiment is the possibility to observe interactions among the factors being controlled. Under industrial environments, it is not unusual to have 5 to 20 factors of interest. Strategies of experimentation change depending on the amount of knowledge possessed by the experimenter.

QUALITY CONTROL TECHNIQUES

An effective quality assurance/quality control (QA/QC) program uses a mixture of control techniques, acceptance sampling, and statistics analysis techniques with the system making emphasis on control. The control depends on the action taken as a result of sampling or testing.

One of the most important statistical process control (SPC) techniques is the control charts, one of the so-called basic seven tools of quality or the "magnificent seven." When used correctly, these can improve productivity, reduce scrap and rework, prevent defects, avoid problems in the next operation, avoid under- and over-control, fill the communication gap between the workers and their job, and are proven techniques to improve the process.

Control charts were developed in the 1920s by Walter A. Shewhart of the Bell Telephone Laboratory as a statistical approach to continuously study process variation with the purpose of improving it by removing the assignable causes of variation. "Control charts differentiate between the

process being in control (within an acceptable range of random variation) and out of control (outside the acceptable range)."[7]

In simpler terms, a control chart is a graphic display of the actual quality performance judged against a reference frame showing a central line representing the average quality value and upper and lower lines called the upper control limit (UCL) and lower control limit (LCL). These lines are positioned so that nearly all the sample results fall between them, as long as the process is in control and the stable system of chance–causes is operating. Control charts, as the frequency histogram, summarize the data but also take time into consideration, indicate changes in the operation, tell us within certain limits when the changes are occurring so corrective action can be taken, and are a tool for decision making.

The control charts can be divided into variable and attribute control charts. Variable control charts are used for important variables or continuous quality data, such as weight control, can seam dimensions, volumes, yield, and chemical, physicochemical, nutritional, and microbiological characteristics. Numerical values give more information than necessary and the results are more precise, with fewer samples than attributes; however, variable charts can only be applied to a single characteristic or property. The attribute control charts are used for quality characteristics data that cannot be expressed as a measurement and are collected by counting. For example, in the visual examination of can seams, we can count a variety of defects such as drops, lips, cut-over, skidding, dents or scratches, etc. and, on the basis of the results, classify the seams into one of two classes, conforming or nonconforming (pass/fail, good/bad), or we can express the nonconformities in units according to their importance.

Variable Control Charts

Variable control charts, or Shewhart control charts, are the most generally used SPC tool in any QA program. Variable charts are based on normal distribution; it is assumed that the statistic plotted on the chart is normally distributed. The original Shewhart control chart, $\bar{X}$, *s* or $\bar{X}$, R, is based on the demonstrated fact (by Shewhart) that the averages of sample sizes > 4 are normally distributed with a mean μ and a standard deviation $\sigma_{\bar{x}} = \sigma/\sqrt{n}$. If a variable is normally distributed, the following probability statement regarding any sample mean can be made:

$$P\left(\bar{X}\right) = \mu + Z_{\alpha/2}\sigma_{\bar{x}} = \mu \pm Z_{\alpha/2}\frac{\sigma}{\sqrt{n}} = 1 - \alpha \qquad (5.20)$$

where α is the level of significance.

Equation 5.20 can be used knowing μ and σ to calculate the control limits for a control chart of sample means. $Z_\alpha/2$ can be chosen to give a certain probability but it is customary, especially in the U.S., to use three sigma limits, which gives a probability of 0.0027 that if the process is under control, a sample mean will fall outside the control limits. In some European countries, the control limits are based on the probability that a point under control falls outside the control limits. Shewhart proposed control charts of S o R to monitor process variability because this cannot be assessed by the $\bar{X}$ chart.

To implement a variable control chart, certain decisions must be made: What is to be measured? How is it to be measured? Where is it to be measured? When is it to be measured? How many observations at one time?[8] Once these questions are answered, it is necessary to know or have an estimate of the mean and the standard deviation. It is customary to estimate these statistics using 20 to 25 samples. Control charts for variables can be based on standard values for the mean and standard deviation without the analysis of past samples. In the case of the acquisition of data involving a long period of time or expensive procedures, the individual observations can be plotted directly to assess the variability, and a moving range (MR) chart can be implemented (two successive observations are used to calculate a range and assess the variability; the moving range is defined as the absolute difference of two successive observations).

Which of the common charts to use may be decided with the variable control chart selector shown in Figure 5.3.

The chart of a $\bar{x}$ and R should not be used with samples ≥10 because the estimator of σ used, $\sigma = \bar{R}/d_2$ (values of d_2 are given in Table 5.9), loses efficiency with moderate to large sample sizes or when the sample size is not constant. In this case, it is better to use a chart of $\bar{x}$ and S. The sample's standard deviations are determined, an average standard deviation is calculated, and then used to calculate the control limits of the S chart.

Once which chart to use has been decided, the control limits must be calculated. Table 5.10 summarizes the formulas and factors needed.

To construct an $\bar{x}$ and R chart, we need an estimate of μ and σ; usually these are estimated based on at least 25 samples of equal size (4 or 5 units each). For each sample, the mean ($\bar{x} = x_1+x_2+x_3+\ldots.+x_n/n$, where n is the sample size) and range ($R = x_{larger} - x_{smaller}$) are calculated.

With these values, the grand average or mean of means $\bar{\bar{X}}$ ($\bar{\bar{X}} = \bar{x}_1 + \bar{x}_2 + \cdots \bar{x}_n/m$, where m is the number of samples) and the $\bar{R}$ ($\bar{R} = R_1+R_2+\ldots..+R_m/m$) are calculated; with Equations 5.21 and 5.23, and the factors tabulated in Table 5.9, the control limits for the $\bar{x}$ and R are calculated. Any point outside the control limits in any of the two charts is considered out of control and a corrective action must be taken to

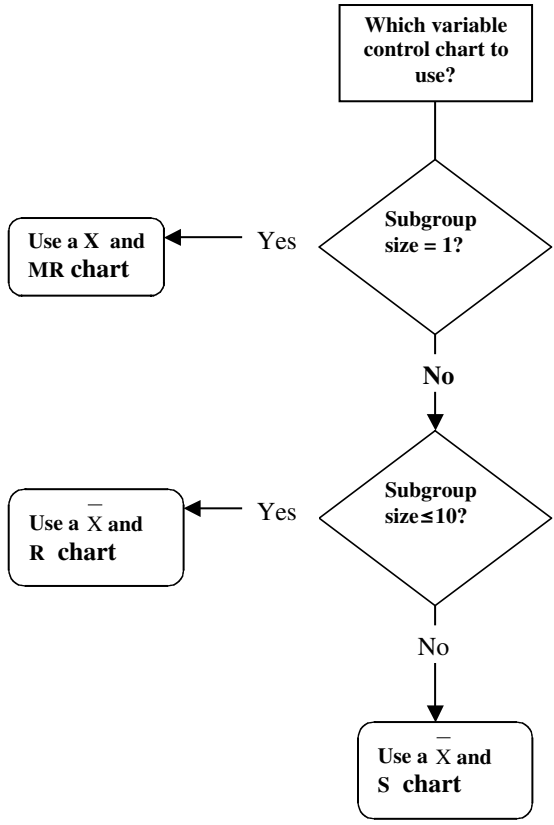


Figure 5.3 Variable control chart selector.

regain control. These control limits usually are considered preliminary and, after obtaining more information, are recalculated excluding all the points outside the control limits.

$\bar{X}$ and R Control Chart

Example 5.4

The net weight in ounces of a product is to be monitored by $\bar{x}$ and R control charts using a sample size of n = 4. Twenty-five samples were taken from a given production line at regular intervals. Table 5.11 shows the data and the computed averages $\bar{x}$ and R.

Table 5.9 Factors for Constructing Variables Control Charts

Sample, n	A	A_2	A_3	B_3	B_4	B_5	B_6	D_1	D_2	D_3	D_4	c_4	d_2
2	2.121	1.880	2.659	0	3.267	0	2.606	0	3.686	0	3.267	0.7979	1.128
3	1.732	1.023	1.954	0	2.568	0	2.276	0	4.358	0	2.575	0.8862	1.693
4	1.500	0.729	1.628	0	2.266	0	2.088	0	4.698	0	2.282	0.9213	2.059
5	1.342	0.577	1.427	0	2.089	0	1.964	0	4.918	0	2.115	0.9400	2.326
6	1.225	0.483	1.287	0.030	1.970	0.029	1.874	0	5.078	0	2.004	0.9515	2.534
7	1.134	0.419	1.182	0.118	1.882	0.113	1.806	0.204	5.204	0.076	1.924	0.9594	2.704
8	1.061	0.373	1.099	0.185	1.761	0.179	1.751	0.338	5.306	0.136	1.864	0.9650	2.847
9	1.000	0.337	1.032	0.239	1.716	0.232	1.707	0.547	5.393	0.184	1.816	0.9693	2.970
10	0.949	0.308	0.975	0.284	1.679	0.276	1.669	0.687	5.469	0.223	1.777	0.9727	3.078
11	0.905	0.285	0.927	0.321	1.646	0.313	1.637	0.811	5.535	0.256	1.744	0.9754	3.173
12	0.866	0.266	0.886	0.354	1.618	0.346	1.610	0.922	5.594	0.283	1.717	0.9776	3.258
13	0.832	0.249	0.850	0.382	1.594	0.374	1.585	1.025	5.647	0.307	1.693	0.9794	3.336

Table 5.10 Formulas and Factors Needed for Calculation of Variable Control Charts

Type of Control Chart	*Characteristic of the Calculation Statistics*	*Upper Control Limit (UCL) Center Line (CL) Lower Control Limit (LCL)*	
Chart of $\bar{X}$	$\bar{R}$ calculated from samples	$UCL = \bar{\bar{X}} + A_2\bar{R}$	
		$CL = \bar{\bar{X}}$	(5.21)
		$LCL = \bar{\bar{X}} - A_2\bar{R}$	
Chart of $\bar{X}$	$\bar{S}$ calculated from samples	$UCL = \bar{\bar{X}} + A_3\bar{S}$	
		$CL = \bar{\bar{X}}$	(5.22)
		$LCL = \bar{\bar{X}} - A_3\bar{S}$	
Chart of R	$\bar{R}$ calculated from samples	$UCL = D_4\bar{R}$	
		$CL = \bar{R}$	(5.23)
		$LCL = D_3\bar{R}$	
Chart of S	$\bar{S}$ calculated from samples	$UCL = B_4\bar{S}$	
		$CL = \bar{S}$	(5.24)
		$LCL = B_3\bar{S}$	
Chart of $\bar{X}$	μ and σ given as standards or known	$UCL = \mu + A\sigma$	
		$CL = \mu$	(5.25)
		$LCL = \mu - A\sigma$	
Chart of R	σ given as standard or known	$UCL = D_2\sigma$	
		$CL = d_2\mu$	(5.26)
		$LCL = D_1\sigma$	
Chart of S	σ given as standard or known	$UCL = B_6\sigma$	
		$CL = c_4\sigma$	(5.27)
		$LCL = B_5\sigma$	

With the results of the previous 25 samples, we set up the control charts. For a sample size of 4, the A_2 factor from Table 5.9 is 0.729 and $D_3 = 0$ and $D_4 = 2.282$. Therefore, the control limits for the $\bar{x}$ chart using Equation 5.21 are:

$$UCL = \bar{\bar{X}} + A_2\bar{R} = 16.065 + (0.729)(0.448) = 16.391$$

$$CL = \bar{\bar{X}} = 16.065$$

$$LCL = \bar{\bar{X}} - A_2\bar{R} = 16.065 - (0.729)(0.448) = 15.738$$

Table 5.11 Group Sampling Record Sheet for an $\bar{x}$ and R Chart

Sample Number	x_1	x_2	x_3	x_4	Σx	$\bar{x}$	R
1	16.0	15.8	16.3	16.1	64.2	16.050	0.50
2	16.3	16.4	15.8	15.9	64.4	16.100	0.60
3	16.1	16.3	16.2	16.2	64.8	16.200	0.20
4	15.8	16.4	16.3	15.9	64.4	16.100	0.60
5	16.3	16.2	16.4	16.1	65.0	16.250	0.30
6	16.0	16.0	16.2	15.8	64.0	16.000	0.40
7	15.8	16.2	15.9	16.1	64.0	16.000	0.40
8	15.9	15.9	15.8	16.0	63.6	15.900	0.20
9	16.1	16.2	16.1	16.2	64.6	16.150	0.10
10	16.2	16.0	16.2	15.8	64.2	16.050	0.40
11	16.4	15.8	16.3	15.9	64.4	16.100	0.60
12	16.3	15.8	16.0	15.7	63.8	15.950	0.60
13	15.8	16.3	15.8	15.9	63.8	15.950	0.50
14	16.0	16.3	16.3	16.0	64.6	16.150	0.30
15	15.8	16.0	16.3	16.1	64.2	16.050	0.50
16	16.2	16.1	16.3	15.8	64.4	16.100	0.50
17	16.3	16.2	15.8	16.3	64.6	16.150	0.50
18	15.8	15.8	15.9	16.1	63.6	15.900	0.30
19	16.2	15.0	16.1	16.4	63.7	15.925	1.40
20	16.1	16.4	16.3	15.8	64.6	16.150	0.60
21	16.3	16.3	16.0	16.2	64.8	16.200	0.30
22	16.1	16.0	15.9	16.0	64.0	16.000	0.20
23	15.9	15.9	15.8	16.2	63.8	15.950	0.40
24	15.9	16.2	16.3	16.2	64.6	16.150	0.40
25	16.0	16.3	16.2	15.9	64.4	16.100	0.40
$\bar{\bar{X}}$ and $\bar{R}$						16.065	0.4480

For the R chart, using Equation 5.23, the control limits are:

$$\text{UCL} = D_4\bar{R} = (2.282)(0.448) = 1.022$$

$$\text{CL} = \bar{R} = 0.448$$

$$\text{LCL} = D_3\bar{R} = (0)(0.448) = 0$$

The $\bar{x}$ and R charts are shown in Figure 5.4 and Figure 5.5.

As can be seen, sample 19 was out of control in the R chart, which means that the process needs to control the variability and that the control

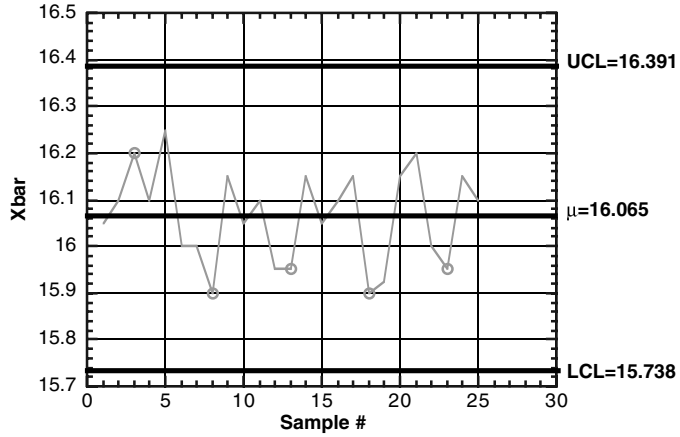


Figure 5.4 Means chart for net weight.

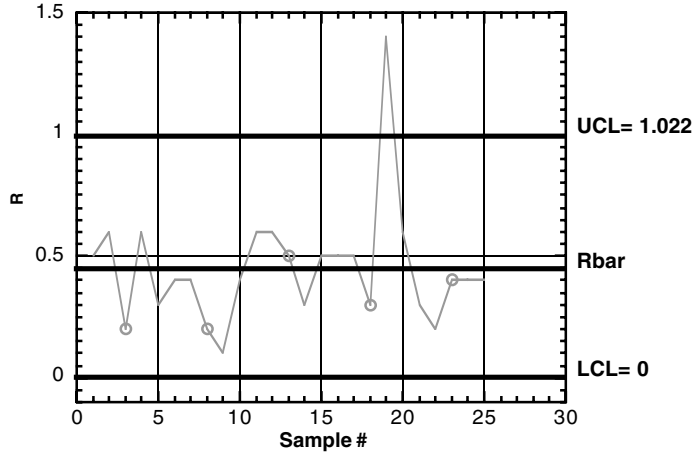


Figure 5.5 Range chart for net weight.

limits of the $\bar{x}$ and R chart should be recalculated when the assignable causes are removed and more data are available. In these recalculations, the data from sample 19 that was out of control and any other data out of control are discarded.

It is common to use computer software packages such as Minitab, StatView, Statistica, etc. to set up the control charts.

$\bar{X}$ and S Control Chart

To construct an $\bar{x}$ and S chart, we need an estimate of μ and S. For each sample, the mean ($\bar{x} = x_1+x_2+x_3+ \cdots +x_n/n$, where n is the sample size) and standard deviation

$$S = \sqrt{\frac{\sum_{i=1}^{n}(x_i - \bar{x})^2}{n-1}}$$

are calculated. With these values, the grand average or mean of means $\bar{\bar{X}}$ ($\bar{\bar{X}} = \bar{x}_1 + \bar{x}_2 + \cdots \bar{x}_n/m$, where m is the number of samples) and the $\bar{S}$ ($\bar{S} = S_1 + S_2 + \cdots + S_m/m$) are calculated; with Equations 5.22 and 5.24 and the factors tabulated in Table 5.9, the control limits for the $\bar{x}$ and S are calculated. As with the $\bar{x}$ and R chart, any point outside the control limits in any of the two charts is considered out of control and corrective action needs to be taken to regain control. These control limits usually are considered preliminary and after obtaining more information, are recalculated, excluding all the points outside the control limits.

Example 5.5

A processor wishes to construct a chart of $\bar{x}$ and S for controlling can fill using a 10-pocket filler with gang-adjusted heads. A net weight of 8 oz is stipulated. A sample plan is devised to periodically collect a sample of 10 cans, one from each filler head. The net weight is measured and recorded in 1/16 oz over and under 8 oz. Data from 20 samples are given in Table 5.12.

With the results of the previous 20 samples, we set up the control charts. For a sample size of 10 cans, the A_3 factor from Table 5.9 is 0.975, B_3 = 0.284, and B_4 = 1.716. Therefore, the control limits for the $\bar{x}$ chart using Equation 5.22 are:

$$\text{UCL} = \bar{\bar{X}} + A_3\bar{S} = 0.05 + (0.975)(2.107) = 2.104$$

$$\text{CL} = \bar{\bar{X}} = 0.05$$

$$\text{LCL} = \bar{\bar{X}} - A_3\bar{S} = 0.05 - (0.975)(2.107) = -2.00$$

The control limits for the S chart using Equation 5.24 are:

Table 5.12 Group Sampling Record Sheet for $\bar{x}$ and S Chart

Sample	*A*	*B*	*C*	*D*	*E*	*F*	*G*	*H*	*I*	*J*	Σx	$\bar{x}$	*S*
1	–3	0	–2	+3	–4	–2	+3	+5	–2	–1	+3	0.3	3.199
2	0	–3	–2	–2	–3	–3	0	+2	+2	0	–9	–0.9	1.969
3	+1	0	–1	–3	–1	+4	–2	–3	0	+3	–2	–0.2	2.348
4	–4	–3	+6	+4	0	–1	0	0	+3	–2	+3	0.3	3.164
5	–2	+4	+2	–1	0	–1	–2	+4	+1	–4	+1	0.1	2.644
6	0	+1	0	–1	–1	+5	+1	+1	–1	–2	+3	0.3	1.947
7	+3	–2	+3	+5	+3	0	–4	–2	0	0	+6	0.6	2.836
8	+4	–1	+1	0	+1	–2	0	–1	–2	+3	+3	0.3	2.003
9	+1	0	–1	–2	–1	–3	+2	0	0	+4	0	0.0	2.000
10	0	–3	0	0	0	–3	0	–3	+3	+1	–5	–0.5	1.958
11	–3	+2	–2	–2	–2	–1	+2	+2	+2	0	–2	–0.2	2.044
12	–1	+1	0	+1	0	0	0	+1	0	–3	–1	–0.1	1.197
13	0	0	+3	–1	+3	0	+3	0	+3	–1	+10	1.0	1.764
14	0	–3	+4	0	+2	–1	+1	–3	–3	0	–3	–0.3	2.312
15	–1	–2	+2	+2	+3	+1	–1	–2	+4	0	6	0.6	2.119
16	+1	0	0	0	–2	–3	0	0	–1	–1	–6	–0.6	1.174
17	+2	+2	–2	–3	0	–1	–2	+2	–1	+1	–2	–0.2	1.874
18	–1	–1	–1	–4	–2	0	0	–1	+5	+2	–3	–0.3	2.406
19	0	–2	0	+2	–1	0	+3	–2	0	–1	–1	–0.1	1.595
20	0	+2	+3	+1	+2	–1	+2	+2	–2	0	+9	0.9	1.595
$\bar{\bar{X}}$ and $\bar{S}$												0.05	2.107

$$\text{UCL} = B_4\bar{S} = (1.716)(2.107) = 3.708$$

$$\text{CL} = \bar{S} = 2.107$$

$$\text{LCL} = B_3\bar{S} = (0.284)(2.107) = 0.439$$

Table 5.12, Figure 5.6, and Figure 5.7 show the data and the $\bar{x}$ and S charts, respectively. It seems that the process is in control; however, the control limits are too wide, indicating an excessive variability. The filler heads weight can be analyzed by an analysis of variance (ANOVA) to show which filler heads are different, and measures can be taken to make the filling operation uniform or, as Kramer and Twigg[8] suggested, the mean square of the error from the ANOVA can be used to calculate the standard deviation and use it to calculate the control limits.

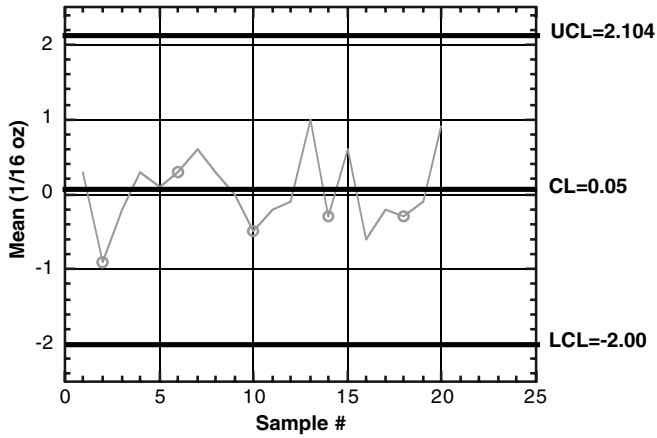


Figure 5.6 Means chart for net weight.

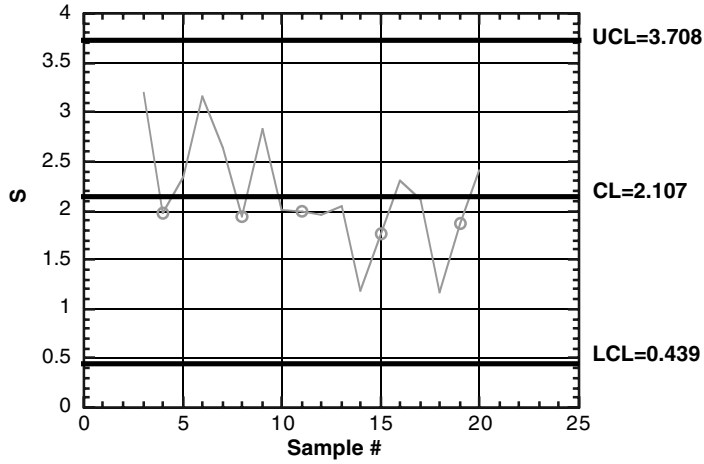


Figure 5.7 Standard deviation chart for net weight.

How to Use Control Charts

Control charts fulfill two equally important functions. One is to indicate when action, i.e., an adjustment in the operation, is needed. The other is to prevent adjustment when action is not needed (Kramer and Twigg[8]). In order to decide if a process is or is not under control, the following criteria should be considered:

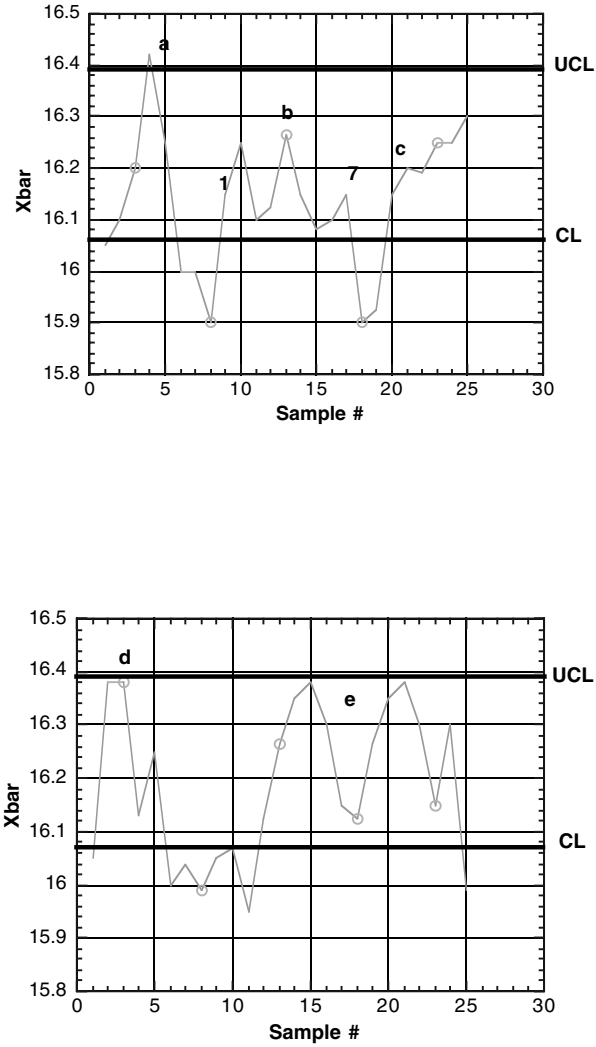


Figure 5.8 Control chart indications for action.

1. A point outside the control limits (Figure 5.8, point a). As previously stated, the probability that a point can fall outside the 3σ limits is 0.0027 (0.00135 for each of the upper and lower control limits).
2. Runs. These refer to a continual series of measurements falling on either side of the central line; the number of measurements is called the run length. The following runs have been suggested.

a. Whenever 7 successive points on the control chart are in the upper or lower side of the central line (Figure 5.8, point b).
b. Whenever at least 10 of 11 successive points on the control chart are on the same side of the central line.
c. Whenever at least 12 of 14 successive points on the control chart are on the same side of the central line.
d. Whenever at least 16 of 20 successive points on the control chart are on the same side of the central line.

Grant and Leavenworth[9] and Montgomery[10] discuss the theoretical bases for these rules. The probability of occurrence of these runs is based on the fact that the probability that a point will fall on either side of the central line is 0.5. For example, for rule a, the probability will be $(2)(0.5)^7 = 0.0156$ that seven successive points fall on either side of the central line. Grant and Leavenworth[9] report that these sequences can occur randomly more frequently than will a point outside the control limit and, for this reason, they provide a less reliable basis for searching for trouble than does the occurrence of a control point outside the control limits.

3. Tendency or trends. When the measurements move continuously in one ascendant or descendant direction (Figure 5.8, point c), the cause can be due to gradual misadjustments or wearing of the machine tools.
4. Closeness to control limits (Figure 5.8, point d). It is considered abnormal if two out of three points fall outside of the two sigma lines (sometimes drawn as warning limits).
5. Closeness to central line. When most of the points tend to cluster around the central line, it does not mean that the process is in control; it can mean that the sample contains a mixture of information from different populations in the subgroups which can overestimate the variability and make the control limits too wide. This situation is solved by changing the way that the subgroups are formed, taking care that they are part of a natural process.
6. Periodicity or cycling patterns (Figure 5.8, point e). It is not normal that the data repeatedly show an ascendant and descendant tendency in a period of time.

It is possible for a process to be statistically in control and not be at a satisfactory level.[10] In this case, the process should be adjusted to meet the requirements or specifications such as the standard of fill weight. If a process is in control, the process capability can be determined and attention should be focused on improving the process.

Attribute Control Charts

Attribute control charts are used when: (a) measurements are not possible (e.g., defect such as dented cans); (b) measurements are not practical (e.g., lengthy chemical analyses of raw products); or (c) several characteristics are combined on one chart (e.g., counts of different kinds of defects).[12] In this case, the various characteristics can be lumped together into a single chart, or at most two or three charts, each covering that group of characteristics which reflects their importance such as minor, major, and critical.[8]

The attribute control charts can be classified into:

- Defective or nonconforming charts [p-chart (fraction nonconforming); np-chart (number nonconforming)]
- Defects or nonconformities charts [c-chart (number of nonconformities); u-chart (average number of nonconformities)]
- Special charts (demerit charts, quality scores charts)

The most used attribute control charts in the food area are the p-, np-, and c-charts.

p-Charts

As with the variable charts, a reference frame or control limit is needed, which can be constructed from past history, if the information is available, or from at least 25 samples. Table 5.13 lists the characteristics and the necessary statistics to implement the p-chart.

When the nonconforming fraction (p) is known or is given as a standard by management, the control chart can be based on those values.

Example 5.6

Canned apricots are peeled by a caustic method; we wish to set up a control chart to improve the fraction nonconforming of the process.

To establish the control chart, 25 samples of variable size were selected during the peeling process. Table 5.14 lists the total number of apricots inspected and the number of nonconforming apricots found for each sample and the calculations of the sample fraction nonconforming, standard deviation for each sample, and the control limits. Figure 5.9 shows a chart of the nonconforming fraction.

Table 5.13 Fraction Nonconforming Control Chart or p-Chart

Based on the binomial distribution.
Assumes a constant probability (p) of occurrence of the nonconforming fraction.
Examines for nonconforming units.
Sample size (n) constant or variable.
Number of samples m.
Nonconforming units in the sample D.

Fraction nonconforming in the sample $p_i = \frac{D_i}{n_i}$

Mean fraction nonconforming $\bar{p} = \frac{\sum_{i=1}^{m} D}{mn}$ for equal sample size or

$\bar{p} = \frac{\sum_{i=1}^{m} p_i}{m} = \frac{\sum_{i=1}^{m} D_i}{\sum_{i=1}^{m} n_i}$ for variable sample size.

Standard deviation of the mean = $\sqrt{\frac{\bar{p}(1-\bar{p})}{n}}$

Central line = $\bar{p}$

Control limits = $\bar{p} \pm 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}}$, if the sample size is variable, the control limits are calculated for each subgroup within the sample size.

np-Charts

The np-chart reports the defects in actual numbers rather than as a fraction. This chart is easier to understand and implement by the operations personnel but requires a constant sample size. In all other aspects, np-charts resemble p-charts.

Example 5.7

The apricot canner in the example above wishes to implement an np-chart for the peeling operation with a constant sample of 500. Assume that the previously $\bar{p} = 0.032$ determined applies. Compute the control limits.

Table 5.14 Data and Calculations for a Control Chart for Fraction Nonconforming with Variable Sample Size

Sample Number i	*Sample Size* n	*Number of Nonconforming Units,* D_i	*Sample Fraction Nonconforming* $\hat{p}_i = \frac{D_i}{n_i}$	*Standard Deviation* $\hat{\sigma}_{\hat{p}} = \sqrt{\frac{(0.032)(0.968)}{n_i}}$	*Control Limits LCL UCL* When $\bar{p} = 0.032$ $\sqrt{p(1-p)} = 0.176$
1	500	11	0.0220	0.0079	0.0083 0.0557
2	650	13	0.0200	0.0069	0.0113 0.0527
3	723	12	0.0166	0.0065	0.0125 0.0515
4	1200	32	0.0267	0.0051	0.0167 0.0473
5	800	23	0.0288	0.0062	0.0134 0.0506
6	450	18	0.0400	0.0083	0.0071 0.0569
7	900	23	0.0256	0.0059	0.0143 0.0497
8	632	20	0.0316	0.0070	0.0110 0.0530
9	566	22	0.0389	0.0074	0.0098 0.0542
10	398	13	0.0327	0.0088	0.0056 0.0584
11	755	28	0.0371	0.0064	0.0128 0.0512
12	823	38	0.0462	0.0061	0.0137 0.0503
13	1010	42	0.0416	0.0055	0.0155 0.0485
14	785	35	0.0446	0.0063	0.0131 0.0509
15	688	33	0.0480	0.0067	0.0119 0.0521

Table 5.14 (Continued) Data and Calculations for a Control Chart for Fraction Nonconforming with Variable Sample Size

Sample Number i	*Sample Size* n	*Number of Nonconforming Units,* D_i	*Sample Fraction Nonconforming* $\hat{p}_i = \frac{D_i}{n_i}$	*Standard Deviation* $\hat{\sigma}_{\hat{p}} = \sqrt{\frac{(0.032)(0.968)}{n_i}}$	*Control Limits LCL UCL* When $\bar{p} = 0.032$ $\sqrt{p(1-p)} = 0.176$
16	925	28	0.0303	0.0058	0.0146 0.0494
17	540	22	0.0407	0.0075	0.0095 0.0545
18	830	34	0.0410	0.0061	0.0137 0.0503
19	450	15	0.0333	0.0083	0.0071 0.0569
20	623	23	0.0369	0.0071	0.0107 0.0533
21	830	25	0.0301	0.0061	0.0137 0.0503
22	645	18	0.0279	0.0069	0.0113 0.0527
23	923	19	0.0206	0.0058	0.0146 0.0494
24	801	12	0.0150	0.0062	0.0134 0.0506
25	725	23	0.0317	0.0065	0.0125 0.0515
Σ	18,172	582	0.0320		

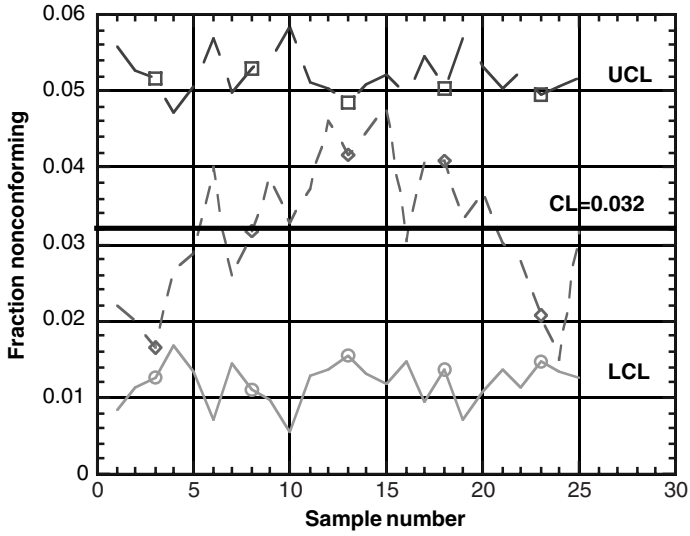


Figure 5.9 Chart of the nonconforming fraction.

The average number of defective $n\bar{p}$ = (500)(0.032) = 16.0.

The standard deviation of the average number of defective $\sigma_{n\bar{p}}$ is calculated with the following equation:

$$\sigma_{n\bar{p}}\sqrt{n\bar{p}\left(1-\bar{p}\right)} = \sqrt{\left(500\right)\left(0.032\right)\left(1-0.032\right)} = 3.935$$

and the control limits applying the determined values are as follow:

$$\text{UCL} = n\bar{p} + 3\sqrt{n\bar{p}\left(1-\bar{p}\right)} = 16 + 3\sqrt{\left(500\right)\left(0.032\right)\left(1-0.032\right)} = 27.806 = 27$$

$$\text{CL} = n\bar{p} = 16$$

$$\text{LCL} = n\bar{p} - 3\sqrt{n\bar{p}\left(1-\bar{p}\right)} = 16 - 3\sqrt{\left(500\right)\left(0.032\right)\left(1-0.032\right)} = 4.193 = 4$$

Control limits are expressed in whole numbers.

c-Charts

These charts report the number of defects by inspection unit and are used when a number of different defects may be found in a unit. Their use is

limited in the food industry, but can have a prominent role in controlling can seaming and labeling and dressing operations.

When the mean nonconformities per inspection unit ($\bar{c}$) are known or are given as a standard by the management, the control chart can be based upon those values.

Example 5.8

In a can seaming operation, the number and type of visual defects that occurred in the seams of 25 sample units of 5 cases of cans (125 cans) were registered.

The average of nonconformities, $\bar{c}$, was = 3.25. Establish the control limits. Using the equations of Table 5.16 we find:

$$\text{UCL} = \bar{c} + 3\sqrt{\bar{c}} = 3.25 + 3\sqrt{3.25} = 8.66$$

$$\text{CL} = 3.25$$

$$\text{LCL} = \bar{c} - 3\sqrt{\bar{c}} = 3.25 - 3\sqrt{3.25} = -2.15 = 0$$

Grant and Leavenworth[9] and Montgomery[10] discuss the application of the attribute special charts. Control charts are tools that indicate the stability or lack of stability of the controlled process; the performance of the operation will depend upon the corrective actions taken when there is lack of control. Control charts are not suitable for operations that must be checked regularly and kept in control; for example, the pH of brines added to acidified products. Furthermore, the common charts discussed are not sensitive enough to detect small changes in the process, and the average run length is large (average number of samples required to detect the change). If a more sensitive chart is required, the cumulative sum control chart (CUSUM) or the exponentially weighed moving average (EWMA) should be used. Control charts pay high dividends to their users. Their implementation usually improves the quality or performance of the process almost immediately.

Table 5.15 Number Nonconforming Control Chart or np-Chart

Based on the binomial distribution
Assumes a constant probability (p) of occurrence of the nonconforming fraction
Examines for nonconforming units
Sample size (n) constant
Number of samples m
Nonconforming units in the sample D

Fraction nonconforming in the sample $p_i = \frac{D_i}{n_i}$

Mean nonconforming units $n\bar{p} = \frac{\sum_{i=1}^{m} D}{mn}$

Standard deviation of the mean = $\sqrt{n\bar{p}\left(1-\bar{p}\right)}$

Central line = $n\bar{p}$

Control limits = $n\bar{p} \pm 3\sqrt{n\bar{p}\left(1-\bar{p}\right)}$.

Table 5.16 Number of Nonconformities per Unit Control Chart or c-Chart

Based on the Poisson distribution.
The probability (p) of occurrence of the nonconformities is inversely proportional to the number of occurrence opportunities.
Examines for nonconformities in inspection units.
Sample size in inspection units (n) constant.
Number of samples m.
Number of nonconformities per inspection unit = c.

Mean of nonconformities per unit $\bar{c} = \frac{\sum_{i=1}^{m} c_i}{m}$.

Standard deviation of the mean = $\sqrt{\bar{c}}$.

Central line = $\bar{c}$.

Control limits = $\bar{c} \pm 3\sqrt{\bar{c}}$.

REFERENCES

1. Kolarik, W.J., 1995. *Creating Quality Concepts, Systems Strategies, and Tools*, McGraw-Hill Co., New York, NY.
2. Moen, R.D., Nolan, T.W., and Provost, L.P., 1991. *Improving Quality through Planned Experimentation*, international ed., McGraw-Hill, New York, NY.
3. Tamborero, J., 2002. Unpublished data.
4. Deming, W.E., 1997. *The New Economics for Industry, Government, Education*, Massachusetts Institute of Technology, Center for Advanced Educational Services, Cambridge, MA.
5. Burguete-Hernández, E., Tamborero-Arnal, J.F., and Morales-Cruz, L., 2003. *Procedimientos Algorítmicos en Diseños Experimentales*, El Cid Editor, Buenos Aires, Argentina.
6. Hubbard, M.R., 1996. *Statistical Quality Control for the Food Industry*, Chapman & Hall, New York, NY.
7. Antony, J., 2000. Ten key ingredients to make SPC successful in organizations, *Qual. Focus*, 4, 4, 38–42.
8. Kramer, A. and Twigg, B.A., 1970. *Quality Control for the Food Industry. Vol. I. Fundamentals*, AVI Publ., Westport, CT.
9. Grant, E.L. and Leavenworth, R.S., 1988. *Statistical Quality Control,* 6th ed., McGraw-Hill, New York, NY.
10. Montgomery, D.C., 2001. *Introduction to Statistical Quality Control*, 4th ed., John Wiley & Sons, New York, NY.
11. Gould, W.A., 1977. *Food Quality Assurance*, AVI Publ., Westport, CT.
12. Kaldy, M.S., 1967. Control charts: their practical use in food processing, *Food Technol.* 21, 505–510.

Chapter 6

MANUFACTURING AUDITS: CONTROL OF PROCESSING OPERATIONS

The success of any food manufacturing operation is dependent upon the degree of control exerted on its various steps.

Quality assurance (QA) programs recognize principles of quality of production and control of production as being their essential elements. These principles require that a producer plan the manufacturing process in such a manner that the process can be carried out under controlled conditions at every step of manufacturing. This process control element of the QA program is recognized as essential for the successful operation of a process and for quality targets to be consistently achieved.[1]

Contemporary process control programs are better executed by an overall function in which in-process inspection represents only one control factor. These programs require that during the design and planning of manufacturing operations, appropriate means must be established so that the process can be carried out under controlled conditions and in a specified manner and sequence, consistent with product quality and specifications.

Process control programs, therefore, include controls of the quality of raw materials (a critical factor governing the quality of a manufactured product), manufacturing equipment, processes and procedures, personnel qualifications, associated supplies, utilities, and environment. An appropriate process control ensures that the manufactured products conform to established quality specifications

In traditional quality control (QC) programs, inspection of the finished products served as the key control function. With the present emphasis

on process control as a critical function in manufacturing, a change in strategy has taken place in industry: from detection to prevention of substandard quality. As a result, finished product inspection is reduced while in-process inspection is emphasized and used as a diagnostic tool.

OBJECTIVES OF PROCESS CONTROL

An effective program of process control aims to:

- Manufacture a product that consistently meets specifications
- Ensure that only acceptable products are released from each step of the overall process
- Favor improved stability
- Reduce variability in the processing steps and in the final product

An appropriate process control program that meets these objectives requires a complete understanding of the process itself, of the equipment and, most important, the establishment of the specifications, which the process is capable of achieving.[2]

ELEMENTS OF PROCESS CONTROL

The development of the appropriate process control program depends, as indicated, on the nature of the process and the type of product manufactured.[2] However, there are certain elements that are inherently characteristic of a process control program: employee training, documentation, processing, QC, etc. Figure 6.1 summarizes a process control program and its key elements.

EDUCATION AND TRAINING

Personnel capability to accurately implement the process control procedures is critical to the success of the program.

Personnel must be trained to perform the assigned process control activities. In many instances, this requires formal training in principles and practices, along with relevant engineering, statistical, analytical, instrumental, or related procedures.

A record of the training program should be maintained so as to know who is knowledgeable and capable of performing a designated process control activity. The plan should also include provisions for upgrading personnel training whenever equipment or instruments are updated or when new procedures are introduced into the process. Such a program will ensure that employees are able to keep up with technological progress.

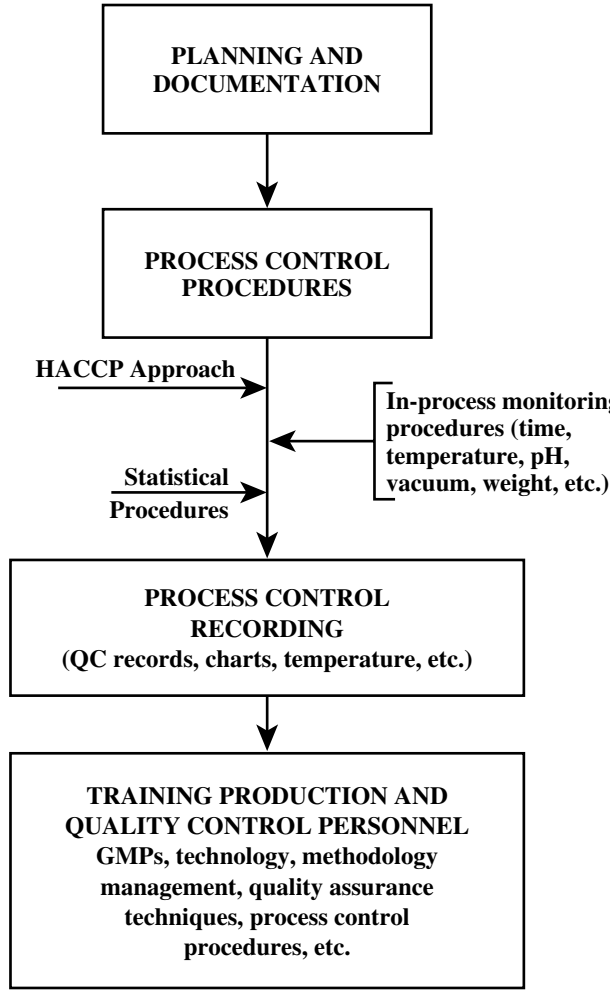


Figure 6.1 Key elements in a process control program.

PROCESS CONTROL DOCUMENTATION

Documentation is a critical requirement for the execution of a well-conceived process control program. Documents must be developed specifically for the process and the product. This requires a complete understanding of the entire process. A flow diagram describing the paths followed by raw materials in their conversion to finished products is valuable. This diagram should identify the operations to be performed, their sequence, facilities and processing equipment to be used, and the

process conditions to be employed. This document serves as the basis for planning process control activities and should include:

- Instructions and procedures to be followed during production
- Procedures for process monitoring and inspection
- Characteristics to be measured
- Procedures for measurement (frequency, time, place, personnel) and methodology to be used
- Procedures for sampling, identification of samples, and analysis of the data obtained from the measurements

The procedures should be documented in a concise and easily understood manner, identifying critical areas and critical elements of the process. The language should be simple so that instructions are easy to follow; a program for process control is of little value if it is not completely understood by the personnel directly responsible for carrying out the control activities.

Where measurements are to be taken, instructions for the calibration of measuring instruments must be described. In addition, the sampling procedures to be used for process control monitoring must be clearly described.

The system used for documentation should recognize the need for updating instructions whenever changes of procedures, new procedures, or new equipment take place. It is essential that the incorporation of new instructions be simultaneous with the use of the new procedures or equipment.

It is not uncommon to find situations where procedure modifications (or new procedures or equipment) have been implemented while the documentation associated with these changes lags well behind the actual use of the new facilities. In these cases, critical risk in processing and product quality can occur due to document misinformation or incorrect instructions.

The best way to maintain control of a manufacturing process is to divide it on the basis of the unit operations involved. The "unit operations" approach will allow control of each factor that plays a role in each step (unit operation) of the manufacturing process. With this approach, not only are the factors involved identified (and modified if there is a change in the process), but it will also be possible to keep control of them, thus optimizing the process.

UNIT OPERATIONS IN THE FOOD INDUSTRY

All food processing involves a combination of procedures to achieve the intended changes of the raw materials. These procedures are conveniently categorized as "unit operations," each of which has a specific, identifiable,

and predictable effect on a food. Unit operations are grouped together to form a process. The combination and sequence of operations determine the nature of the final product.

A unit operation is defined as the operation of a piece of equipment or equipment system that accomplishes some specified function on the product being processed and is typically labeled by the function it accomplishes. Some of the unit operations commonly found in food processing are batching, heating, cooling, blending, pasteurization, sterilization, freezing, evaporation, dehydration, fermentation, distillation, extraction, separation, etc. For any unit operation, a wide variety of different types of equipment and systems can be used, depending on the specific nature of the product being processed.[3]

Most unit operations are utilized in the making of a variety of food products. Heat exchanging, or heating, for example, is used in the manufacture of liquid and dry food products, in such diverse operations as pasteurizing milk, sterilizing foods in cans, roasting peanuts, and baking bread.

Unit operations may include numerous different activities. Mixing, for example, includes agitating, beating, internal diffusing, dispersing, emulsifying, homogenizing, kneading, and whipping. Food processing is the selection and combination of unit operations into unit processes and more total processes.

Materials Handling

This operation includes such varied procedures as hand and mechanical harvesting on a farm, refrigerated trucking of perishable produce, boxcar transportation of live cattle, and pneumatic conveying of flour from rail car to bakery storage bins. Throughout such operations, emphasis must be given to maintaining sanitary conditions, minimizing product losses (including weight loss of livestock), maintaining raw material quality (e.g., vitamin content and physical appearance), minimizing bacterial growth, and timing all transfers and deliveries so as to minimize holdup time, which can be costly as well as detrimental to product quality.

Cleaning

Cleaning ranges from simple removal of dirt from egg shells with an abrasive brush to the complex removal of bacteria from a liquid food by passing it through a microporous membrane. Cleaning can be accomplished with brushes, high velocity air, steam, water, vacuum, magnetic attraction of metal contaminants, etc., depending upon the product and the nature of the dirt.

Separation

This procedure encompasses the separation of solids from solids or solids from liquids, as in many types of filtration; or a liquid from a solid, as in pressing juice from a fruit. It may involve the separation of a liquid from a liquid, as in centrifuging oil from water; or removing a gas from a solid or a liquid, as in vacuum removal of air from canned food in vacuum canning. One of the most common forms of separation in the food industry is the hand sorting and grading of individual units as in the case of vegetables and fruits.

Disintegration

A wide range of operations used to subdivide large masses of foods into smaller units is classified as disintegrating. It may involve cutting, grinding, pulping, homogenizing, etc.

Pumping

Pumping is one of the most common unit operations in the food industry. It allows the moving of liquids and solids from one processing step into another by using different types of pumps, depending on the character of the food to be moved.

Mixing

Different types of mixers or blenders are used in the food industry depending upon the characteristics of the material to be mixed. It may be necessary to mix solids with solids, solids with liquids, liquids with liquids, gases with liquids, etc.

Heating

Heating of foods is used to destroy microorganisms and preserve the food (pasteurization, sterilization). It is also used to drive off moisture (dehydration, drying), to develop flavors (coffee roasting, peanut roasting), for cooking (making foods more tender and palatable), to inactivate enzymes, and to destroy natural toxic substances. Common methods of heating are conduction, convection, and radiation, and a combination of these.

Cooling

Cooling is primarily used to preserve a food-keeping quality. Some foods however, owe their entire character to their frozen state (e.g., ice cream).

Evaporating

Used principally to concentrate foods by removal of water, evaporation is also used to recover desirable food volatile compounds.

Drying

This operation's objective is to remove water from a food with minimum damage to it. While evaporation can concentrate foods two- or threefold, driers will take foods very close to total dryness (97 to 98% solids). Driers are used to prepare food products such as dried milk powder and instant coffee.

Packaging

Packaging is used primarily to protect a food from microbial contamination, physical dirt, insect invasion, light, moisture pickup, undesirable flavor pickup, moisture loss, flavor loss, etc.

Foods are normally packed in metal cans, glass and plastic bottles, paper, various plastic and metallic films, and combinations of these materials.

Controlling

Controlling may be considered a unit operation in itself. Its tools are valves, thermometers, scales, thermostats, and a wide variety of other components and instruments to measure and adjust such essential factors as temperature, pressure, fluid flows, specific gravity, viscosity, time, and liquid level.

Overlapping Unit Operations

The absolute individual classification of unit operations is not perfect and usually they are present in an overlapping fashion.[1] For example, filtering bacteria out of beer might logically be considered cleaning or it might be considered separating; moving milk to a cheese vat might be viewed as pumping or it might be considered material handling. Overlapping, however, does not seriously detract from the value of the unit operations concept. Common sense usually helps the professional in the appropriate classification for his most beneficial assessment of a process.

Figure 6.2 through Figure 6.10 are examples of unit operations flowcharts for the manufacture of tomato sauce.

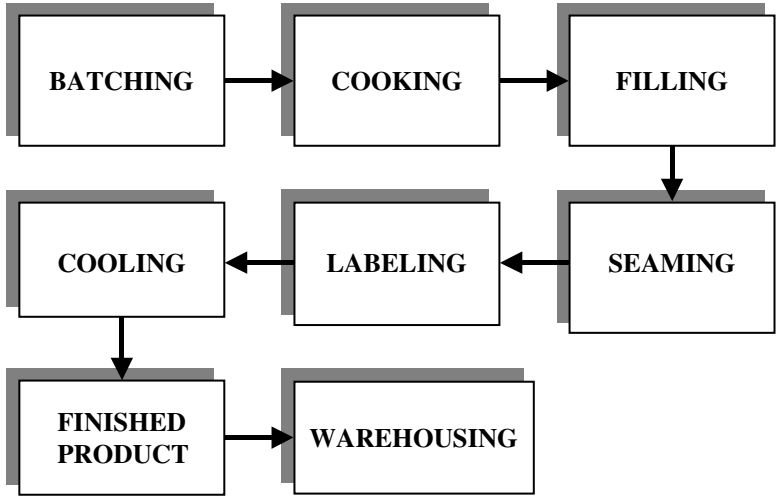


Figure 6.2 Tomato sauce manufacturing flowchart.

PRODUCT MANUFACTURING AUDITS

The purpose of a product manufacturing audit is to verify that all of the general conditions for the manufacturing of food in a processing plant are met.[1]

The conditions involve not only the task of certifying or reporting errors regarding formulation accuracy, the prevention of possible adulteration and contamination incidents, and the handling of ingredients, but also the proper function of the instruments and equipment directly (or indirectly) involved in the manufacturing process of a given product, as well as proper and accurate analysis of ingredients and product at the different stations within the conditions stipulated in the quality control program for the product being audited.

Planning the Audit

Manufacturing audits should be planned, and the plant being audited should be notified well in advance of the scheduled date. The audit should not be a surprise visit to catch wrongdoing, but rather a tool to help the company.

An audit plan should identify:[4]

- The purpose and scope of the audit
- The auditee and organizational units to be audited

- The audit team members
- The standard being audited against (specific sections of the standard may be included)
- Logistic issues such as the date and place of the audit, the expected duration of the audit, and the expected date of issue of the audit report

In addition, when applicable, the audit plan may list confidentiality requirements, transportation requirements, or required health and safety permits or security clearances.

A product-manufacturing audit is a comprehensive inspection of a manufacturing process to determine if it is performed satisfactorily, under normal day-to-day operation. The audit is usually limited to a small portion of units produced, but the manufacturing processes involved are reviewed thoroughly.[5] An audit does not replace normal QC efforts, but rather supplements them.

A manufacturing process is audited by direct observation of the manufacturing "in-site," and by auditing the records of the procedures maintained by the plant. This is done because the records contain detailed information of the manufacturing process; they specify not only what work is to be accomplished but also where and who is doing it. The auditor should also have access to the manufacturing and analytical records for the work being carried out.

There are many reasons for conducting a product-manufacturing audit.[5] Among these are:

- Assuring that the procedures reflect actual practices
- Uncovering inaccuracies so that they can be quickly corrected
- Determining the consistency of a process (from person to person, or day to day)
- Demonstrating a proactive approach to process improvement
- Encouraging ongoing corrective action

Manufacturing audits are not meant to catch people doing something wrong. A manufacturing audit is more than just walking into a working area, looking for problems; on the contrary, during an audit it is expected to find people doing things right. Thus, a good approach to a product-manufacturing audit is to announce it in advance.

The auditors should be familiar with both the area they will be observing and with auditing techniques.[6] They should classify their observations on the basis of a rating scheme that can allow them to rank problems in order to prioritize corrective actions. Ideally, employees

working on the process would assist in the resolution of any problems found. This approach increases the employees' sensitivity to the problem.

Audits must be carefully planned and orchestrated for maximum benefit. The following steps help in planning and conducting an audit.

- **Select the manufacturing process to audit.** It may be best to begin with a relatively efficient process that has a history of success. However, it may preferable to jump right into a process that has had a record of ongoing performance problems.
- **Decide who will conduct the audit.** Ideally, the audit team should be made up of individuals who have audit experience, and are also generally familiar with the process to be audited.
- **Decide the frequency of the audit.** It should be decided how often members of the audit team will observe the process. The more nonconformances discovered, the more frequent the observations, until such a level of confidence is gained that the observations can be scaled back.
- **Record the audit schedule on a form.** Audit times should be as random as possible and scheduled throughout an entire shift. There should be a written record of this schedule that is distributed to each member of the audit team.
- **Conduct the audit according to the audit schedule.** Once you make the permanent schedule, it should be followed. This requires a commitment from everyone involved with the process.
- **Document problems discovered.** This becomes the permanent record and the basis for all follow-up actions.
- **Inform all those affected.** While on the site, inform the manager and the supervisors of the results of the audit, so that critical deviations are corrected as soon as possible. Ideally, not only should the employees working in the process be informed of the audit results, but all employees affected by the performance of the process should be notified also. This will assure that everyone is aware of problems discovered and may generate additional suggestions for improvement. However, this decision is up to the plant's management personnel; they may decide to review the results with the employees in a different manner.
- **Monitor corrective action results.** Observe the corrective action to determine if it really eliminated the problem. Auditing is a proactive effort to assure that a manufacturing process is under control. Auditing also indicates a willingness to go beyond the status quo and commit to continuous improvement.

In general, a product manufacturing audit involves the following areas:[1]

Documentation

Product-Specific Manufacturing (PSM) Procedures

This document directly addresses the manufacturing procedure of a given product, specifically establishing the processing parameters at each stage, referring to General Manufacturing Operation (GMO) documents when these are required for handling or QC procedures, and to Quality Control Analytical Methods (QCA) when these are required for analysis of the product at any given processing step.

An example of this type of document is included in Figure 6.3 (Salsa, South American Style, Product Code: SS001).

In the document, the requirement for spices in preparing the seasoning mix includes 7.2 lb of chili spice, 2.75 lb of cayenne pepper, and 0.97 lb of ginger. The specifications for these ingredients are IC319 for chili spice, IP011 for cayenne pepper, and IG044 for ginger. In total, preparation of the seasoning mix corresponds to six risk requirements (three for ingredient weight and three for ingredient specification). These are considered risks because they are required in amount and ingredient specifications in the document, and because a change in weight and specification might result in a change in the sensory and general quality of the finished product. Water is not considered a risk requirement in this stage because its function is to help dissolve/suspend the dry ingredients and because in the following stage, the total amount of water required in the total formulation will be completed.

Analysis of the manufacturing process for risk requirements in every stage, considering the requirements present in each general manufacturing operation document, sanitation document, and analytical test methods involved, will result in a number of requirements against which the audit will be carried out and evaluated. Figure 6.4 shows a final evaluation of a manufacturing audit.

General Manufacturing Procedures

These documents describe a certain activity related to the manufacturing process of a specific product. They are used in conjunction with the prescribed manufacturing document to control the manufacture of the product. They address different aspects of the total manufacturing process, for example:

- The Can/Glass Container Packaging Document addresses the procedure by which a product is canned, labeled, and coded, and the container handled, to the warehouse, so as to preserve intact quality.
- The Weight Control Document addresses the procedure for determining the net weight of the product during manufacture.

An example of these documents is presented in Chapter 3.

Eureka Foods, Inc.
Quality Assurance/Quality Control
PRODUCT-SPECIFIC MANUFACTURING PROCEDURE

Product: SALSA, SOUTH AMERICAN STYLE — Product Code: SS001
Manuf. Plant: NAMPAHC — Location: Orange, CA
Revision: 1st Issue — Issue Date: 09/17/00
V. P. Operations. Approval: _____ — V. P. QA. Approval: _____

I. General Requirements per General Maintenance Requirements (GM001)

II. Clean per Sanitation Standard Procedures (GS040)

III. MANUFACTURING PROCEDURES

A. **Seasoning Mix Vessel:** Combine chili spice, cayenne pepper and ginger (as indicated in the operating formula) with 40 lb of water. Let stand a minimum of 10 minutes.

B. Add tomato puree to processing tank.

C. While agitating, add salt, starch, remaining water, sugar and the seasoning mix from **A**.

D. Heat product to a minimum of 195°F.

E. Add vinegar and mix well.

F. Fill containers to 175°F minimum. MT001.

G. Seam the cans per GS002.

H. Check net weights per GN010, MN001.

I. Cool product to 120°F maximum center jar temperature per MT001, MC010, GC010, MS020, GI020.

J. Code per GC030.

K. Case per GC005, GS020.

IV. PRODUCT QUALITY CHARACTERISTICS

Characteristic	*Limit*	*Frequency*	*Method*
Acid	1.20	1/hour	MA001
Brix	46.5	1/hour	MB001
Bostwick	TBD	1/hour	MC001
Flavor/Odor	Typical	1/hour	Organoleptic
Appearance	Typical	1/hour	Visual
pH	3.6-3.7	1/hour	MP001
Torque	TBD	1/hour	MT010
Headspace	TBD	1/hour	MH001
Vacuum (min.) @ 70°F	5″	1/hour	MV001

Figure 6.3 Example of a product-specific manufacturing procedure document.

V. OPERATING FORMULA

Ingredient	*(lb)*	*Formula (%)*
Tomato Puree (IT049)	673.20	67.320
Sugar (IS025)	120.00	12.000
Vinegar (120 gr) (IV002)	100.00	10.000
Water	80.00	8.000
Salt (IS004)	8.38	0.838
Starch (IS092)	7.50	0.750
Chili Spice (IC319)	7.20	0.720
Pepper, Cayenne (IP011)	2.75	0.275
Ginger (IG044)	0.97	0.097
		100.000

Figure 6.3 (Continued)

Standard Sanitary Operation Procedures

Sanitation Standard Operating Procedure (SSOP) documents describe the procedures that must be followed in order to make sure that cleaning and sanitation activities are performed correctly.

A detailed description of these documents is reviewed in Chapter 3.

Analytical Control Procedures

These methods can be used, as such, or adapted to the company's needs, as long as the variations do not affect their accuracy and replication when used against the official version and have been tested and checked by collaborative studies with other laboratories. Examples of this type of document are reviewed and presented in Chapter 3.

Definitions

Quality Management Areas (Unit Operations)

Using the TQM terminology, quality management areas are those corresponding to the unit operations employed in the food industry. They can be classified as product-dependent operations when they can directly affect the properties or characteristics of the product and as product-independent operations if they do not affect the quality of the product. They could, however, affect the product indirectly if they are not carried out appropriately.

Mustard, Mayonnaise and Salad Dressing Manufacturing Programs

Quality Areas		*# Items Audited*			*# Deviations*			*% Compliance*		
		Overall	*Risk*	*Nonrisk*	*Overall*	*Risk*	*Nonrisk*	*Overall*	*Risk*	*Nonrisk*
I.	**Batching**	**255**	**233**	**22**	**41**	**40**	**1**	**84**	**83**	**95**
	Mustard	96	77	19	21	20	1	78	74	95
	Mayonnaise	106	104	2	16	16	—	85	85	100
	Salad dressing	53	52	1	4	4	—	92	92	100
II.	**Filling**	**99**	**9**	**90**	**—**	**—**	**—**	**100**	**100**	**100**
	Mustard	44	4	40	—	—	—	100	100	100
	Mayonnaise	33	3	30	—	—	—	100	100	100
	Salad dressing	22	2	20	—	—	—	100	100	100
III.	**Seaming***	**15**	**9**	**6**	**4**	**1**	**3**	**73**	**89**	**50**
IV.	**Sterility**	**62**	**62**	**—**	**6**	**6**	**—**	**90**	**90**	**—**
	Mustard	22	2	20	—	—	100	100	100	
	Mayonnaise	22	2	20	—	—	100	100	100	
	Salad dressing	22	2	20	—	—	—	100	100	100
V.	**Packaging***	**27**	**3**	**24**	**2**	**—**	**2**	**93**	**100**	**92**
VI.	**General Quality**	**51**	**51**	**—**	**14**	**14**	**—**	**73**	**73**	**—**
	Mustard	20	20	—	3	13	—	85	85	—
	Mayonnaise	22	2	20	—	—	—	68	68	—
	Salad dressing	22	2	20	—	—	—	58	58	—
VII.	**Product Disposition***	84	2	82	5	2	3	94	0	96
VIII.	**Test Methods**	**12**	**—**	**—**	**0**	**—**	**100**	**—**	**—**	

* Product independent operation.

Figure 6.4 Summary. Program compliance by quality management areas.

Product-Dependent Operations

Ingredient Preparation. This unit operation or quality management area consists of selecting the ingredients to be used for the manufacture of a product according to their correct specification, and by weighing or measuring them and getting them ready for preparing the formulation during the batching operation. The preparation of ingredients is carried out in accordance with the procedures delineated in the Product Specific Manufacturing (PSM) document for the product being produced, and in the General Manufacturing Operations (GMOs) documents and production schedules.

Ingredient preparation equipment may include tanks, pumps, scales, mixers/blenders, material handling equipment. Confirming equipment status involves checking that hygiene and sanitation standards are met, all safety guards are in place, and equipment is operational.

Materials used in the water phase of the ingredient preparation step may include potable water, milk, milk products and other protein sources, and preservatives, of which the most common are salt, acids, and antioxidants. Materials used in the oil phase of the ingredient preparation step may include emulsifiers, vitamins, colors, and flavors. Services may include electrical power, water, heating, and refrigeration. Monitoring the process may involve the use of production data such as performance control charts. Process operation and monitoring functions may be manual or involve the use of a process control system.

In an audit process, this area also includes the ingredient specification documents, as well as the weight of the ingredients and the instructions for preparation of each one of them, as specified in the corresponding section of the PSM document.

Batching. The procedure, as specified in the corresponding PSM document, by which a formula is prepared to produce a given quantity of product. Batching includes the amount of each ingredient, the sequence in which these are to be added, the temperature of processing, and the time that the product mixture is to be kept at the processing temperature (Figure 6.5 and Figure 6.6).

Generally, the batch method uses a vat pasteurizer, which consists of a jacketed vat surrounded by either circulating water or steam or heating coils of water or steam.

Filling. The process of filling the heat-processed product into containers. The product then can be sealed or subjected to thermal processing (sterilization or pasteurization) (Figure 6.7).

Thermal Processing (Pasteurization, Sterilization). Pasteurization describes a process whereby a food is heated at a specific temperature for a period of time, to destroy microorganisms of human health signifi-

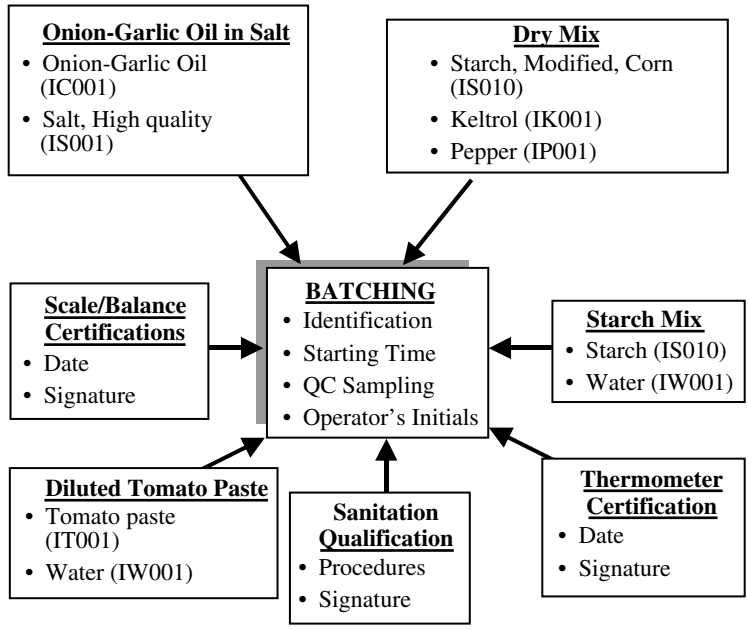


Figure 6.5 Tomato sauce manufacturing flowchart, batching operation.

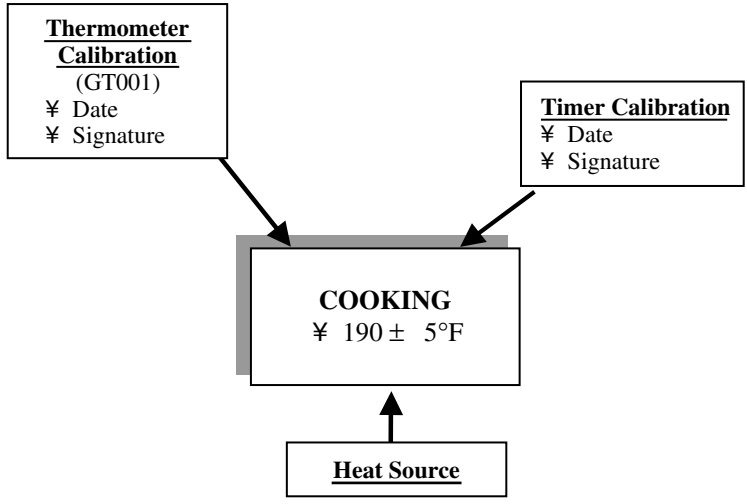


Figure 6.6 Tomato sauce manufacturing flowchart, thermal process operation.

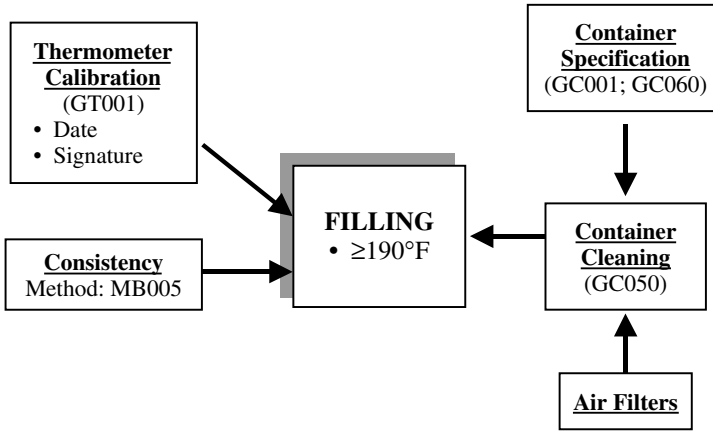


Figure 6.7 Tomato sauce manufacturing flowchart, filling operation.

cance. Temperatures can range from 65 to over 100°C, and the heat kills all the undesirable germs in the food that would otherwise cause the food to spoil or cause persons to become sick. Some high acid products do not require this thermal process. The cooking and maintenance of the cooking temperature in the batching stage are enough to pasteurize the product. They are further preserved by the high acid characteristic.

General Quality. This area refers to the control of all the biological, chemical, and physical quality characteristics that identify a product for what it is. The general quality area includes the permissible limits of each of the product characteristics (acidity, pH, texture, etc.) and the frequency and the method by which these characteristics should be determined.

Product-Independent Operations

Seaming. The process of hermetically sealing the can to protect the product (Figure 6.8). Can seaming machines, also referred to as "seamers" or "closers," mechanically attach component ends to can bodies in a reliable hermetic manner, i.e., air-, liquid-, and bacteria-tight to prevent leakage and spoilage, thus preserving the product.

Packaging. The process of preserving products from any possible damage caused by contamination after processing accomplishes three basic functions: protect and hold the product in containers, provide information about the product (product labeling), and identify the product by distinguishing it from other similar products (brand name) (Figure 6.11).

Product Disposition. The process by which the plant management decides the destiny of a manufactured product. The product may be

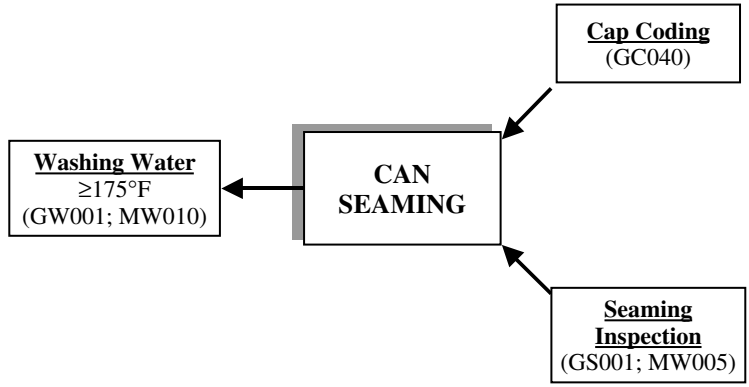


Figure 6.8 Tomato sauce manufacturing flowchart, can seaming operation.

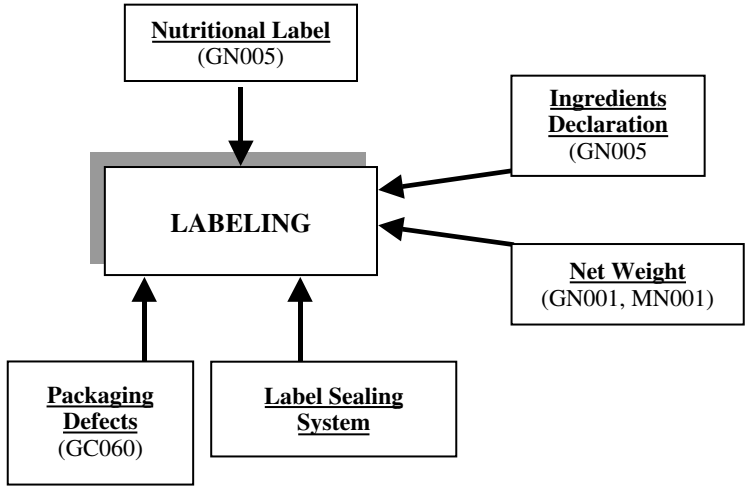


Figure 6.9 Tomato sauce manufacturing flowchart, labeling operation.

released to the warehouse, following the proper procedure indicated in the PSM and the GMO documents (Figure 6.12), or the product may be put on hold, so the dispositions of the GMO document (Hold, Product GH001) can be followed; the product then can be disposed of as specified in the GMO document GD001 (Product disposition).

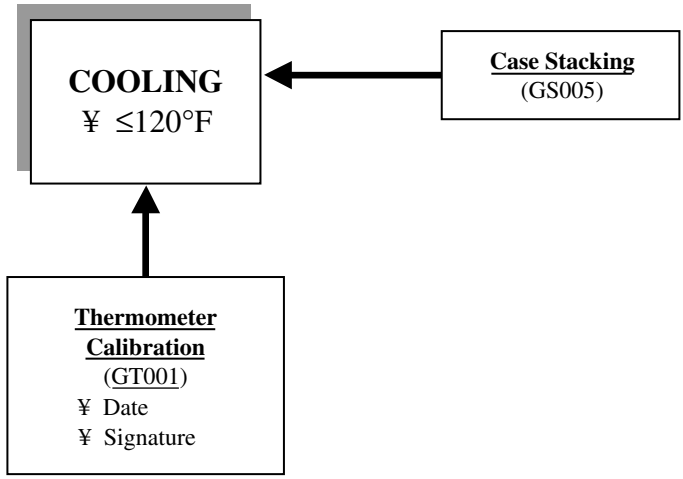


Figure 6.10 Tomato sauce manufacturing flowchart, cooling operation.

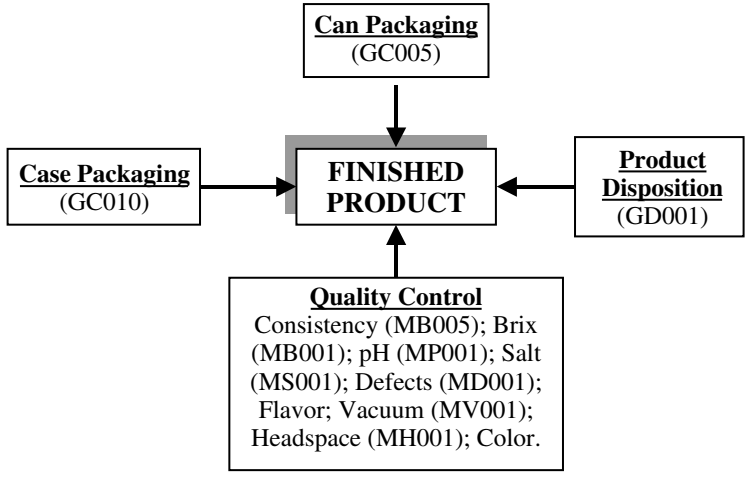


Figure 6.11 Tomato sauce manufacturing flowchart, finished product QC qualification.

Process Control Points

Control points refer to key points in a work process, which must be monitored and controlled. This includes food safety (critical) quality and regulatory control points as well as inspection points. Information systems may be print or screen based.

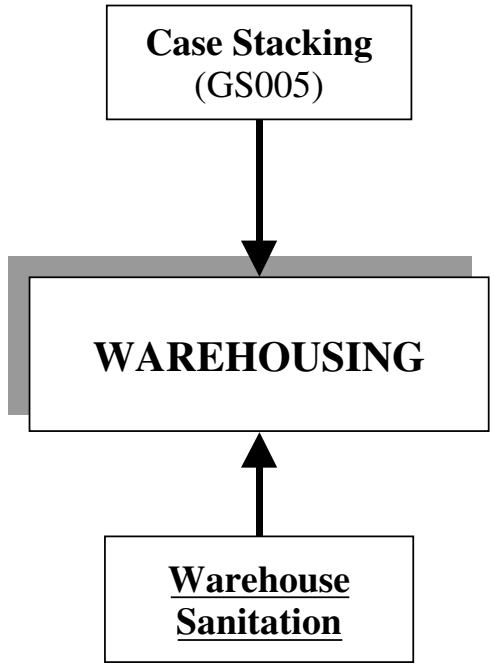


Figure 6.12 Tomato sauce manufacturing flowchart, warehouse storage operation.

Batching

Ingredient specification/identification. Materials are confirmed and available to meet production specifications; services are confirmed as available and ready for operation.

Cleaning procedures. Equipment is checked to confirm readiness for use. The process is set to meet production specifications.

Product formulation. Ingredient amounts (scale certification, standardization, etc.), premix preparation, and sequence of ingredient addition are verified.

Operate and monitor the process. The process is started up according to company procedures; materials are batched, prepared, blended, and cooked to specification. Mixing requirements, heating procedure, and heating time are followed as prescribed in the manufacturing document. Control points are monitored to confirm product meets specification (thermometer calibration, standardization records, etc.).

Equipment is monitored to confirm operating condition. Out-of-specification product, process, and equipment performance are identified, rectified, and reported.

Shutdown the process and clean equipment. At the end of the processing operation, the equipment used is shut down according to company procedures and prepared for cleaning. Waste generated by the process is collected, treated, and disposed of or recycled according to company procedures.

Record information. Workplace information is recorded on the appropriate forms.

Manufacturing Procedure Deviations

Risk Deviations

The manufacturing process includes certain points or requirements that are considered quality risks if not carried out as required in the manufacturing document and in the GMO documents. Analytical tests are, by definition, risk requirements.

Risk deviations are defined as manufacturing process practices that deviate from risk requirements, or practices that could result in the production, nondetection, or prolonged manufacture of a product not meeting its quality objectives.[1] Risk deviations could include deviations from specified process parameters, from formulation, from testing frequency, and from test methodology.

When test methodology is a risk deviation, it is reported relative to the unit operation for which the test is required, as well as from the test methodology quality management area.

Nonrisk Deviations

Nonrisk deviations are manufacturing process deviations not categorized as risk deviations in the manufacturing procedure document, or substitute procedures used by the plant, provided that the procedure is not likely to result in the production or nondetection of an off-quality product or decrease in safety.[1] If appropriate, the auditor should recommend substitution of such procedures in the manufacturing document to reflect actual manufacturing practices.

Nonrisk Deviations to Risk Requirements

Nonrisk deviations from program requirements, classified as risk items, may occur during an audit process. In such cases, in order to follow the QA system evaluation and comply with the quality program on the basis of the definitions or risk and nonrisk deviations indicated above, the following alternatives are considered:

1. Although the deviation is of a nonrisk nature, classify it as a risk deviation since it is related to a risk requirement.
2. Classify the deviation as a nonrisk, but do not use it to calculate % compliance to either risk or nonrisk items.
3. Change the requirement, previously classified as risk, to nonrisk ONLY to make the requirement consistent with the observed deviation in the particular audit where the observation was made.
4. Include the deviation for calculation of percent compliance to nonrisk requirements, although the nature of this deviation is different than any of the nonrisk requirements.

Obviously, the best alternative, and the one to be used, is number 2.

Figure 6.4 shows a summary of manufacturing program requirements, number of risk and nonrisk deviations, and percent program compliance.

Audit Deviations: Example

Deviations from the Manufacturing Program

Batching and Formulation Practices

Traditional Chocolate Manufacturing Line

Observation #001 — RISK. Granular Sugar Addition

The manufacturing document requires a 900 lb/batch to be used. During manufacturing, the scale used to weigh this ingredient (Toledo-Honest Weight — 2000 lb. capacity — calibration record 6/5/00) was set at 900 lb (Figure 6.13).

After delivery from the silo into the sugar hopper, the scale went beyond the zero mark (side 2) and showed 920 lb (on side 1), indicating that 920 lb were delivered instead of the required 900 lb (Ref. HACCP Observation #007).

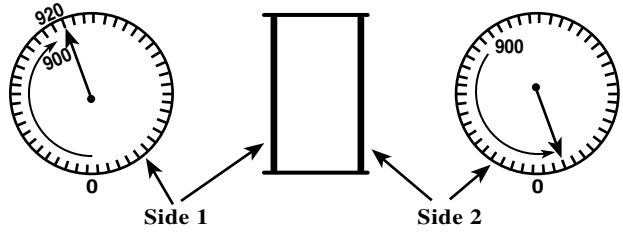


Figure 6.13 Weighing scale readings.

Observation #002 — RISK. Vegetable Oil Addition
During manufacture, the operator at the batching station was not compensating for the tare weight of the container (2 1/2 lb) when weighing this ingredient. As a result, 85 1/2 lb per batch were being added instead of the required 88 lb.

Upon notification, the error was immediately corrected by the shift supervisor.

De Luxe Chocolate Manufacturing Line

Observation #003 — RISK. Granular Sugar Addition
The amount of sugar required was 750 lb. Due to the condition of the Toledo scale, as reported in Observation #001, the actual weight of sugar added to a batch of this product was 761 lb (Ref. HACCP Observation #007).

Strawberry Topping Manufacturing Line

Observation #004 — RISK. Granular Sugar Addition
The amount of sugar required for this product was 688 lb. Due to the condition of the scale used, as reported in Observation #001, the actual weight of sugar added to a batch was 695 lb (Ref. HACCP Observation #007).

Ingredient Qualification and Storage Program

Ingredient Analysis Program

The following deviations from the required program procedure were observed.

Observations #005–006 — RISK. Consistency Brabender
Consistency Brabender was not determined for starch samples, as required. The plant lacked the appropriate instrument, as indicated by the corresponding test method. This deviation affected the qualification of two ingredients (modified waxy starch and regular starch) that are used in the manufacture of several products.

Analytical Test Methods

Consistency Brabender

Observation #005–006 — RISK. Ingredient Qualification
The plant did not determine starch sample consistency. The quality control laboratory did not have the appropriate instrument to determine Brabender consistency.

The manufacturer of modified waxy starch provides the Brabender characteristics of this product.

HACCP Analysis

Batching and Formulation Program

Granular Sugar — Weighing Scale

Observation #007 — RISK.
The deviation reported in Observations #001, 003, and 004 showed that the Toledo scale used to weigh the sugar was in need of calibration. The plant was made aware of the situation and action was immediately taken to correct the individual deviation. The plant management indicated that the scale would be serviced and calibrated during downtime, the week of August 8, 2000. A service log and records of calibration, and periodic check-ups will be kept by the QC department.

Recommendation
The plant should make sure that all scales are properly calibrated at all times.

Strawberry Topping Batching

Observation #008 — NONRISK.

a. In preparing the premix for this product, the plant used two 30-lb cans (or 60 lb total) of frozen strawberries. The required amount of this ingredient is specified as 54 lb in the corresponding manufacturing document.
b. For a final batch, an additional 52 30-lb cans (or a total of 1560 lb) of frozen strawberries were used. Per the manufacturing document the additional amount required to be added to the final batch was 1566 lbs.

When considering these two deviations, it was noted that the total amount of strawberries added to a batch was 1620 lb, as required by the document; the partial amounts (as described in a and b) were different.

Recommendation
The practice regarding the amount of strawberries added during the premix preparation, and the amount added to the final batch did not affect product quality. If appropriate, the manufacturing document should be changed to reflect the practical aspects of the plant's premix and final batch preparation.

Maple Walnut Topping

Observation #009 — RISK. Handling of Filled Jars
This product is hand-filled and water-activity controlled.

After the jars were filled with the product, they were hand capped. An operator manually transferred the open jars to a cart. Prior to transferring the jars, he rinsed his hands in a sanitizing solution. Since the jars were open, residual water dripped from the operator's hands into the product. This could have been cause for product contamination as well as a possible source for localized water spots in a water-activity controlled product.

The observed practice was corrected by management upon notification.

Recommendation
The plant should instruct the operators in the proper handling of sensitive products.

REFERENCES

1. Vasconcellos, J.A., 2002. Quality Assurance for the Food Industry, A Practical Approach. Personal Notes.
2. Alli, I., 1990. Food quality assurance: process control, *J. Inst. Can. Sci. Technol. Aliment.*, 23(4/5), 156–159.
3. Potter, N. and Hotchkiss, J., 1998. *Food Science*, Aspen Publ., New York, NY.
4. ASQ Quality Audit Division, 2000. *Quality Audit Handbook*, 2nd ed., ASQ Quality Press, Milwaukee, WI.
5. American Institute of Baking (AIB), 1991. *Quality Assurance Manual for Food Processors*, American Institute of Baking, Manhattan, KS.
6. Arter, D.R., 1994. *Quality Audits for Improved Performance*, 2nd ed., ASQ Quality Press, Milwaukee, WI.

Chapter 7

FOOD PLANT SANITATION: GOOD MANUFACTURING PRACTICE AUDITS

Modern, more diversified, and large-volume operations in the food manufacturing industry have increased the need for workers to understand the term "sanitation" — a term frequently applied only to the cleaning of equipment and production areas — and how to attain and maintain hygienic conditions. Over the years, sanitary practices have become more complex, and include activities designed to prevent product adulteration during the processing of foods. Persons working in the food industry, and companies producing food for human consumption have the obligation to perform all operations in clean surroundings and with due regard to the principles of sanitation; each has obligations to uphold sanitary standards in common practices for food handling establishments. Those who comprehend the logic and biologic bases behind these practices become more effective workers.

Besides the protection of the consumer's health as the utmost importance, a food sanitation program also includes activities designed to minimize economic losses due to spoilage and to prevent contamination of foods. To the food manufacturer, sanitary practices are not only good in an economic sense, but also because the law requires them. Section 402.a.4 of the Food, Drug, and Cosmetic Act states a food shall be considered adulterated "if it has become contaminated with filth, or whereby it may have been rendered injurious to health." However, sanitation should never end with the satisfaction of having met a regulatory inspection. Sanitation is every person's job in the food manufacturing plant, and it should be a part of the everyday policy of a food company.

Sanitation is a responsibility that every person handling or working with food must constantly fulfill. If properly conducted and maintained, sanitation will remove the worry about spreading communicable diseases and will eliminate the potential of food poisoning; products free of defects will be produced and waste and spoilage will be eliminated.

Each food plant should have a sanitarian, directly responsible to management, to oversee matters of sanitation and to make a sanitary program effective.

FOOD PLANT SANITARY PRACTICES

The employer is responsible for establishing and maintaining a sanitary program to protect the public health and maintain a positive image. The problem of establishing, applying, and maintaining the program falls on the plant sanitarian. He must ensure that the sanitary practices adopted are essential to public health and are economical to the company. He is both the guardian of public health and the counselor to management in matters of quality control (QC) as influenced by sanitary practices.

A food-processing company should have a sanitation department — on the same level as the production, and the research and development departments — in charge of all operating plants.[1] At the plant level, a sanitation department should exist at the same level with other plant departments. Production, QC, and sanitation are complementary functions and are best performed when properly coordinated and synchronized.[1] All functions and operations of a food manufacturing plant must be included in the sanitation program on an ongoing basis.

The federal regulations (21 CFR Part 110 — Current Good Manufacturing Practices In Manufacturing, Packing, or Holding of Human Food, also known as "CGMPs" or "umbrella" GMPs)[2] published by the Food and Drug Administration (FDA), establish the criteria for acceptable food plant sanitation and provide important guidelines for the production of safe and quality foods. The FDA also promulgates regulations for thermally processed low-acid foods packaged in hermetically sealed containers (21 CFR, Part 113) and for acidified foods (21 CFR, Part 114). The U.S. Department of Agriculture (USDA) requirements for sanitation in animal and animal product establishments are covered in 9 CFR, Part 416.[3] The purpose of these regulations is to ensure that the processing establishments are operated and maintained in a manner sufficient to prevent the creation of unsanitary conditions and to ensure that products are not manufactured under conditions that could render the foods unfit for human consumption. They also ensure that the foods have not been prepared, packed, or held

under unsanitary conditions whereby the foods may have become adulterated or contaminated, or may have been rendered injurious to health.[3,4]

Canned foods are the safest commercially processed foods; they are given a final heat treatment designed to destroy or inactivate microorganisms capable of causing human illness and foods to spoil. The hermetically sealed containers also protect the foods against recontamination.

A thermal process, however, is designed to destroy and inactivate only a limited number of microorganisms; therefore, canning operations must include a comprehensive sanitation program as essential for minimizing and controlling the number of microorganisms in a food-processing plant that are present on the foods before those foods are placed into containers. This is especially important for those microorganisms that are heat resistant. Chlorine and other sanitizing agents are used for this purpose. But sanitizers alone cannot ensure food safety nor prevent product spoilage; effective cleaning of equipment and raw product, proper operating procedures and practices, and appropriate controls over all factors that can lead to food contamination are all important elements of a successful sanitation program.

Food Contamination

More food processing is conducted now at plants near the area of production. This is particularly true in the production of fresh produce and of minimally processed foods. Many of these foods are hygienically designed; however, they can be contaminated with spoilage microorganisms or those that cause foodborne illness if proper sanitary practices are not followed. Food products generally have a pH value in the range needed to contribute to proliferation of microorganisms; thus, they provide an ideal nutrition source for microbial growth. Foods normally are contaminated with soil, air, and waterborne microorganisms during harvesting, processing, distribution, and preparation. Extremely high numbers of microorganisms are found in meat animals' intestinal tracts, and some of these find their way to the carcass surfaces during slaughter. Procedures necessary to be followed in order to provide a safe product with extended shelf life include agricultural practices and sanitation, plant sanitation, equipment maintenance and sanitation, processing procedures, employee sanitation, product handling, waste disposal procedures, QC, processing parameters control, and record keeping.[5] At each of these stages, appropriate control points must be determined so as to guarantee proper processing and the finished product's quality and safety. Products and waste products that are not handled in a sanitary way become contaminated.

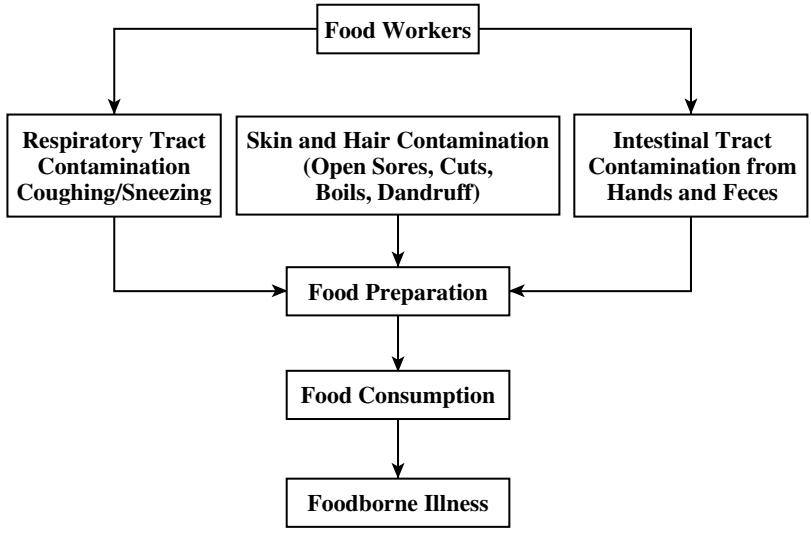


Figure 7.1 Potential contamination of food by humans. (From Marriott, N.G., *Principles of Food Sanitation*, 1999. Aspen Publ., Gaithersburg, MD. With permission.)

Humans

Of all the viable means of exposing food to microorganisms, besides food itself, humans are the largest contamination source. Employees come in contact with spoilage and pathogenic microorganisms through work and the environment. Because the human body is warm, microorganisms proliferate rapidly, especially in the absence of hygienic practices; if the workers do not follow sanitary practices, they contaminate the food that they touch. The hands, hair, nose, and mouth harbor microorganisms that can be easily transferred to food during processing by touching, breathing, coughing, or sneezing. Figure 7.1 illustrates the patterns for the potential contamination of foods by humans.[1]

Equipment

Contamination of equipment occurs during production, as well as when the equipment is idle. Equipment can collect microorganisms and other debris from the air, from employees, and from materials during production. Improved hygienic design and effective cleaning can reduce product contamination from equipment.

Air and Water

Contamination can also result from airborne microorganisms. This contamination can result from unclean air surrounding the food processing, packaging, storage, and preparation areas in the plant or from contamination through improper sanitary practices. The most effective methods of reducing air contamination are through sanitary practices, filtering of air entering food processing areas, and protection from air by appropriate packaging techniques and materials.

Water is used as a cleaning medium during the sanitation operation and is also an ingredient in the formulation of various processed foods. It can also serve as a source of contamination.

Sewage

Raw, untreated sewage contains pathogen microorganisms eliminated from the human body, as well as other materials of the environment. Examples are microorganisms responsible for typhoid and paratyphoid fevers, dysentery, and infectious hepatitis. Sewage may contaminate food and equipment through faulty plumbing.

If raw sewage drains or flows into potable water lines, wells, rivers, lakes, and ocean bays, the water and living organisms such as seafood are contaminated. To prevent this kind of contamination, toilets and septic tanks should be sufficiently separated from wells, streams, and other bodies of water. Raw sewage should not be applied to fields where fruits and vegetables are grown.[5]

Insects, Rodents, and Birds

Flies and cockroaches are associated with living quarters, eating establishments, and food processing facilities, as well as with toilets, garbage, and other filth. These pests transfer filth from contaminated areas to food through their waste products; mouth, feet, and other body parts; and during regurgitation of filth onto clean food during consumption. To stop contamination from these pests, eradication is necessary, and food processing, preparation, and serving areas should be protected against their entry by sound sanitary practices.

Rats and mice transmit filth and disease through their feet, fur, and intestinal tract. Like flies and cockroaches, they transfer filth from garbage dumps and sewers to food or food processing and food service areas.

Birds are recognized as a major health issue. Pigeons and sparrows can cause significant problems for any type of facility. Besides the unsightly nature of droppings, nests, and feathers, pigeons can carry more than 25 different disease organisms.[5]

The Value of a Planned Sanitation Program

A properly planned sanitation program can help to produce a better product and a more efficient operation, as efficiency is directly related to sanitary conditions. A proper sanitation also results in greater employee productivity, fewer accidents, and perhaps most important, it reflects the quality of the operations.

Storage Facilities

Storage facilities should provide adequate space with appropriate control and protection against dust, insects, rodents, and other extraneous matter. Storage area floors can be swept or scrubbed and shelves or racks cleaned with appropriate cleaning compounds and subsequent sanitizing. Trash and garbage should not be permitted to accumulate in a food storage area.

Litter and Garbage Disposal

The food industry generates a large volume of waste. To reduce contamination, refuse (used packaging materials, containers, and waste products) should be placed in appropriate containers for removal from the food area. The preferred disposal method is to use containers for garbage that are separated from those for disposal of litter and rubbish. Clean, disinfected receptacles with close-fitting lids that should be kept closed except when the receptacles are being filled and emptied, should be located in work areas to accommodate waste food particles and packaging materials. Plastic liners provide added protection. All receptacles should be washed and disinfected regularly. Containers in food processing and food preparation areas should not be used for garbage or litter, other than that produced in those areas.

Toxic Substances Control

Poisons and toxic chemicals should not be stored near food products. Only chemicals required for cleaning should be stored on the same premises. Cleaning compounds, supplies, utensils, and equipment approved by regulatory or other agencies should be used in food handling, processing, and preparation. Cleanup chemicals should be clearly labeled.

QUALITY ASSURANCE AND SANITATION

In addition to employee training, food producers need to develop awareness of total plant sanitation. In many instances, floors, walls, ceilings,

and drains may not be sanitarily designed. Areas such as rough welds need to be smoothed out to prevent bacterial growth sites. Particular emphasis must be placed on the sanitary design of operating plants and equipment.[6]

When properly conducted, sanitation removes the worry about spreading communicable diseases or the potential of food poisoning. A company should organize its sanitation program within company guidelines and standards. A plant sanitation committee should regularly measure the accomplishments. A regular schedule of meetings reinforces the importance of the sanitation program. The plant sanitarian is the key to the success of cleanliness and good operations in the food plant. The final aspect of the sanitation program should be the sanitation audit or sanitary evaluation of the plant.

Company personnel from either the home office or the local plant may conduct the sanitation audit, or the sanitary evaluation can be conducted by outside agencies. The audit should include the outside as well as the inside of the facility, with observations made to the program listed as critical, major, and minor, depending upon the degree they pose for food adulteration and/or contamination. An important part of the inspection is a final written report, filed with plant management at the local level and the home office, conveying the pertinent information about current conditions. Management should act upon the report accordingly, as it will be worthless unless the information is used advantageously. By making inspections by outside agencies, areas that may have been overlooked by local personnel can be noted.

The sanitary evaluation of a food plant depends in great part upon the standards of cleanliness established. Generally, these are divided into three basic areas:

- **Physical cleanliness.** Defined as the absence of visual product waste, foreign matter, slime, etc.
- **Chemical cleanliness.** Defined as the freedom from undesirable chemicals. Contamination could occur from cleaning compounds, germicides, pesticides, etc., which might be left on the product and on the equipment. In general, proper washing and rinsing can easily correct this.
- **Microbiological cleanliness.** Probably the most dominant factor in sanitation today; it is influenced by the amount of microorganisms that may be present on the product, the equipment, the building, and the workers. These can and must be controlled through proper sanitary cleanups.

Packaging Technology

Changes in the environmental conditions surrounding minimally processed fruits and vegetables may result in significant changes in microflora. The risk of pathogenic bacteria may increase with film packaging (high humidity and low oxygen conditions), the packaging of products with low salt content and high cellular pH, and with the storage of packaged products at too high temperatures (>5°C/41°F). Under such conditions, food pathogens such as *Clostridium botulinum*, *Yersinia enterocolitica,* and *Listeria monocytogenes* can potentially develop on minimally processed products.[7,8] The Federal Food, Drug and Cosmetic Act places the responsibility for assessing the safety of food packaging materials on the FDA.

Product Distribution

The proper transport of processed foods from the processing plant to markets or to distribution centers helps to reduce the potential for possible contamination. An active and ongoing discussion with the personnel responsible for transportation is essential for ensuring the success of any program designed to deliver safe foods to the consumer. The sanitation conditions during transport should be evaluated, as microbial cross-contamination from other foods and nonfood sources as well as from contaminated surfaces may occur during loading, unloading, storage, and transportation. Workers involved in the loading and unloading of processed foods during transport should practice good hygiene and sanitation. Transportation vehicles must be kept clean to reduce the risk of contamination. Trucks and transport cartons must be inspected for dirt or debris before loading. Trucks that have been recently used to transport animal products may increase the risk of contaminating fresh produce or minimally processed foods if the trucks have not been properly cleaned.

All processed foods should be carefully loaded in trucks or transport cartons in a manner designed to minimize physical damage and to reduce the potential for contamination during transport. Operators should work with transporters to ensure adequate control of transport temperatures. Transporters should be aware of temperature requirements and avoid delivery of mixed loads with incompatible refrigeration requirements.

Personnel Sanitation and Health Considerations

Processors of fresh produce or minimally processed foods should operate their facilities or farms in accordance with the laws and regulations for field and facility sanitation practices. The field sanitation laws prescribed under the Occupational Safety and Health Administration (OSHA)[9] specify the appropriate number of toilets for a given number of workers, proper

handwashing facilities, maximum worker-to-restroom distance, and how often such facilities should be cleaned. OSHA standards also provide regulations relative to toilet facilities and other sanitation issues.[9]

Toilet facilities should be accessible; the more accessible, the greater the likelihood that they will be used when they are needed. However, it is necessary to ensure that facilities in the field are not located near a water source used in irrigation or in a location that would subject such facilities to potential runoff in the event of heavy rains.[6] Toilet facilities should be well supplied with toilet paper; handwashing stations should be equipped with a basin, water, liquid soap, sanitary hand-drying devices such as disposable paper towels, and a waste container, and should be cleaned on a regular basis.

Management should have a plan for the containment and treatment of any effluent in the event of leakage or a spill, and must guarantee that systems and practices are in place to ensure the safe disposal of waste water from permanently installed or portable toilets, preventing drainage into a field and fresh produce contamination. Operators should be alerted to and prepared for the event of any leakage incidence or spillage of effluent in a field and should follow Environmental Protection Agency (EPA) regulations for the use or disposal of sewage sludge; 40 CFR Part 503[10] should be enforced.

Disease-infected employees who work in the field with fresh produce during harvesting increase the risk of transmitting foodborne illnesses. Operators should place a high priority on ensuring the use of agricultural and management practices that minimize the potential for direct or indirect contact between fecal material and fresh fruits and vegetables.[6] They should be aware of and follow the applicable standards for protecting worker health established under the Occupational Safety and Health Act. In addition, the U.S. Code of Federal Regulations (CFR) Title 21, Section 110.10[2] prescribes worker health and hygienic practices within the context of GMPs in the manufacturing, packing, or holding of human food. Workers can unintentionally contaminate fresh produce, water supplies, and other workers, and transmit foodborne illness if they do not understand and follow basic hygienic principles.[6] It is important to ensure that all personnel, including those indirectly involved in fresh produce operations, such as equipment operators, potential buyers, and pest control operators, comply with established hygienic practices. All employees, including supervisors and full-time, part-time, and seasonal personnel, should have a good working knowledge of basic sanitation and hygiene principles. In most circumstances, single-service disposable gloves can be an important and effective hygienic practice in combination with handwashing. The use of gloves, however, in no way lessens the need or importance of handwashing and proper hygienic practices.

Product inspectors, buyers, and other visitors to the farm or processing or packing facilities must comply with the established hygienic practices of the plant. Persons known to be suffering from, or known to be carriers of, a disease likely to be transmitted through food must be restricted from any food-handling area. Likewise, persons afflicted with infected wounds, skin infections, sores, etc., must also be restricted from these areas. Any person with open cuts or wounds should not handle food unless the injury is completely protected by a secure, waterproof covering.

A wide range of communicable disease and infections may be transmitted by infected employees to consumers through food or food utensils. An important part of an ongoing program to ensure the safety of food products is to institute a system of identifying any worker showing symptoms of an active case of illness and exclude him or her from work assignments that involve direct or indirect contact with fresh produce or in the sorting and packing of products. The following is a partial list of communicable diseases transmitted through food, and their symptoms:[11]

- Hepatitis A virus (fever, jaundice)
- *Salmonella typhi* (fever)
- *Shigella* species (diarrhea, fever, vomiting)
- Norwalk and Norwalk-like viruses (diarrhea, fever, vomiting)
- *Staphylococcus aureus* (diarrhea, vomiting)
- *Streptococcus pyogenes* (fever, sore throat)

FOOD PLANT SANITATION MANAGEMENT

Applied to the food industry, sanitation can be defined as "the creation and maintenance of hygienic and healthful conditions."[1] As this author asserts, food sanitation is a fundamental component of the preparation and processing of foods, contributing to the production of wholesome products, handled in a clean environment, prevented from contamination with pathogenic microorganisms, and minimizing the proliferation of food spoilage microorganisms. A sound sanitation program will help a food plant to accomplish these goals.

Sanitation as an Applied Science

Sanitation is of utmost importance to the food industry for the protection of human health. Sanitation scientists in the field of food science thoroughly understand the microorganisms responsible for food spoilage and foodborne illness in the processing and preparation of foods, and seek to control them, maintaining food safety through improved waste disposal; this results in less pollution and improved ecologic balance. Poor hygienic

practices, on the other hand, contribute to outbreaks of foodborne illnesses. Therefore, food sanitation and general sanitary practices for our environment should be closely allied.

The Food Plant Sanitarian

A food company assigns the responsibilities of its sanitation program to a qualified professional, the plant sanitarian. The plant sanitarian is directly responsible to management; his duties and responsibilities, according to Gould and Gould,[12] include:

- Developing a successful sanitation program with firm and well-defined guidelines
- Striving to constantly improve the program, securing the support of management and employees
- Studying sanitary problems, evaluating results, and keeping informed about new developments
- Maintaining adequate cleanup
- Supervising matters of personal hygiene
- Supervising sanitation and health in the company-owned lunchroom
- Supervising water supply, sewage, and waste disposal
- Maintaining the sanitation of restrooms and toilets
- Maintaining and supervising the pest control program. Eliminating rodents and insects
- Checking general plant-keeping practices
- Supervising sanitary storage of raw and finished products and taking correct action to prevent contamination
- Conducting organized training programs for plant personnel
- Making individual inspections of the plant and reporting to management; cooperating with local, state, and federal inspectors

In view of the wide spectrum of his activities, the position of the plant sanitarian in the company and the support that he receives from top management is vital. The plant sanitarian must have an education based on considerable science and knowledge of the food industry and an understanding of microbiology, chemistry, entomology, parasitology, and sanitary engineering. The position requires a professional with personality, tact, and enthusiasm for his job. His success depends in great part upon his training and the training that he conducts for the employees. These educational programs should emphasize the methods used and the responsibility of each individual in practicing proper sanitation behavior in the food plant.

As previously indicated, the accomplishments of the program should be evaluated regularly by a plant sanitation committee consisting of the plant manager, production manager, quality assurance (QA) manager, maintenance engineer, personnel supervisor, and the plant sanitarian.[12] The existence and regular activities of the plant's sanitation committee enforce the importance of the sanitation program and encourage the workers to set high goals of quality.

Personnel Training Programs

A sanitation training program is of great importance in the food processing plant and should be an ongoing activity. Everyone in the organization, including the highest level of management, should participate, as all employees should be familiar with the company's sanitary practices.

Most owners or managers of food processing facilities want a clean operation. However, unsanitary operations frequently result from a lack of understanding of the principles of sanitation and the benefits that effective sanitation will provide.

The success of a sanitation program depends in great part upon training, which should point out methods to be used and the responsibility of each individual to practice proper housekeeping in the food plant. Periodic refresher or follow-up sanitation training programs for the employees are recommended in any food processing facility, including the requirements under the Occupational Safety and Health Act applicable to worker health and training.[9] Training and retraining of the sanitation personnel should be undertaken continuously. A manual should be developed containing the minimum standards for each of the plant areas.

Plant Facilities Construction and Maintenance

Exterior of the Building

All materials of construction in a food processing plant should lend themselves to easy cleaning.

Grounds/Yard Areas/Landscaping

All ground surfaces in the immediate area of the plant and warehouses should be paved, cleaned, and graded so as to provide natural drainage from the building and the products. Appropriate steps must be taken to contain and control any potential sources of contamination. There should be no standing water except for what is typical of good cleanup practices. Grass, weeds, and hedges should be controlled to prevent the harborage

of insects or rodents, and roads should be kept free from dust. Gravel, cinders, and oil-covered or paved roads are recommended. Outside surroundings should be evaluated for sources of contamination such as vermin, bird harborage areas, drainage problems, odor problems, debris, refuse, and pollution (smoke, dust, and other contaminants).

The parking lot should be kept orderly and the parking spaces well arranged and marked. The buildings should be clean and well maintained. The roof should be leakproof and there should be no uncovered openings. All exterior openings should be screened and rodentproof. Unused and old equipment in yard areas should be stored appropriately, in an orderly fashion and off the ground, if possible.

There should be no areas of dirt adjacent to the building that would allow tracking dirt or blowing dust into the plant. All spilled or spoiled products should be cleaned up immediately and removed from the premises. Broken containers, etc., should not be allowed to accumulate in the receiving and shipping areas; all debris should be removed daily.

Landscaping should consist of a low ground cover, such as grass, around the building perimeter. There should be no tall plants, which would act as rodent harborage, growing against the building. Lawn areas should be properly maintained.

Interior of the Building

The facility should have been built using approved materials; durable, smooth, and easy to clean. The walls, doors, partitions, pipes, ceilings, etc. should be kept clean and painted when and if needed. Structural deficiencies refer to areas of plant buildings and structures that are not in good repair or are not structurally sound.

Doors/Windows/Other Openings

All plant openings should be either closed, sealed, or properly protected. Warehouses should also be properly sealed and protected. In warehouses where in-and-out traffic is frequent and ongoing (i.e., seasonal operations), the doors may be left open, but the plant should have a program to monitor the building's integrity and cleanliness, and to make sure it remains free of insects, birds, rodents, etc.

Openings through walls for conveyors, tunnels, pipes, and other equipment should be properly sealed or protected to prevent insects and rodents from entering the building. The openings should be no larger than the situation requires. Windows and doors must be tight and close-fitting to prevent the entrance of rodents and insects. The doors in the food processing areas should be self-closing. Windows and skylights in the

processing areas and near any exposed product should be shatterproof or screened on the inside, in order to prevent contamination in case of breakage. Any open doors or windows should be screened or have properly operating air curtains. Warehouse doors should be closed, unless they are used for constant traffic. Drive-through doors should be in good condition and fit properly.

Openings to the outside or to nonfood-processing or handling rooms must be sealed. Instrument panels should be locked and sealed to prevent harborage of insects. When some openings, such as flumes, can tracks, case conveyors, etc. are necessary to enter or leave a building, the openings should be no larger than absolutely necessary to perform their function. Measures should be taken to safeguard against insects and rodents (i.e., plastic flaps, insectocutors on the inside of the building, and rodent traps appropriately placed near the openings).

Air Curtains

In order for air curtains to be effective, they must be properly installed and blow outward. Check this by putting a small piece of paper into the air stream near the floor. They should be on at all times that doors are open and have sufficient capacity to keep flying insects out of the building.

Plant Walls/Ceilings/Floors

Interior walls and ceilings should be free of peeling paint. Walls should be sound and not have holes; they should be light-colored and well joined. If the walls or ceilings are constructed of corrugated metal or a plastic, they should fit tightly at the base of the building and at all seams. Concrete, wood, or other potentially absorbent construction material should be sealed so as to avoid possible insect or rodent harborage.

The floors should be water-tight, smooth surfaced, and appropriately sloped to 1/8 to 1/4 inch per foot to ensure good drainage into gutters or sewers, located approximately 10 feet apart.[12] Floor drains and gutters should be free flowing, clean, screened, void of any off-odors, and capable of handling the necessary waste material. They should be covered with removal grates so that they can be kept clean. Floor–wall junctures should have a good seal so that water or product cannot accumulate. Floor–wall junctures in new construction should be radiused.

Heating, Ventilation, and Air Conditioning (HVAC)

The building should be properly ventilated to remove contaminated air, with the system designed and installed so as to prevent buildup of heat, steam, condensation, dust, the growth of mold, and the deterioration of

paint or structures. The ventilation also should be adequate to provide suitable working conditions for the employees. Positive air pressure is required in microbiologically sensitive areas.[13] HVAC systems should be designed to be cleanable, and air intakes located to prevent intake of contaminated air.

Drainage and Sewage Systems

Appropriate traps and vents are to be used throughout the plant. There should be no potential for cross connections between human waste effluent and other wastes in the plant. Appropriate vacuum breakers or air breaks must be used.

Waste Facilities

Facilities should be provided for the sanitary storage of waste and inedible material prior to their removal from plant or surroundings. Waste containers are to be clearly identified.

Catwalks/Stairs

If located in processing areas near exposed product or ingredients, catwalks and stairs should have kick plates on the sides and be enclosed on the bottom. The underside and sides should be clean, and there should be no peeling paint that could fall into the product.

Lights in Processing Areas/Exposed Food Ingredient Areas

The lighting should be adequately designed according to the quality of light necessary for the job under way. Good lighting promotes cleanliness and makes the sanitation job much easier.

All light bulbs and/or fixtures in product exposed areas (above an open cap feeder container, batching, mixing and filling areas, or inside a flour mixing bin), should be properly enclosed in order to prevent glass contamination of food in case of breakage. Acceptable enclosures consist of plastic housing for light fixtures, plastic tubes with end caps over fluorescent tubes, or incandescent bulbs that have an exterior plastic coating.

In buildings where product adulteration is unlikely (i.e., finished product warehouses) covered lights are not mandatory. In each case, when determining whether light covers are required, it is necessary to evaluate the area with regard to its use.

Mirrors in Processing Areas

There should be no glass mirrors in any processing area.

Equipment

Equipment should be maintained adequately from both a mechanical and an appearance viewpoint. Equipment surfaces should be easily accessible, easily cleaned, and rust free. If surfaces are painted, the paint should not be chipping or loose, so that it could fall into the product. All idle equipment should be kept clean. New equipment should be constructed of noncorrosive materials, preferably stainless steel. Equipment welds should be smooth and evenly constructed.

Product conveyors should be constructed of noncorrosive materials and, if painted, should be free of rust and peeling paint. Moving equipment/parts should be abrasion free, to avoid the possibility of metal shavings contaminating the product.

Metal Surfaces/Support Structures

Metal contact surfaces and support structures immediately above any exposed product should be made from stainless steel, especially in new installations. Items and structures constructed of stainless steel need not be painted. New construction should utilize stainless steel materials. If they are made from painted mild steel, the paint should not be peeling or flaking and the metal should be rust free. Any areas of peeling paint or exposed rust should be cleaned and repainted; all painted structures should be in good repair.

Can Conveyors and Can Tunnels

Empty can conveyors, located prior to the can washer and above or near exposed product, should not have any litho dust that could fall into the product or into other clean cans. The can conveyor rails located after the can washer through the case packer should be clean. A can conveyor located above or near any exposed product should have catch-pans underneath so as to prevent litho dust from entering the product. The inside of the catch pan should never have an excess buildup of litho dust, and the outside should be clean. Can tunnel floors should be designed and constructed so as to prevent litho dust or other dirt from falling onto any exposed product or clean cans located below.

Conveyors/Sorting Belts/Shakers/Size Graders/Fillers/Flumes, etc.

Conveyor belts should be in good condition, void of exposed fibers or tears. Conveyor belts for unpackaged product should be made of stainless steel or some other nonabsorbent material such as rubber or plastic. In the case of rubber or plastic that have been reinforced with fibers, the

fibers should not be exposed. All belts should have chlorinated water sprays on both surfaces.

The bottom return sides of product conveyors and sort belts should always be checked to make sure they are not rubbing against the floor or any other equipment. The inside of the drive belt and the pulley covers located near or above the product should be clean.

The inside tops of cylinders on piston fillers should be free of old product buildup and foreign material. If a lubricant is used, it should be mineral oil.

Flume Make Up Water

Make up water should be chlorinated.

Mold Buildup

Mold buildup is a function of the passage of time and should be checked at the end of a shift or toward the end of a processing week. Areas where water is prevalent, flumes, sort belts, etc. should be checked frequently. Common sources of mold buildup are clogged or plugged water sprays, nonchlorinated flume water, and infrequent or incomplete cleanup practices. If mold is suspected, a sample should be taken to the QC lab to be verified. Slime and mold are visible as whitish-gray patches.

Belt Sprays

Belt sprays become plugged and require constant control for proper function. The sprays should be checked frequently to ensure that they are functioning and provide adequate coverage.

Tomato conveyors and sort belts should have sprays on both sides. Typically, sprays are located at the end of the belt on the return side after the drive pulley and are frequently on a timed cycle.

Equipment above Product

Any equipment above exposed product should be free of condensate, dust, or dirt, which could fall into the product. If not, line covers should be installed over exposed-product areas.

Moving Equipment or Parts that Rub Together

Moving equipment should be free of abrasion, which is indicative of the possibility of metal falling into the product.

Motors/Gear Boxes/Pulleys/Other Drive Mechanisms

Drive mechanisms should not be mounted above exposed product. If older equipment has been mounted above exposed product, it should have catch-pans underneath in order to prevent dirt, paint, grease, oil, etc. from getting into the product. Catch-pans should in turn have sides and an appropriate drain, which would prevent foreign material from getting into the product. If the equipment or catch pans are mounted on supports attached to the conveyors, the supports should be designed in such a way so that liquids — ice, water, or oil — will not run down the support structure and onto the product below.

Equipment must not be over-lubricated and no leaking lubricants allowed. All machinery should be free of excess grease, especially around grease fittings, bearings, or other moving parts.

Water Sprays

All spray heads should be functioning, not plugged, providing complete coverage of the area being washed; they should be made from a noncorrodible material.

Can/Bottle Lines

Can/bottle lines, from the washer to the seamer/capper, should be completely covered in order to prevent overhead material from falling into containers. The edges of covers should extend beyond the container opening so that condensate will not drip into it. Covers should be clean, especially the underside. All cover seams should be welded.

Line Covers

Line covers should be installed in those areas where the product is exposed to overhead contamination, from the point where product containers (cans, bottles, jars) are cleaned/washed and are to be used for filling purposes, until they are sealed, seamed, or capped, as well as in any other areas where product quality may be affected.

Pipe endcaps should be present on pipes that are used to transfer liquid ingredients. If there is a potential for product or ingredient contamination, these endcaps should be in place when the pipes are not being used; otherwise preprocessing sanitation/cleanup may be adequate to ensure product sterility.

Line covers should be constructed of appropriate noncorrosive/nonabrasive materials (stainless steel, plexiglass, etc.). Construction should involve smooth welded seams, appropriate coverage for all exposed

product, and proper angling to preclude anything overhead — condensate, dirt, dust — from falling into the product.

Fillers

All fillers should be covered. Where a seamer and filler are situated side-by-side, a canopy-type cover, covering both machines and the area in between, should be installed.

The sides of fillers and seamers should be clean, free of accumulated product, etc. The presence of machinery mold should also be checked. Machinery mold, appearing as whitish-gray patches, can occur in those areas where water is constantly present. Fillers should not have a buildup of old product around the edges.

Shears and End Plates

These should be constructed of a nonabsorbent, noncorrosive material such as metal, plastic, or rubber. In the case of plastic or rubber, they should not be fiber-reinforced types.

Tanks and Batching Kettles

All tanks and batching kettles should be covered. If the cover has seams, they should be welded. If the cover is not an integral part of the tank, it should extend beyond the edges of the tank so that material cannot run off the top into the inside of the tank. All tanks located outdoors should have tight-fitting tops, preferably welded to the tank so that water, dirt, or insects cannot enter.

Pipes entering tanks through the top or sides should be welded at the entry point.

Covers should either be sloped or angled so that condensate or other liquids do not drip into containers or into the product itself.

Batch, process, or holding tanks should have covers over any openings, in those areas susceptible to overhead contamination.

These covers should be form-fitted, tight, and not allow any foreign materials to enter the tank. On batch decks, false ceilings and overhead hanging hoods are acceptable. If no covers are present, the ceiling, overhead structures, pipes, etc. must be clean and free of any possible sources of contamination. When exposed product is present, fillers should also be covered. An umbrella-type cover, one that covers the entire filler-seamer area, is best. Indoor tanks having top mounted mixers, or tanks on which pipes are not welded, should have collars around the bottom of the motor and shaft, to prevent material from running into the tank. The area between the pipe and collar should be clean.

Covers that are hinged should be constructed so that material on top will not run into the tank when the cover is opened. Any uncovered tanks, such as Hamilton mix kettles, should be free from potential sources of overhead contamination. If conditions of potential contamination exist, appropriate measures should be taken, i.e., cleaning overhead structures or installing covers.

Cooking Kettles

Cooking kettles should have closed doors or hoods over all openings in order to prevent overhead contamination.

Utensils

Utensils should not have wood handles, and should be fabricated from noncorrosive material, clean, and stored off the floor and away from walls and beams.

Ingredient Containers

Ingredient containers should be covered, clean, and made from a food-grade material.

Ingredient Bags

If ingredients are dumped directly into a product, the bags should either be cleaned off or the outer covering stripped. Holes in the bags in storage should be sealed by taping food-grade paper or plastic over the opening. The tape should not come in contact with the contents.

Plastics and Rubber in Contact with Product or Ingredients

Plastics and rubber should be approved for the way they will be used in conjunction with processing.

Exhaust Fans and Vents

Air fans, located around processing lines or open food containers, should not be blowing directly onto product. All fans, the housing and the blades themselves, should be checked for cleanliness. Exhaust fans, roof vents, and other vents should be clean and free of dust and dirt that could fall into the product, containers, fillers, sort belts, etc.

All vents to the outside should have proper seals, i.e., screening, to keep birds and insects from entering the facility. In areas where steam and condensate are present, appropriate and sufficient venting should be present.

The pans should not have a heavy buildup of dead insects, which could fall into the product or become a growth location for mold.

Outside Surfaces of Equipment

The outside surfaces of all equipment, which employees might come in contact with during the course of handling food, should be clean in order to prevent transferring adulteration to food.

General Construction of Equipment

All machinery and equipment must be in proper working order, operating as intended, and be free of peeling paint or leaking fluids, i.e., oil, which could possibly affect product quality.

Wherever tubing is used for railing, supports, or similar use, the ends should be sealed to avoid any accumulation of foreign substances. All inside corners on new equipment and installations should be radiused in order to facilitate cleaning.

Seams on all equipment should be permanently sealed. If welded, the welds should be smooth.

Chemicals

Any chemicals (lubricants, cleaning oils, soaps, aerosols, etc.) which could get into a food as a result of their use are considered incidental food additives and must be approved as such. This includes chemicals used in food processing areas, areas adjacent to food processing, and packaging departments. All chemicals must be approved for use. Proper approval and conditions of use should be confirmed by checking the current "List of Chemical Compounds Authorized for Use Under USDA Inspection and Grading Programs." Nonfood chemicals should not be stored with foods and food ingredients.

Lubrication Practices

All equipment located near exposed products or ingredients should be free of excess lubricant that could fall into the food.

Cleanup Practices

Sweeping, or the use of an air hose, is an unacceptable cleaning practice. Washing should not result in water splashing onto the product or product-contact surfaces. During wash-down periods, unsealed cans and bottles should be removed from the line in order to prevent splashing by the wash water.

After passing through the empty can washer, unseamed cans should be cleared from the line during cleanup. If not, the cans should be removed before the start of production. This practice should be checked at the end of lunch-break cleanups.

If product from QC lab samples is saved and returned for reprocessing — a frequent practice — it will be necessary to check with the QC lab to assure that the product had been properly stored and protected from adulteration.

Storage of Surplus Equipment/Supplies/Ingredients/Product/etc.

All materials in storage in processing areas and warehouses should be stored in an orderly fashion, off the floor, preferably on pallets, and at least 18 inches away from the interior wall. Food materials should be covered whenever necessary to prevent contamination.

Raw Fruits and Vegetables

All raw fruit and vegetables entering the processing plant should receive a final wash with fresh water and should be inspected prior to use. The wash water should have residual chlorine at the spray head exit. Fruit and vegetables on wash and inspection belts should be only one layer thick.

Food Residuals

There are numerous places in a food processing plant where food is reclaimed, such as product that falls out of cans, off sorting belts, and out of fillers. Wherever this occurs, the surfaces that the food contacts upon falling should be inspected to see that they are clean and free of lubricant or other foreign material. If not, the product should not be used without prior cleaning. Similarly, products such as tomatoes, which fall on the floor, should not be used without prior washing.

Condensate and Heavy Steam

Some condensate and steam are unavoidable in food processing plants. Heavy accumulations, however, should be eliminated by the installation of adequate exhaust systems.

Pest Control

Each facility should have a formal pest control program which should include appropriate placement of bait stations and rodent traps, frequent monitoring of the facility's buildings and grounds for insect, rodent, and other animal activity, and proper storage of related equipment and supplies.

Bait Stations/Rodent Traps

Bait stations and rodent traps should be placed around any openings to buildings that contain areas of food processing or food ingredient storage. "Building openings" generally refers to doorways, loading dock doors, side doors, etc. Bait stations should be placed outside the buildings and should have fresh bait and be in good condition. Rodent traps can be placed either inside or outside the building. Rodent traps should be operable and have secured lids; damaged or inoperable traps should be replaced. Program compliance is based upon checking a plant-provided map that lists the locations of the facilities' bait stations and rodent traps.

All traps and stations should be inspected on a regular basis set at a reasonable, routine inspection schedule. The schedule may be area specific and dependent upon various activity and seasonal factors.

Evidence of activity, i.e., rodent droppings, rodent urine, live animals, an abundance of flying insects, burrows in surrounding yard areas, gnawed packages and materials, etc., should be checked, the source identified and eliminated along with the evidence.

Insectocutors

Insectocutors should be present in areas where flying insects can be a problem. Insectocutors should not be used as alternatives for air doors, but as a preventive mechanism within processing and warehousing facilities. Insectocutors should not be located too close to doorways so as to serve as insect attractants.

The presence or absence of insectocutors should be evaluated on an individual facility basis and as the need requires. They should be operable and contain an appropriate insect catch pan that should be emptied regularly to prevent accumulation of dead insects.

Employee Practices

Employee practices regarding the handling, storage, and cleaning of utensils should be controlled.

All employees should be observed for proper, safe, and sanitary practices while working. Employee practices, especially those of line janitors, should be closely observed. Employees should be wearing appropriate, clean clothing that is not loose fitting. Tank tops are not permitted. All insecure or loose jewelry should be removed during periods where food is manipulated by hand, according to the following guidelines:

- Any jewelry that cannot be adequately sanitized shall be removed.
- Any loose items within shirt pockets shall be removed.
- Proper hair and beard coverings are required.
- Employees and other personnel should not eat, drink, or smoke within the processing areas. Eating, drinking, and smoking should occur only in designated plant areas. Any designated area should be clean and orderly.

  Many facilities allow certain practices to evolve for many years, some of which may not be acceptable. In those instances where eating, drinking, or smoking is taking place in improper areas, plant personnel should be notified. Its unacceptable status should then be discussed with QA/QC management.
- Empty food containers cannot be used for any other purpose than that for which they are designed.
- Glass bottles, etc. shall not be permitted in work areas.
- Employees' belongings, i.e., purses, jackets, lunches, should be stored in designated storage areas or in employee lockers. No items shall be stored at workstations. Designated areas may include the cafeteria, a coatroom, or a supervisor's desk that is centrally located and away from a food processing area.
- As with the designated eating areas, each facility may have its own rules regarding the storage of personal belongings. It is necessary to check with plant management about its specific policy. In any case, the policy should not involve storing items at workstations, especially food-type items, i.e., lunches and thermoses.
- Many workers wear gloves. It is necessary to observe how these are handled and stored during breaks and lunch, and whether they are cleaned prior to returning to work.

Incoming/Outgoing Material Control

All elements and operations involved with receiving, storage of ingredients, packaging material, and other incoming materials, as well as outgoing products, must be evaluated and monitored to prevent potential contamination of the food product manufactured and being distributed to the market.

Raw Material Receiving

Incoming materials must be received into an area separated from the processing areas. Only safe, approved food-grade direct and indirect additives and ingredients shall be used. Incoming materials should be carefully inventoried and evaluated to assure quality standards. Packaging materials used must be safe and approved. All incoming goods should be inspected for possible damage and rodent or insect infestations.

Storage

The handling of materials in a processing plant for both incoming and outgoing warehousing is very important. The requirements include clean and well-marked aisles. The lanes and aisles in the storage area should be marked accordingly. Food materials, packages, etc. should be protected from insects, rodents, dust, and dirt.

Management of storage in food plants is probably one of the secrets to good housekeeping, since storage is one of the major areas of a food plant. All storage should be cleaned at least once per week.

Temperature and Humidity Controls

Where appropriate and applicable, the temperature and humidity of storage rooms for raw materials, ingredients, packaging materials, and food should be maintained and monitored. All stored products should be placed away from the walls and in proper storage temperatures.

Returned Foods

Foods returned from retail outlets must be clearly identified and stored in a designated area for appropriate disposition. Storage conditions must be such that the safety of the returned food is not compromised.

Outgoing Products

The policy of First In, First Out (FIFO) should be strictly adhered to. Outgoing materials must be properly identified in terms of shipments and qualities of products. Great losses occur in warehouses by improper housekeeping practices in terms of breakage, pilferage, looting, etc.

Process Control: Sanitary Operations

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food should be conducted in accordance with adequate sanitation principles.

The equipment in use in the food plant should be constructed not only for its functional use, but also with due regard to its cleanability and protection from contamination. Materials of construction should be smooth, hard, nonporous, and preferably of stainless steel. All pipe lines, fittings, etc. handling food should be of the sanitary type. The elimination of sharp corners in tanks, flumes, and other equipment greatly facilitates cleaning and prevents spoilage organisms from building up. All equipment should be directly accessible for cleaning. All open equipment, such as tanks, hoppers, buckets, elevators, etc., should be covered; containers used to transport food materials should be kept clean and not used for other purposes. Excess lubricant should be cleaned off after lubricating. The hoses and cleanup equipment should be properly put away after each use, and all unused equipment and equipment on repair should be removed from the processing area and properly guarded. Pails and trays should not be put away until they have been cleaned. The waste in the food plant should be collected in containers properly designed and removed daily.

Employee Hygiene and Sanitary Handling of Food

Basic requirements for good employee and product sanitation are:

- Protective clothing should be worn at all times.
- All employees should share responsibilities to maintain lockers and washrooms in a clean and orderly manner. Most important, all employees should be required to observe proper habits of cleanliness.
- Gloves are required for individuals that directly handle food ingredients (sorter, cooks, other batching personnel). Gloves should be clean and suitable for the required task.
- Ingredients and materials should be used properly.
- Containers and ingredient bags should be cleaned prior to use. Burlap bags should be brushed clean, while the outer paper covering on ingredient sacks should either be stripped off or both layers peeled back to prevent small pieces of paper from falling into the product.
- Batching and formulation utensils should be clean and proper practices followed to assure that product quality is not compromised.
- Mechanics working in and around food products should shield these areas to prevent potential product adulteration. Product should be shielded from welding and cutting spray. If working above the product, the product should be shielded. Particularly important are ladders that may be located above the product.
- Facilities with hot water for handwashing must be provided and must be convenient to food handling areas.

- All personnel involved in food handling must thoroughly wash hands with soap under warm-running, potable water. Hands must also be washed after handling contaminated materials and after using toilet facilities. Where required, employees must use disinfectant hand dips. Hands shall be washed and sanitized in the following instances:
  - when reporting for work
  - after a break time
  - after smoking or eating
  - after picking up objects from the floor
  - after coughing or sneezing and covering mouth with hand
  - after blowing nose
  - after using the toilet facilities
- All employees must report any blemishes or breaks in the skin to the supervisor prior to reporting for work. Bandages or adhesives, which may become loose and fall off during the work time, unless covered with gloves, are not to be used.
- Safe personal conduct should be strictly observed within the food plant. Running, horseplay, riding on trucks or lifts, taking shortcuts (ducking under conveyors, etc. whether operating or not) are prohibited.
- A food factory should not employ any person afflicted with infection or contagious disease. Health certificates should be required.
- Signs should be used throughout the company's food processing facilities as to smoking, eating habits, washing habits, and general sanitary requirements.

Sanitation and Housekeeping

Generally, this category involves basic housekeeping: things that should be taken care of on a regular basis. Cleaning practices should be instituted so as to prevent accumulation of mold, slime, dirt, dust, or product on equipment, related structures, and within the facilities themselves. Concealed or hard-to-reach areas should be closely examined. Floors should be free of accumulated product and void of standing water. Walls and support structures should be free of dirt, dust, and peeling paint and should not be constructed of absorbent-type materials.

The condition of the neighboring property can affect the condition of the facility. For example, if weeds or old buildings are present on adjacent property, these areas may serve as potential harborage areas for rodents and could affect rodent control on the facility.

Any chemicals used, i.e., soaps, cleaning oils, aerosols, lubricants, should be on the USDA's current list of approved "Incidental Food Additives." Their acceptability must be confirmed by checking the listing.

The plant should maintain a running inventory of all dangerous chemicals, including insecticides and herbicides.

Inner Perimeter Area of Buildings

The perimeter areas of processing and warehousing facilities should not be obstructed. They should be clear of obstacles, clean, and able to be inspected regularly by walking the entire building perimeter. An 18-in. clear border is common to most facilities. A blocked perimeter may provide potential pest harborage areas.

If pesticides are used, they shall be appropriate and shall be applied in consistence with stated label directions. Pesticides and other chemicals should be segregated from food products and appropriately labeled and stored in a safe manner. The pesticide applicator shall be trained and certified in the safe and proper usage of the particular pesticides.

Housekeeping Practices

Good housekeeping practices should result in the overall clean and orderly appearance of a plant, processing facility, or warehouse. Special storage areas should be provided for handling of clean uniforms, towels, and personal toilet articles; soiled uniforms and linens; equipment and supplies; lockers for personal belongings of permanent employees; pesticides; and garbage and wastes. Other areas highly significant in housekeeping practices are the lunch/breakroom area and the restrooms.

Equipment and supplies — ingredients, container materials, etc. — should be stored off the ground and 18 in. away from inner walls. Ingredients should be stored in a safe area, protected from external intrusions. Bags, boxes, and other ingredient containers should be appropriately sealed when not in use.

Toilets should be provided with double doors and never open into any processing room. They should be constructed of sanitary materials, adequately ventilated with all openings screened. The toilet facilities should be kept scrupulously clean for both men and women, and must be plainly marked. There are minimum requirements depending upon the number of employees; these must be part of any sanitation program. Adequate facilities include liquid soap and throw-away towels in the restrooms and within reasonable distances from each workstation.

Food products should be stored at their proper temperature. Refrigerators and freezers used to store the products should be operating correctly. All warehouse and storage areas should be free of spilled or spoiled product.

Drinking fountains, provided with side-outlets of water, or taps with throwaway cups should be used. The area of the lunchroom will vary depending on the size of operation. Minimum lunchroom facilities, if no more than vending machines, should be provided and kept in good housekeeping order. In addition to these facilities, first-aid rooms are a must.

There should be no trash, debris, or foodstuffs in and around the property perimeters. Yard and plant areas should be free of excess dust and dirt. Air hoses should not be used for sweeping, as the potential for airborne contamination is too great. Spider webs should be removed, and if spiders are a problem, spraying should eliminate the source.

Pest Control in Food Processing Plants

Pest control needs a sustained effort. Rodent proofing, storing the food off the floor, keeping good sanitation and cleanliness, and inspecting the premises for insect and rodent activity should be carried out on a regular basis. A carefully designed and implemented sanitation and pest control program must be maintained if unwanted food safety and quality issues are to be prevented. Control of pests and use of pesticides are particularly critical in places where food is prepared, served, or packaged. Food companies are inspected for sanitation to assure that food has been prepared, packed, and held under sanitary conditions. Section 402 of the Federal Food, Drug, and Cosmetic Act of the Food and Drug Administrtion (FDA) (http://www.fda.gov/opacom/laws/fdcact/fdcact4.htm) states: "A food shall be deemed to be adulterated… (a)(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (a)(4) if it has been prepared, packed, or held under unsanitary conditions whereby it *may* have become contaminated with filth, or whereby it may have been rendered injurious to health…" revealing that any food product containing filth may be in violation if it is even held under conditions where food *may* become contaminated, regardless of whether it is a hazard to health. Regulatory action can be taken if food becomes contaminated, or is prepared, packed, or held under conditions where it could become contaminated with insect fragments, rodent hair, bird feathers, feces, etc.

Commercial food processing plants present unique challenges to pest management programs. Food processing plants attract pests with odors, moisture, temperature, and outside lights. All processing plants also present challenges due to regulations issued by the FDA, USDA, and other federal and local agencies, and poor pest control can result in fines levied against the company, which can be disastrous.

Pest refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae. Types of pests include:

- **Insects.** Such as roaches, termites, mosquitoes, aphids, beetles, fleas, and caterpillars.
- **Insect-like organisms.** Such as mites, ticks, and spiders.
- **Microbial organisms.** Such as bacteria, fungi, nematodes, viruses, and mycoplasms.
- **Weeds.** Any plants growing where they are not wanted.
- **Mollusks.** Such as snails, slugs, and shipworms.
- **Vertebrates.** Such as rats, mice, other rodents, birds, fish, and snakes.

A pest control program basically consists of:

- **Inspection.** The inspection process determines what might cause contamination of food products. The thoroughness and accuracy of the inspection determine the effectiveness of the pest management program.
- **Pest Identification.** When pests are discovered, each must be accurately identified in order to prescribe the most effective and efficient methods of control. Considering the dozens of insect and rodent pests that invade food processing plants, proper identification is critical to program design. It requires an expert whose experience assures the proper diagnosis and implementation of an effective pest management program.
- **Pest Control Techniques.** Sanitation, pest exclusion, trapping, biomonitoring, and other nonchemical control procedures, and chemical methods are used if necessary. This approach involves evaluating all aspects of the pest management program.
- **Record-Keeping.** Each aspect of the pest management program must be continually monitored and evaluated through continued inspections and monitoring and by seeking feedback from plant staff. Record keeping is essential because it aids in identifying conditions conducive to pest outbreaks, noticing seasonal trends, and providing additional information related to effective control measures. This step provides early detection of subtle changes that indicate the pest management program must be adjusted.

  Effective communication between plant management, personnel, and food plant inspectors is crucial. To enhance the communication process, service record notebooks, sighting logs, application records, and sanitation reports should be kept to help prevent possible health and financial problems associated with pest infestation.
- **Program Evaluation.** QA professionals inspect the food processing plant to evaluate the program. Written reports are issued to plant management for a thorough evaluation; should the situation warrant action, this is immediately implemented.

Insects

Small amounts of accumulated food debris left in the bottom of a trash container can be the food source and breeding area for literally millions of flies and other pests, not to mention multitudes of microorganisms. A scraper or hose can be used to loosen the caked material at the bottom of the trash container, then wash and spray it. This can disrupt the cycle and eliminate this particular source of insect infestation. Research has shown that a single housefly is capable of carrying six and a half million bacteria, many of which may be pathogenic.[14]

Rodents

Surround the building foundation with an 18- to 24-in. strip of 88-in. pebbled rock piled 4 in. deep in a trench. This discourages rodents from burrowing around buildings and keeps some turf pests from entering buildings. It makes an excellent area for traps and bait stations at food processing and storage facilities. If the bottom of the trench is lined with tar paper, weed growth will be retarded for a short time.[14]

Birds

Of all the pest problems facing the food industry, birds are probably the most common. Birds are naturally attracted to food and moisture, so they like to perch outdoors, awaiting an opportunity to infiltrate food facilities.

The most common offenders are pigeons, sparrows, and starlings. Particularly vulnerable are places where garbage is removed or placed in a dumpster. The bird problem is magnified in food storage warehouses and large processing plants, due to the occurrence of more doors, ledges, windows, and delivery vehicles coming and going through open doors. Evidence of bird droppings, feathers, or nesting materials in food processing plants, warehouses, or any other food establishment is also evidence of a possibility for adulteration and consequent regulatory problems.

Bird droppings can be a health hazard, harboring disease and parasites that are harmful to humans. Birds' close proximity to food is recognized as a major health issue. Besides the unsightly nature of droppings, nests, and feathers, pigeons can carry more than 25 different disease organisms. Birds are a perfect mechanism for spreading disease because they travel great distances, harbor over 40 types of parasites and can host internally over 60 types of infectious diseases. Health inspectors are quick to shut down a food processing plant if nuisance birds are found inside.

Cleanliness outside the facility is one solution to the problem. The less birds have to eat, the less attractive the site becomes to them.

Besides proper cleanliness and sanitation, one of the common methods to deter birds outside food facilities is to erect a physical barrier. A physical

barrier disrupts the natural pattern of bird behavior. Densely branched and spaced spikes prevent birds from roosting, hopping on platforms, finding ledges, overhangs, and niches to settle on, and from squeezing between the spiky extensions. Other control methods consist of sonic devices or "scare tactics" such as balloons, fake owls, and holograms, but these are only temporary. Birds get accustomed to them, whereas physical barriers continue to prohibit nesting and perching. For long lengths of ledge, low-voltage electric tracks can be installed that give a bird a slight shock when landing. Birds quickly learn to go elsewhere. Others methods consist of the use of toxicants and bird repellents for application to roosting areas. Poison is a method of last resort.

Use of Pesticides

Insecticides and rodenticides are acceptable as long as they are used properly, according to label instructions; these pesticides must not contaminate food or packaging materials with illegal residues.[15]

Finished Products

Food handlers should receive proper training in handling finished products to prevent damage and possible contamination.

Finished products intended to be stored frozen should be maintained at a temperature of –18°C or below. They should be labeled properly, including a statement of storage conditions.

Finished products should be transported, distributed, and displayed in a proper manner and at appropriate temperatures to protect them from contamination and deterioration. Clear instructions on the proper methods of storing, handling, and displaying the product should be available and given to retailers.

Lab Practices

A laboratory equipped to assist the housekeeper or sanitarian is a must, and the standards of cleanliness must be part of the minimum specifications for the operation of a factory. These standards of cleanliness can be established through the QA personnel.

SANITATION LAWS AND REGULATIONS

Sanitation requirements developed by legislative bodies and regulatory agencies are contained in laws and regulations. The agencies responsible for enforcement of the laws prepare regulations designed to implement them through the development of a wide range of requirements more

specific and detailed than the laws. Regulations for the food industry include standards for building design, equipment design, commodities, tolerances for chemical or other food additives, sanitary practices, labeling requirements, and training for positions that require certification.

There are two types of regulations: substantive and advisory.[1] Substantive regulations have the power of law. Advisory regulations are intended to serve as guidelines. Sanitation regulations are substantive because food must be made safe for the public. In regulations, the use of the word "shall" means a requirement, whereas "should" implies a recommendation.

FDA Regulations

The FDA indicates approved cleaning compounds and sanitizers for food plants by their chemical names, not by their trade names. For example, sodium hydrochlorite is approved for bleach-type sanitizers, sodium or potassium salts of isocyanuric acid for organic chlorine sanitizers, n-alkyl-dimethylbenzyl-ammonium chloride for quaternary ammonium products, sodium dodecylbenzenesulfonate as an acid anionic sanitizer component, and oxypolyethoxyethanol-iodine complex for iodophor sanitizers.[1]

The sanitary operations section of the FDA's GMP establishes basic rules for sanitation in manufacturing, processing, packing, or holding food in a food establishment. General requirements are provided for the maintenance of physical facilities, and minimum demands are included through requirements for water, plumbing design, sewage disposal, toilet and handwashing facilities, and solid waste disposal.

Specific GMPs supplement the umbrella GMPs and emphasize wholesomeness and safety of manufactured products. Each regulation covers a specific industry or a closely related class of foods. The critical steps in the processing operations are addressed in specific detail.

USDA Regulations

The USDA has jurisdiction over three areas of food processing, based on the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. The agency that administers the area of inspection is the Food Safety and Inspection Service (FSIS), established in 1981.

By design, federal jurisdiction usually involves only interstate commerce. However, the three statutes on meat, poultry, and eggs have extended USDA jurisdiction to the intrastate level if state inspection programs are unable to provide proper enforcement as required by federal law. Products shipped from official USDA inspected plants into distribution channels, found to be adulterated or misbranded, come under the jurisdiction of the Food, Drug, and Cosmetic Act. The FDA can take legal steps to remove

this product from the market. Normally, the product is referred back to the USDA for disposition.

EPA Regulations

The EPA regulates pesticides under two major federal statutes. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the EPA registers pesticides for use in the U.S. and prescribes labeling and other regulatory requirements to prevent unreasonable adverse effects on health or the environment. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), the EPA establishes tolerances (maximum legally permissible levels) for pesticide residues in food. Tolerances are enforced by the Department of Health and Human Services/Food and Drug Administration (HHS/FDA) for most foods, USDA/FSIS for meat, poultry, and some egg products, and the USDA/Office of Pest Management Policy. Sanitizing compounds are recognized by federal regulators as pesticides; thus, their uses are derived from the FIFRA. Antimicrobial efficacy, toxicologic profiles, and environmental impact information are required by the EPA. For over two decades, there have been efforts to update and resolve inconsistencies in the two major pesticide statutes, but consensus on necessary reforms remained elusive.

In 1996, Congress unanimously passed landmark pesticide food safety legislation supported by the administration and a broad coalition of environmental, public health, agricultural, and industry groups. President Clinton promptly signed the bill on August 3, 1996, and the Food Quality Protection Act (FQPA) of 1996 became law (P.L. 104-170, formerly known as H.R. 1627). The FQPA of 1996 amended FIFRA and FFDCA, fundamentally changing the way the EPA regulates pesticides. The requirements included a new safety standard — reasonable certainty of no harm — that must be applied to all pesticides used on foods.[16]

The 1996 law represents a major breakthrough, amending both major pesticide laws to establish a more consistent, protective regulatory scheme, grounded in sound science. It mandates a single, health-based standard for all pesticides in all foods; provides special protections for infants and children; expedites approval of safer pesticides; creates incentives for the development and maintenance of effective crop protection tools for American farmers; and requires periodic reevaluation of pesticide registrations and tolerances to ensure that the scientific data supporting pesticide registrations will remain up to date in the future.

The Federal Water Pollution Control Act

The Federal Water Pollution Control Act (Clean Water Act) is important to the food industry because it provides for an administrative permit

procedure for controlling water pollution. Regulations covering the food industry are published by the EPA.[1]

The Clean Air Act

This act, devised to reduce air pollution, is of concern to food operations that may discharge air pollutants through odors, smokestacks, incineration, or other methods. The Clean Air Act provides the principal framework for national, state, and local efforts to protect air quality. Under the Clean Air Act, the Office of Air Quality Planning and Standards (OAQPS) is responsible for setting standards, also known as national ambient air quality standards (NAAQS), for pollutants which are considered harmful to people and the environment. Generally, state and local agencies set pollution standards based on EPA recommendations, and are responsible for their enforcement.

FIFRA

The primary focus of FIFRA is to provide federal control of pesticide distribution, sale, and use. The EPA was given authority under FIFRA not only to study the consequences of pesticide usage but also to require users (farmers, utility companies, food companies, and others) to register when purchasing pesticides. Through later amendments to the law, users also must take exams for certification as applicators of pesticides.[17] Those who are certified, either by the EPA or by a state, to use or supervise the use of restricted pesticides, must meet certain standards, demonstrated through written examination and/or performance testing. Commercial applicators are required to have certain standards of competence in the specific category in which they are certified.

All pesticides used in the U.S. must be registered or licensed by the EPA. Registration assures that pesticides will be properly labeled and, if in accordance with specifications, will not cause unreasonable harm to the environment. The EPA classifies each pesticide for either restricted use or for common use, with periodic reclassification and registration as necessary. A pesticide classified for restricted use must be applied only by, or under the direct supervision and guidance of, a certified applicator.

Current EPA regulations permit the use of certain residual insecticides for crack and crevice treatment in food areas of food establishments. The EPA lists residual pesticides that are permitted in crack and crevice treatment during an interim period of 6 months, while registrants apply for label modification.[1]

The Resource Conservation and Recovery Act

The Resource Conservation and Recovery Act (RCRA) was provided to develop a national program designed to control solid waste disposal.

RCRA gives the EPA the authority to control hazardous waste, including the generation, transportation, treatment, storage, and disposal of hazardous waste. RCRA also set forth a framework for the management of nonhazardous wastes.[18]

The act authorizes the EPA to recommend guidelines in cooperation with federal, state, and local agencies for solid waste management. It also authorizes funds for research, construction, disposal, and utilization projects in solid waste management at all regulator levels.

Hazard Analysis and Critical Control Points Program

The USDA and FDA have proposed voluntary programs to replace continuous inspection with constant supervision in an effort to reduce costs by altering the traditional inspection procedures. Although other voluntary programs have been developed, the Hazard Analysis Critical Control Points (HACCP) approach is emphasized.[1,19] Since this concept was developed, it has been adopted to ensure food safety through the prevention of hazards. Although this program was initially voluntary, more recent regulations have been developed that require HACCP and have changed the status of this program from voluntary to required in some segments of the food industry. A number of U.S. food companies already use the system in their manufacturing processes, and it is in use in other countries, including Mexico and Canada.

Many of the principles of HACCP already are in place in the FDA-regulated low-acid canned food industry. FDA also established HACCP for the seafood industry in a final rule December 18, 1995, and for the juice industry in a final rule released January 19, 2001. The final rule for the juice industry took effect on January 22, 2002, for large and medium businesses, January 21, 2003, for small businesses, and will take place on January 20, 2004, for very small businesses.

In 1998, the USDA established HACCP for meat and poultry processing plants. Most of these establishments were required to start using HACCP by January 1999. Very small plants had until January 25, 2000. (USDA regulates meat and poultry; FDA all other foods.) The FDA now is considering developing regulations that would establish HACCP as the food safety standard throughout other areas of the food industry, including both domestic and imported food products.

A major portion of the hazards in the food supply is microbial related and is affected by the effectiveness of sanitary measures adopted. Thus, HACCP has been recognized as a voluntary program to enhance sanitation. To help determine the degree to which such regulations would be feasible, the agency is conducting pilot HACCP programs with volunteer food companies. The programs have involved cheese, frozen dough, breakfast cereals, salad dressing, bread, flour, and other products.

HACCP has been endorsed by the National Academy of Sciences, the Codex Alimentarius Commission of the United Nations, and the National Advisory Committee on Microbiological Criteria for Foods.

THE SANITATION/GMP AUDIT

The sanitation/GMP audit is the cornerstone to any successful food processing operation. Most of the recalls and seizures regarding processed foods can be traced back to poor sanitation and handling practices within the processing facility. Effectiveness of the cleaning and sanitation of a food manufacturing facility can be evaluated by their adherence to GMPs.[2] To such purposes, periodic GMP audits should be conducted by visual inspections that can be documented. Any deviations or unclean areas should be noted and corrected.

GMP audits should be made by the company's QA personnel. In addition, annual or biannual audits by independent auditors will help uncover areas potentially overlooked by the internal audits.

The sanitation/GMP audit focuses on four areas:

1. **Plant Facilities.** A detailed and defined review is conducted to determine the acceptability of the building and facilities. In close cooperation with plant management, walls, floors, and ceilings are closely scrutinized. Utilities and support services are evaluated to determine measures to be taken to provide a more effective food safety environment.
2. **Employee Hygiene.** Employee hygiene policies, procedures, and practices are reviewed in detail. Determinations are made as to the appropriateness of the plant's practices relative to the food safety risks associated with the goods produced.
3. **In-Process Controls.** Plant operating conditions are observed in detail. Determinations are made as to the adherence to food safety and sanitation plant policies and procedures.
4. **Pest Control.** It is important for the sanitation manager or someone in QA to be at least cursorily trained in the area of pest control. A food company should not attempt to perform its own pest control, but rather rely on a dependable outside firm; still, sanitation or QA should be aware of the warning signs of potential problems or infestations. Credentials and references provided by the pest control firm should be reviewed, and their continuing education in the regulations and newest methods of pest control should be verified. When reviewing a pest control program, QA must look for a written pest control policy, and check the location maps of traps, records of pest inspections, and the condition and location of electronic

exterminators. Sealing of outside doors and windows of a facility should be ensured.

The management staff works with the experienced auditor to define needed improvements, as a means of aiding plant management decision making. This approach provides an independent review, helping organizations become "best-in-the-business" in food safety and sanitation operations.

A plant sanitation audit should include inspection of all functions and operations of a food manufacturing facility, according to the GMP guidelines of the Code of Federal Regulations, Title 21, Part 110, the following items must be included for observation and verification during a sanitation audit.[2,20]

- Buildings and facilities construction
- Plant and grounds maintenance and cleanliness
- Sanitary operations
- Sanitary facilities and maintenance
- Personnel hygienic practices and control of employee health conditions that could result in microbiological contamination of food
- Control and enforcement of handwashing and sanitizing practices
- Quality of the water that comes into contact with the food or food surfaces
- Conditions and cleanliness of the food contact surfaces
- Proper use of gloves and outer garments
- Equipment and utensils maintenance and cleanliness
- Prevention of cross-contamination from unsanitary objects
- Warehousing and distribution
- Review of sanitation standard operating procedure (SSOP) documents[20]

Other records that also need to be examined as part of an audit include:

- Means of protection of food ingredients, raw materials, and food products from contamination from the point of receiving through distribution
- Ways of protecting food, food packaging materials, and food contact services from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, etc.
- Proper labeling of cans, boxes, bags, etc. for identification of contents
- Instructions provided for the proper storage and use of toxic compounds
- Measures for the exclusion of pests from the food plant
- Maintenance of sanitation control records to document the monitoring of the program and any corrective measures taken

Auditors must evaluate the ability of plant sanitation to adequately clean and sanitize food facilities before plant production begins. These services are coordinated with food safety controls to provide a more complete set of precautions, especially suited to high-risk ready-to-eat products.

Preoperational sanitation audits assess a plant's SSOPs for compliance to regulatory requirements.[20] Actual plant performance is reviewed against written sanitation procedures. These audits evaluate chemical handling and sign-off documents necessary to confirm that proper and regularly scheduled cleaning and sanitation have taken place.

In addition to observations made before production begins, audits review the ongoing sanitation program after production commences, evaluating details and documents that confirm that the impact of proper sanitation continues throughout the manufacturing of the food products.

An additional sampling of the key items that should be covered in an audit of a sanitation program is contained in the following sections.

In accordance with federal GMP guidelines, observations made during a food plant audit are classified by a cause-and-effect approach. Cause, the types of observations made, and effect, the areas of the sanitation program in place, following those cited in the regulations, that are affected by the observations. Furthermore, the observations are classified by their severity into critical, major, and minor.

Recommendations on Sanitation Audits. Some observations are a function of plant and equipment design and construction and can be identified during the initial inspections. Others are related to plant practices or procedures and are therefore a function of time; these should be checked several times during an audit or at specific times.

Be sure to look *up* at the area immediately around you, as well. Whenever possible and it is *SAFE*, go up on top or above the equipment and look down. Throughout the audit, good manufacturing practices utilizing common-sense judgment should prevail.

Locate and check product remanufacture areas for complete GMP compliance. The product remanufacture areas should be considered one more processing area.

Objectives

GMP audits have four primary objectives:

1. To assess the plant facility's compliance to GMPs and to minimize risk of regulatory action by enumerating the GMP observations and classifying their severity.
2. To assist operations in correcting problems by providing the plant personnel with complete information regarding GMP compliance.

3. To evaluate the effectiveness of an operations GMP compliance program by classifying observations in broad cause-and-effect categories and by specifically evaluating the design and construction of new installations and major changes to existing installations.
4. To maintain a database in order to measure changes of GMP compliance over time.

Audit Checklist

The GMP checklist contains the written detailed sanitation/GMP observations and consists of three parts: a general description sheet, the audit worksheets, and a sheet for listing and classifying all GMP observations. All three should be completed for each plant processing area.

General Description Sheet

The general description sheet describes the particular processing area, i.e., types of processing or activity performed, major pieces of equipment, number of each, and general layout of equipment. It specifically identifies new equipment and major modifications since the last audit.

Prior to each audit, it is necessary to check with the central engineering department in order to identify capital projects which have been approved and have GMP implications and, specifically, to identify approved GMP projects. At the plant, it is necessary to check with the plant engineer in order to identify maintenance and repair projects, equipment changes, installations which would also have GMP implications, and to determine the status of capital projects.

All of these should be identified on the General Description checklist and should be evaluated for good GMP design and construction. These projects and installations should not have GMP shortcomings built into them.

This information is needed for reference at the exit meeting, for management reviews, or other meetings with corporate staff. It is most important as part of the historical information/database for evaluating the operations GMP program.

Definition of GMP Observations

By Class

This form (Figure 7.2) serves two purposes and should be completed for the exit meeting at the plant.

1. It provides the plant with a listing of all GMP observations, classified as critical, major, or minor. As such, the observation section should

SANITATION/GMP OBSERVATIONS
Critical, Major, and Minor Classification

OBSERVATIONS	CLASSIFICATION TOTAL	CRITICAL	MAJOR	MINOR
1. Slime and mold				
2. Unclean equipment other than mold				
3. Tank/line cover – MISSING				
4. Tank/line cover – INADEQUATE				
5. Tank/line cover – OUT OF PLACE				
6. Lights uncovered or inadequately cover				
7. Unprotected or inadequately protected openings				
8. Insect/rodent infestation				
9. Peeling paint and/or rust				
10. Product ingredients. Handling and storage				
11. Processing utensils. Handling and storage				
12. Product adulteration/contamination				
13. Eating/drinking/smoking				
14. Housekeeping				
15. Miscellaneous				

Figure 7.2 Sanitation/GMPs observations. Classification by class.

be sufficiently detailed so that plant personnel can identify the areas of concern and the specific pieces of equipment involved.

2. It provides a management tool for identifying plant-wide and, ultimately, operations-wide GMP program shortcomings by summarizing observations into broad cause-and-effect categories, by highlighting chronic problems, and by identifying GMP inadequacies in new installations.

Sanitation/GMP observations are classified into critical, major, and minor classes.

Critical Observations: Any condition of actual product or container adulteration or condition in which adulteration is imminent or inevitable

Examples:

- Rust, peeling paint, or mold on product-contact surfaces or surfaces in contact with product-contact surfaces
- Oils, dirt, condensate, etc., on equipment immediately above or in close proximity to exposed product
- Use of unapproved chemicals in direct food-contact situations or in situations in which there is a high likelihood of product contact

Major Observations: Any condition or practice that is a source of potential product or container adulteration

Examples:

- Evidence of eating or smoking in processing areas or ingredient storage areas
- Exposed light bulbs
- Unprotected openings from processing areas to the outside
- Peeling paint on ceilings or overhead structures in processing areas
- Inadequacies in pest control programs
- Inadequate personnel hygiene

Minor Observations: Any other deviation from GMPs

Examples:

- Poor housekeeping in the plant
- Inadequate maintenance of grounds which are not immediately adjacent to the plant
- Product or foreign material on the exterior of seamers

By Program/Control Area and Type of Observation

This form (Figure 7.3) summarizes the audit observations, classifying them by program control area (upper horizontal listing) and by type (left columnar listing).

Under the Program Control Area, the following characterizations are made:

Employee Hygiene. Relates to unacceptable hygiene practices by the individual.

Observations would include inadequate hair covering, dirty or torn clothing, not washing hands, loose jewelry, chewing gum, improperly bandaged/covered sores, and improper care of gloves. This category is

	A TOTAL	B EMPLOYEE HYGIENE	C EMPLOYEE PRACTICES	D CLEANING & SANITATION	E PEST CONTROL	F PROCESS EQUIPMENT DESIGN & CONSTRUCT.	G PROCESS EQUIP-MENT MAINTENANCE	H NONPROCESS EQUIPMENT CONSTRUCT. & INSTALL.	I BUILDING CONSTRUCTION	J BUILDING MAINTENANCE
TOTAL										
1. Slime and mold										
2. Unclean equipment other than mold										
3. Tank/line cover – MISSING										
4. Tank/line cover – INADEQUATE										
5. Tank/line cover – OUT OF PLACE										
6. Lights uncovered or inadequately covered										
7. Unprotected or inadequately protected openings										
8. Insect/rodent infestation										
9. Peeling paint and/or rust										
10. Product ingredients. Handling and storage										
11. Processing utensils. Handling and storage										
12. Product adulteration/contamination										
13. Eating/drinking/smoking										
14. Housekeeping										
15. Miscellaneous										

Figure 7.3 Sanitation/GMP observations. Classification by program control area and by type.

often not used as employees are usually well versed in proper hygiene practices.

Employee Practices. Relates to poor work-oriented practices that result in GMP observations.

Observations would include tank covers left open; line covers not returned to their normal location after being removed for cleaning purposes; improper use and storage of ingredients, materials, and processing utensils; eating, drinking, or smoking in unauthorized areas; excessive lubrication of equipment; improper storage of personal belongings; poor housekeeping which results from employees' littering of eating and drinking materials and containers; and doors and windows left open.

In reality, most observations result from poor employee practices. This suggests the need for employee training as one of the most important aspects of GMP enforcement in the food industry.

Cleaning and Sanitation. Observations include slime and mold on equipment, support structures, floors, and rails; excessive dirt, dust, and grime on equipment, support structures, and the building's walls, windows, floors, etc.; inadequate cleanup such as excessive litho dust on can rails, dirty rails on full can conveyors; improper use of soaps or detergents that result in either the wrong types being used (not approved by USDA) or not being properly applied or rinsed off.

Pest Control. Inadequacies within the total pest control program involving presence of rodent harborages or insect breeding conditions, improper maintenance of grounds and yard areas, improper placement and maintenance of bait stations and rodent traps, insect monitoring, inadequately maintained insectocutors. Inappropriate use of insecticides and chemicals. Improperly stored equipment and materials, holes in walls or ceilings. Inoperable air curtains and windows without screens could be categorized also as faults in the employee practices or in the building maintenance program control areas.

Process Equipment Design and Construction. Observations are infrequent within this category.

Observations refer to inadequate design and construction of equipment, both process and nonprocess, and relevant support structures for the equipment; observations may include also improper product-contact surfaces, constructed from corrodible and absorbent materials, improper construction (nonradiused corners, deadend gaps, rough welds), absence of line covers, absence of inline bottle/can cleaners, and motors without catch pans or appropriate sleeving where mixing motor shafts enter mixing tanks; product-contact surfaces constructed from corrosive materials; nonradiused inside corners. All these items are directly related to inadequate design considerations and poor construction practices.

Process Equipment Maintenance. Observations include fillers leaking product, product leaking from inadequate seals or tanks, inadequate junctures between tanks and pipelines, inoperable inline equipment such as can/bottle cleaners and packaging machines, peeling paint on product-contact surfaces immediately above exposed product, motors without catch pans mounted above exposed product, reinforcing fibers exposed on product conveyor or sort belts; spray heads plugged or not properly covered, open seams, uncovered tanks, uncovered can lines, inadequately constructed line covers, condensate buildup overhead.

Building Construction. Inadequate building construction such as glass windows or skylights in processing areas; inadequate catwalks or staircases; sewers that don't drain.

Building Maintenance. Refers to inadequacies within a facility's structure; walls, floors, ceilings, etc., resulting from a poor building maintenance program; most of these items are related to poor building maintenance

programs and are usually found in older facilities. Most observations made are considered major.

Observations include holes in walls and ceilings, broken unscreened windows, inadequate floor–wall junctures, exposed insulation in walls, peeling paint on walls and ceilings, deteriorated floors, poorly fitting doors, inoperative air curtains, loose walls (sheet metal type), holes in the roof, cracks or holes in floors. Poor yard maintenance — unpaved or poorly paved yard areas where cracks or holes in the pavement result in puddles of water/product — are also included in this area.

By Type

Slime and Mold. Refers to any incidences of slime and mold observed on processing equipment, sort belts, on the sides of flumes, conveyors, chain guides, etc. The following are places to check for mold:

- Both sides of conveyor belts, particularly in areas where sprays are observed to be plugged or to not completely cover
- Bottom edge of side rails on sort belts and conveyors
- Underside of the tables on handpack fillers
- Inside and bottom outside of chutes on sort belts
- Pans used for holding food
- Backside of shears and conveyor endplates
- Bottom side of shaker screens and dewatering screens
- Upper rails on unseamed full can conveyors

In addition to visual observation, areas of suspect mold should be scraped with a fingernail in order to determine whether there is any buildup.

Observations noted during the course of an audit are classified as minor if the observed mold is in an area before the final product wash, before the product is (heat) processed, or if it is in any other area that would have minimal impact on product quality. Examples include wall mold, mold in wash flumes, and mold slime on seamer housings.

Observations are critical or major if mold is observed in areas where it may have an impact on product quality. Severity of the observation depends upon its impact to final product quality. Examples include mold in choppers, mix/batch tanks, or inside pipes, and mold found in accumulated grain or flour dust and in and around product contact areas.

Unclean Equipment, Other Than Mold. Refers to any instance of accumulated dirt, grime, excessive dust, product build-up, or other debris found on food-processing equipment and related structures. Specifically, reference is made to overhead pipes, beams, fixtures, fillers, conveyors, hoppers, tanks, closing machines, etc. Most observations result from either inadequate or infrequent cleaning and sanitizing practices.

Observations noted are minor if the buildup is minor or is inherent to the facility, and the impact upon product quality is unlikely.

Examples include dusty or dirty idle equipment; dried, splashed product on equipment; or any other evidence of inefficient cleanup procedures.

Observations are classified as critical or major if the buildup is excessive to the point that it may affect product quality, i.e., is directly over exposed product or can come in contact with product currently being formulated or processed.

Tank or Line Covers. This area refers to situations where open, exposed, or unsealed product exists. Lines that convey unsealed product-filled containers should have line covers in areas susceptible to overhead contamination — conveyors, between fillers and seamers, etc.

This type of observation utilizes three categories for reporting purposes:

- Missing Covers. Refers to covers not installed on lines, pipes, or tanks when the initial construction or installation of equipment took place, or that were subsequently removed. Missing covers are considered a critical type of observation.
- Inadequate Covers. Refers to covers that are too short, angled improperly, of a faulty design, made of improper materials, or otherwise creating a potential source of product adulteration/contamination. Observations made in this category are major.
- Out-of-Place. Refers to covers that were removed for cleaning, maintenance, or related reason and were not replaced or were replaced improperly. These covers are adequate for their intended purpose, but not being returned to their proper place are, therefore, out-of-place. In most cases, the bracket covers are in place but the covers themselves are missing. Observations made are major. Of course, if the practice results in product contamination/adulteration, the observation is classified as critical.

Exposed/Inadequately Covered Light Bulbs. Refers to cases where light bulb covers are not present or are cracked, broken, or otherwise inadequate. Observations are major if they occur in product-exposed areas, such as above an open cap feeder container or batching, mixing, and filling areas, or inside a flour mixing bin; otherwise they are considered minor.

Nonfunctioning/Inadequately Functioning Equipment. Applies to any machinery or equipment that is not functioning as designed or intended, or is malfunctioning for one reason or another. Most instances of malfunctioning equipment relate to inadequate equipment maintenance or old and worn equipment. Examples include items such as fillers spilling excess product due to worn or clogged piston valves and inadequate adjustments made to the fillers, plugged spray heads on various types of equipment, and inoperable or faulty in-line container cleaners. Also

included are torn or worn conveyor belts and inadequate can tracks (that could cause container dents, breakage, etc.).

Most observations are considered minor if they do not have a serious impact on product quality.

Unprotected/Inadequately Protected Openings. This category refers to plant/warehouse openings (doors, windows, etc.) that should be closed, properly sealed, and properly protected against the ingress of insects, birds, rodents, etc.

Examples of observations within this category include open plant or warehouse doors without air curtains, unscreened open or broken windows, large openings in walls where equipment goes through, and open doors with air curtains that are either inoperable, are blowing in, or have insufficient capacity to keep insects and birds from entering. This category does not include items such as poorly fitting doors and windows or holes in the wall; these are included under the structural deficiency category. Observations made are considered major.

Insect/Rodent Infestation. Refers to instances of actual infestation found within or around the plant structure, buildings, etc. Examples include findings of droppings and urine, gnawed packages, containers, and walls; actual sightings of rodents and insects, and any other signs that lead the auditor to believe that rodents or insects have infested the facility (active rodent burrows, cat feeding bowls, etc.).

Observations made are critical or major depending on the extent and location of the findings. Extensive findings or findings within processing areas would be considered critical. Isolated findings within warehouses are considered major.

The auditor surveys the facility and checks for protection adequacy and for the presence or absence of the stations and traps. All doorways and openings to the outside should be protected. Stations and traps should be strategically placed. In high traffic areas, the need for stations and traps may not be necessary, as the potential for rodent ingress is low. The auditor must use discretionary judgment in these cases. When stations or traps are missing, according to the plant-provided map, the observations are counted as sanitation/GMP deviations. When the auditor feels protection is inadequate, these observations are considered HACCP recommendations.

The insect/rodent infestation type of observation considers two categories to be used for reporting bait station/rodent trap control:

1. Missing. Traps or stations not present per the plant-provided map
2. Damaged. Traps or stations that have been crushed, run over, or are otherwise inoperable

Observations made in these categories are considered major.

Peeling Paint and/or Rust. Refers to any metal contact/support structure in the area around, above, or near product that is exposed.

Observations made over areas of exposed product are considered major. Other observations are considered minor.

Product Ingredients and Materials — Handling and Storage Practices. Applies to the handling practices of product ingredients and materials during formulation, batching, processing, and storage of food items. Also refers to the subsequent storage practices of finished goods, as well as raw ingredients, packaging, and other materials — chemicals, pallets, drums, etc. — used at a particular facility. Any unsanitary or improper handling and storage practices are included in this category: inadequate chemical control, such as lubricant or soap with the wrong rating for the particular use; improper use of insecticides.

Observations made can range from critical to minor, depending on their impact on final product quality. Examples include:

- Minor. Storage of pallets against building walls
- Major. Open ingredient containers, dirty ingredient containers, improper storage temperatures, unsanitary employee practices by employees in the batching and formulation areas, containers left on processing lines, and spilled ingredients within storage areas
- Critical. Infested ingredients or product materials

Processing Utensils — Handling and Storage Practices. Refers to items other than ingredients and materials used in the batching, formulation, or processing of food products. Specifically, reference is made to safe, sanitary, and appropriate practices in using mixing and measuring utensils and the appropriate storage of these utensils.

Observations include ingredient hoses tucked in steel floor grates, hoses found uncapped or on the ground, dirty measuring/mixing cups, containers, and the use of wood (brooms, sticks) utensils in mix kettles.

Observations are classified as either critical or major depending upon their impact on product quality.

- Critical. Actual or imminent adulteration or contamination
- Major. Potential for adulteration or contamination

Product Adulteration/Contamination. Refers to actual instances or potential situations that could result in the contamination or adulteration of product ingredients, batched product, or the final product itself. Examples include overhead contamination from a foreign substance, dirty containers, dirty-ingredient containers that are emptied directly over ingredients and into good product.

In most cases, sources of potential product adulteration or contamination can be traced to poor employee practices in the handling of ingredients and materials, inadequate housekeeping practices, and lack of adequate on-line equipment, i.e., no line covers, inadequate filler corners, no can or bottle washers.

Observations made are usually classified as either critical or major, depending on their impact or potential for adulteration or contamination. The following guidelines should be used:

- Critical. Actual or imminent adulteration or contamination
- Major. Potential for adulteration or contamination

Eating/Drinking/Smoking. Refers to instances of eating, drinking, or smoking occurring within the plant processing, warehousing, or any other nondesignated eating area. Designated eating/drinking/smoking areas can vary at each facility, so it is wise to find out the plant's specific policies regarding these areas before conducting the audit.

Cases such as these require case-by-case analysis, and the auditor should use common sense judgment when making his or her assessments.

Observations made of individuals eating/drinking/smoking in nondesignated areas are considered major.

Housekeeping. Refers to any instances of unsightly plant appearance — the result of trash, litter, debris, weeds, and thick shrubbery around plant perimeters: spider webs and cobwebs, etc. It also refers to dirty equipment (accumulated dirt, grime, dust, etc.).

Cleaning personnel should be observed for their cleaning practices. Excess detergents and soaps should be rinsed off. Normal washing should not result in water splashing into or onto product-contact surfaces. All product containers, i.e., cans, bottles, jars, should be removed during any cleanup, avoiding possible incidental contamination with detergents or wash water.

Observations made are usually considered minor because they have no impact on product adulteration or contamination. In those cases where the auditor feels that product integrity is potentially threatened, the observations would be considered major.

Miscellaneous. Refers to any previously uncategorized observation or items that are unusual and do not fit the list of categories. A good example here would be the improper storage of personal belongings, such as jackets or other clothing, lunches, thermoses, etc. These items found in production areas, packaging areas, or anywhere else outside of designated storage areas would constitute improper storage. These observations are classified as minor. Lack of proper beard and hair covering are also classified as miscellaneous; these observations are major.

GMP OBSERVATION LIST

DATE:_____
PLANT:_____ **AUDITOR:**_____
CLASS: C = Critical; M = Major; m = Minor

PROGRAM CONTROL AREAS

***For classification of the observations by type, see the back of this page.**

#	Class	Type*	OBSERVATIONS	TOTAL	EMPLOYEE HYGIENE	EMPLOYEE PRACTICES	CLEANING & SANITATION	PEST CONTROL	PROCESS EQUIPMENT DESIGN & CONSTRUCT.	PROCESS EQUIPMENT MAINTENANCE	NONPROCESS EQUIPMENT CONSTRUCT. & INSTALL.	BUILDING CONSTRUCTION	BUILDING MAINTENANCE

Figure 7.4 The audit worksheet.

Standing water, due to inadequate drainage, also constitutes a miscellaneous observation. Try to have these areas observed throughout the audit to determine if it is actually standing water or if the water is due to a recent rain, a leaking hose, or a leaking cooler, etc. These observations are considered minor.

The Audit Worksheet (Observations Listing Form)

These sheets are to be used for recording observations during the audit. They consist of several pages covering the various areas in a plant (Figure 7.4). Each page has a listing of the items to be inspected; columns in which to record the number of critical, major, and minor items inspected; and space for notes regarding the specifics of each item. After the form is completed, the total number of critical, major, and minor observations for each category is entered in the appropriate space at the top of the page.

The listing of items for each area in general is an observation guide only and does not limit the scope of the audit.

During the audit, items which are not on the list should be added, so that specific detailed checklists evolve for each plant. GMP observations for all new equipment or existing installations that have undergone major modifications should be specifically identified. The following section illustrates the format of a sanitation audit report. Table 7.1 is an illustrative example of the classification of observations made on the basis of their class, type, and program control areas affected.

Table 7.1 Classification of Observations. Illustrative Example

Observation	*Class**	*Type*	*Area of the Program*
Bags containing starch, chili, and salt, were left open and unprotected in the spice blending preparation room.	M	Ingred. Handling	Employee Practices
A dirty bag of salt (empty) was left over the feeding opening of the batching kettle, during preparation of the product batch. The bag was normally shaken by the operator over the opening, when preparing the batch.	C	Product Contam.	Employee Practices
Condensate accumulation was observed under the surface of the ketchup line cover, between the filler and the bottle capper.	C	Product Contam.	Process Equip. Design
Some ingredient bags, kept in the refrigerated room, were not stored off the floor.	m	Ingredient Handling	Employee Practices
Two dented cans of a certain product (codes OCT98/RN154 and FEB98/RN4N25) were found on a wall support beam by the west wall of the warehouse.	m	Miscellaneous	Employee Practices
Residues of food (bread pieces, a soft drink can) were left on top of a pallet of product apparently ready for shipping. The product pallets were covered with newspaper.	M	Eating/Drinking	Employee Practices
Some small plastic bags were observed hanging from a horizontal water line leading to the product batching tank.	M	Product Contamin.	Employee Practices
Two open boxes of cloths used for filtering were stored next to a press, and showed dirt accumulated in them.	C	Product Contamin.	Employee Practices
The concrete floor of the packaging section showed several cracks, and was in need of repair.	M	Insect Infestation	Bldg. Maintenance
Salt was weighed out into an empty bag previously used. The operator used his bare hands to handle the salt.	C	Ingredient Contamin.	Employee Practices
Three cans of Eureka product (codes AUG98/RN451 and DEC97/RN8N52) were found left on shelf in the south wall of the sterilizer room.	C	Miscellaneous	Employee Practices
The blending tank used for preparation of spice slurry (spice blending room) had a cover, but was maintained open during operation. Dust or dirt was observed accumulated on the ceiling above the tank.	C	Processing Utensils	Employee Practices

Table 7.1 (Continued) Classification of Observations. Illustrative Example

Observation	*Class**	*Type*	*Area of the Program*
During the second shift, on 8/24/98, four (4) workers were observed in the packaging area wearing beards, but no beard nets. The plant requires the workers to wear hair and beard nets while working in the manufacturing area.	M	Miscellaneous	Employee Practices
An open blue trash container was located inside the plant, by the south side of the emergency door (east wall, ketchup palletizing area). The trash can was open. Food cups, food containers, cigarette wraps and cigarette butts were in the trash container and some on the floor. Flies were around the container.	M	Insect Infestation	Cleaning and Sanitation
Bags containing starch, chili, and salt were left open and unprotected in the spice blending room.	M	Ingredient Handling	Employee Practices
When not in use, scoops for weighing out ingredients for the spice slurry preparation (spice blending room) were left unprotected over a dusty counter.	M	Processing Utensils	Employee Practices
Several cigarette butts were found on the catwalks, north side of the tomato flume running by the south side of the tomato processing building.	M	Smoking	Employee Practices
Inspection of the rat trap #78 was prevented by the material that was stored in the area (old equipment, wood, old empty bags). Access to the trap from the south side was also prevented by iron angles and glass stored in the area.	M	Insect Infestation	Pest Control
The support bars for water sprays at the sort belts #1 through #9 were painted. The paint was flaking in certain segments. Rust was evident.	M	Peeling Paint	Bldg. Maintenance
The air curtain at the door by the ketchup cooler discharge was blowing in instead of blowing out.	M	Inadeq. Protected Openings	Nonprocess Equipm. Install.
Several ceiling panels were missing in the area by the product cook deck.	M	Insect/rodent Infestation	Bldg. Maintenance
The empty room located east of the cook deck for Eureka sauce manufacture was not protected by a door or air curtain. The room was directly exposed to the outside.	M	Inadeq. Protected Openings	Non-Process Equipm. Install.

Table 7.1 (Continued) Classification of Observations. Illustrative Example

Observation	*Class**	*Type*	*Area of the Program*
Eighteen (18) bait stations located in the Benny's product area of the warehouse were either damaged (no records existed indicating that they had been serviced or repaired during the last twelve (12) months.	M	Rodent Infestation	Sanitation
Some welds on the inner side of the tomato flumes were rough and difficult to properly clean.	m	Miscellaneous	Process Equipm. Maintenance**
Some tiles and floor/wall junctions were missing in the product batching area.	M	Insect Infestation	Sanitation

*C = critical; M = major; m = minor.
**Could also be process equipment design and construction.

The Sanitation Audit Report

Report Format

Facility Name

Sanitation/GMP Audit — Dates of Audit

Auditor: _____
(Auditor's Name)

I. Objective
To audit (Facility name) for Sanitation/GMP Compliance

II. Definitions
Critical Deviations
Major Deviations
Minor Deviations
HACCP Observations

III. Protocol
A brief description of the work done, areas audited, and dates of the audit. A brief description of the exit meeting, which reviewed findings and includes a list of those in attendance.
On separate pages:

Audit Summary Charts

A. Sanitation/GMP Observations
Critical, Major, and Minor Classifications

B. Sanitation/GMP Observations
Classifications by Program Control Area

IV. Detailed Listing of Observations
A detailed, area-specific listing for each observation. Begin by listing all Critical observations followed by Major and Minor observations. The order of the observations should be grouped according to the following priority schedule:
1. By Degree of Severity
2. By Program Control Area
3. By Types of Deviations within a Program Control Area

Example of a Plant Sanitation Audit Report

NAMPAHC Mexican Foods Manufacturing Plant
Sanitation/GMP Audit
April 15, 2002

I. Objective
To audit the NAMPAHC Mexican tortilla manufacturing plant for compliance to sanitation/GMP requirements.

II. Definitions
Observation Categories
Critical. Any condition of actual product adulteration, or conditions in which adulteration or contamination is imminent or inevitable.
Major. Any condition or practice that is a source for potential product or container adulteration or contamination.
Minor. Any other observation from the Sanitation/GMP requirements.

III. Summary
The results of this Sanitation/GMP audit indicated that the plant needed improvement in areas related to employee practices. In general, these practices were rather poor. Implementation of a program to instruct the employees on methods for handling food materials, hygiene, and eating and drinking habits, as well as housekeeping, will dramatically improve the sanitary conditions of the plant, guaranteeing a high quality finished product.

Another aspect of the sanitation program needing improvement is building maintenance (repairs of the walls and floor) to prevent possible pest infestation.

IV. Detailed Audit Observations

EMPLOYEE PRACTICES

Observation #1 (Major)
Several 18 lb blocks of shortening, to be used in the batch formulation for flour tortillas, were left uncovered on the table adjacent to the batching tank.

Recommendation
All product ingredients should be kept covered at all times, unless they are being weighed or actually being added into the formulation or batching tank. Covering the product ingredients will prevent their contamination or adulteration by dust, water, any nonproduct, or nonedible material.

Observation #2 (Major)
Three (3) boxes containing scraps of wheat flour tortilla dough were left unattended against the west and south walls of the batching area.

Recommendation
Boxes, buckets, bags, or any other container for the collection of product scrap or residues, garbage, etc., should be kept closed when not in use, properly identified, and used only for the material specifically indicated on the identification.

After disposal of the material in the containers, these should be thoroughly cleaned prior to reuse.

Observation #3 (Major)
A plain, nonlabeled plastic wide-mouth bottle which contained unidentified tablets was located on top of a large plastic bucket, at the southwest corner of the flour tortilla batching area.

Recommendation
This type of occurrence should be avoided at all times. Every container should be properly labeled, indicating the material it contains, *the purpose or use for the material and how to use it*. In the case of the indicated bottle, if it did not have any use at the batching station, it should definitely not have been there, but rather in the place or area where it belonged (laboratory, etc.).

Observation #4 (Minor)
Small plastic bags were observed hanging from the water line to the flour tortilla batching tank.

Recommendation
Nonfood items should be thrown away into garbage, drums, or bags, immediately after having been used. Plastic bags particularly should be disposed of as soon as possible in batching or processing areas, to prevent their possibly falling into the batching tanks, causing not only a problem in the handling of the food material (dough), but also adulteration and contamination of the formula with nonfood material.

Observation #5 (Critical)
The operator handling the pans for the sized dough had very dirty hands (appeared as if his hands were stained with black ink). It was not possible to identify the origin of the stains on his clothes and hands. He placed the dough pieces on the pan using his bare, dirty hands.

Recommendation
Another case of product contamination. The operator should be requested to use disposable gloves and to clean his hands as frequently as needed.

Observation #6 (Major)
Various operators at the flour tortilla batching area did not use hairnets, or, if using them, the nets were placed on the top of their heads, inadequately covering their hair completely, which in most cases was long.

A similar situation was observed with ladies working in several areas of the plant, particularly at the packaging stations, at the end of the flour tortilla lines.

Recommendation
The plant should request that the personnel use their hairnets properly and at all times during their shift. The personnel packing the tortillas in bags at the end of the processing lines should use gloves to avoid handling the product with their bare hands.

Observation #7 (Major)
The finished product (wheat flour tortillas) often fell to the floor when it reached the end of the line at the packaging stations. The product remained in the floor during the entire morning and was only collected at the lunch break.

Recommendation
Product falling to the floor should be collected and disposed of as soon as possible. Buckets could be used between the lines to collect this rejected product, rather than allowing it to remain on the floor for long periods of time.

Observation #8 (Major)
Boxes containing yeast, emulsifier, and calcium propionate remained open most of the time in the ingredient weighing section near the wheat flour tortilla batching area.

Recommendation
Same as in Observation #1

Observation #9 (Minor)
Equipment not in use was placed against the east and south walls in the wheat flour tortilla packaging area.

Recommendation
Equipment not in use should be kept in a specially designated area apart from the processing areas. It should be stored against a wall, leaving a space of about 12 in. between the wall and the equipment, to allow for proper cleaning of the area adjacent to the wall against which the equipment is stored.

Observation #10 (Minor)
After the product is packed, the plastic bags containing it are placed in boxes, which are then covered laterally with a plastic band, palletized, and ready to be transported to storage. They remained uncovered on the top and accumulated dust (flour) on the upper surface of the bags.

Recommendation
The palletized product should also be covered on the top of the pallet to minimize dust accumulation.

Observation #11 (Minor)
A rack containing various corn chip cutting rolls was placed against the west wall of the corn chips batching area. The rack was open and the rolls showed heavy accumulation of dust.

Recommendation
A proper rack should be designed to keep the rolls clean. It would be appropriate if a storage section were designated, away from heavy dust areas, to store these manufacturing tools.

Observation #12 (Major)

(a) An empty plastic bottle, apparently used for drinking water, was left at the entrance of Line #3 of the tortilla chip manufacturing room.

(b) A can of soda was observed left against the west wall beside the wheat flour tortilla batching tank.

Recommendation

Poor drinking or eating habits of employees could result in product adulteration/contamination.

The plant should implement a plan to prevent the workers from eating or drinking in the manufacturing areas. An area should be designated, away from the manufacturing areas, for the employees to eat and drink. The plant has the room where the soft drink machine is located which could be designated as the eating/drinking room, and forbidding those activities anywhere else.

Observation #13 (Major)

The plastic curtain of the door located by the north wall of the tortilla chip manufacturing room (east of the corn-soaking area) was kept open by the employees at all times, to allow for ventilation. Air from the outside was blowing into the plant.

Recommendation

The plastic curtain should remain closed at all times. A system for proper plant ventilation should be designed.

Observation #14 (Major)

Areas outside the plant, against the north wall, near the entrance door to the corn tortilla manufacturing room, showed accumulation of debris.

Recommendation

Keep the areas adjacent to the plant walls clean at all times. Debris or garbage can attract insects or rodents. Garbage and debris should be disposed of in garbage collection cans, which should be covered and located in designated areas, away from the plant grounds.

Observation #15 (Major)

Residues of food (bread pieces, a soft drink can) were left on top of a stack of product — blue corn chips — apparently ready for shipping.

Recommendation

Same as for Observation #14

Observation #16 (Major)
A soft drink plastic bottle had been left on the crossbar of the structure of the grain tank, outside the plant near the north wall entrance door to the corn tortilla manufacturing room.

Recommendation
Same as for Observation #14

Observation #17 (Major)
In the area immediately west of the grain tank, outside the plant, there were two bags of salt left abandoned and exposed to environmental conditions.

Recommendation
Same as for Observation #14

Observation #18 (Major)
Plastic cups and several nonfood objects were observed left on the ground, near the exit door by the east wall of the plant.

Recommendation
Same as for Observation #14

Observation #19 (Major)
A cardboard drum containing seasoning ingredients was left uncovered against the east wall dividing the corn chip manufacturing and packaging rooms. There was evidence that blue corn dust had contaminated the seasoning.

Recommendation
Same as Observation #1

Observation #20 (Critical)
The wheat flour tortilla dough coming out of the batching tank was of a large volume. To handle the dough, the operator in charge cut the dough into two large portions. Using his arms and part of his body (neck and face), he transferred the portions from the stainless steel table into the sizing machine. Sweat from the operator's body contaminated the dough during this handling procedure.

Recommendation
Obviously, this was a flagrant case of product contamination (sweat into product) and constitutes a highly critical sanitation observation.

If a better mechanical handling procedure is not available to improve handling of the dough, instruct the operator to cut the dough into four to five smaller portions and transfer them into the sizers, using a small, hard plastic or stainless steel shovel.

Observation #21 (Major)
The wheat tortilla lines were not covered over most of their length. Of much importance were the sections *between the rollers and the ovens and between the ovens and the east wall of the processing room*, where there was a great deal of flour dust production and accumulation resulting from the batching operation. This dust fell on the equipment and onto the freshly manufactured tortillas.

Recommendation
An effort should be made to cover the sections indicated, due to their proximity to the dust source.

Observation #22 (Critical)
The operators at the tortilla chip batching area were sweating profusely while handling and placing the prepared corn tortilla chip dough into the line feeder. Their sweat came in contact with the dough.

Recommendation
Same as for Observation #20

EQUIPMENT CONSTRUCTION AND DESIGN

Observation #23 (Minor)
The air doors located (a) by the north wall of the tortilla chip manufacturing room (east of the corn-soaking area), and (b) by the east wall of the plant (tortilla chip conveyor line to the bag feeder), were blowing in instead of out.

Recommendation
It appeared that the air curtains were not powerful enough to overcome the wind coming from the outside.

It may be possible that the electrical polarity of the air curtains needs to be reversed to obtain the proper effect, that is for the air to blow out rather than into the plant.

Observation #24 (Major)
The fluorescent light tubes located right above the blue corn tortilla lines in the packaging area were extremely dusty.

Recommendation
The dust can fall onto the product. The tubes should be kept clean and, if possible, relocated to an area not directly above the line.

BUILDING MAINTENANCE AND DESIGN

Observation #25 (Major)
The wall between the processing and the packaging rooms, by the feeding line #1 of the wheat tortilla, had a large hole.

Recommendation
Repair is needed in order to prevent possible insect or rodent harborage.

Observation #26 (Minor)
Various light passages on the ceiling were opened to allow for ventilation into the plant. The openings were located right above several production lines.

Recommendation
Such openings are to provide light *not ventilation* and therefore, they should not be used for that purpose. A different method should be devised to provide for ventilation into the manufacturing plant.

Observation #27 (Major)
The floor in certain parts of the processing area, particularly in the corn soaking (nixtamalization) section was broken, with holes that accumulated substantial amounts of water.

Recommendation
The floor should be repaired, taking care not to leave crevices that could serve as insect harborage.

Observation #28 (Major)
Opened crevices and cracks were observed in the floor of the corn tortilla chip manufacturing and packaging rooms.

Recommendation
The floor should be repaired, taking care not to leave crevices that could serve as insect harborage.

Observation #29 (Major)
The walls of the corn tortilla manufacturing and packaging rooms had sections that were broken or showed peeling paint.

Recommendation
The walls need to be repaired. Holes can serve as harborage grounds for insects or rodents. Peeling paint might end up in the product (possibility for product adulteration).

PEST CONTROL

Observation #30 (Major)
An overturned mouse trap was left very near to bags of salt.

Recommendation
Same as for Observation #14

Observation #31 (Major)
Although a pest control program is in action at the plant, maintained by an outside contractor, no evidence existed of the program being enforced (mouse trap overturned outside, broken walls, etc.).

Recommendation
The plant should have an exhaustive meeting with the contractor and request a complete copy of the program being followed, guidelines, details and the personnel training contemplated in the program. This will allow the plant manager, the QC/QA manager, the plant supervisor, and the line supervisor to maintain proper control and enforcement of the program.

HOUSEKEEPING

Observation #32 (Major)
Scraps and balls of wheat tortilla dough were observed on several sections of the batching and processing areas. Some were smashed against the floor as a result of having been stepped on by people walking in the area.

Recommendation
Product/ingredient/or any other residues should be collected from the floor as soon as possible and thrown into a garbage collection can for their proper disposal.

REFERENCES

1. Marriott, N.G., 1999. *Principles of Food Sanitation*, Aspen Publ., Gaithersburg, MD.
2. FDA, 2002a. Title 21. Foods and Drugs, Part 110. Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. Food and Drug Administration, Washington, D.C.
3. USDA/FSIS, 2003. Title 9. Animals and Animal Products, Part 416. Sanitation.
4. Gavin, A. and Weddig, L.M., 1995. *Canned Foods. Principles of Thermal Process Control, Acidification and Container Closure Evaluation*, The Food Processors Institute, Washington, D.C.

5. Gorham, J.R., 1991. *Ecology and Management of Food Industry Pests*, AOAC International, Arlington, VA.
6. Vasconcellos, J.A., 2000. Regulatory and safety aspects of refrigerated minimally processed fruits and vegetables. A review, in Alzamora, S.M., Tapia, M.S., and Lopez-Malo, A., *Minimally Processed Fruits and Vegetables. Fundamental Aspects and Applications*, Aspen Publ., Gaithersburg, MD.
7. Prince, T.A., 1989. Modified atmosphere packaging of horticultural commodities, in Brody, A.L., *Controlled/Modified Atmosphere/Vacuum Packaging of Foods*, Food & Nutrition Press, Trumbull, CT.
8. Ryser, E. and Marth, E., 1991. *Listeria, Listeriosis and Food Safety*, Marcel Dekker, New York, NY.
9. OSHA, 1998. 29 CFR 1910.141, Subpart J. Sanitation. General Environmental Controls. As amended, June 1998. Occupational & Health Administration, U.S. Department of Labor, Washington, D.C.
10. FDA, 2002b. Title 40. Protection of Environment, Part 503. Standards for the Use or Disposal of Sewage Sludge, Food and Drug Administration, Washington, D.C.
11. USDA, 1997. Agricultural Marketing Service Program. Qualified through Verification for Fresh Cut Produce. Processed Products Branch. Fruit and Vegetable Programs, Agricultural Marketing Service, USDA, Washington, D.C.
12. Gould, W.A. and Gould, R.W., 2001. *Quality Assurance for the Food Industry*, CTI Publications, Timonium, MD.
13. Schmidt, R.H., 1997. Basic Elements of a Sanitation Program for Food Processing and Food Handling. Food Science and Human Nutrition Department, Florida Cooperative Extension Service, Institute of Food and Agricultural Sciences, University of Florida. http://edis.ifas.ufl.edu/FS076. Accessed March 2, 2003.
14. Schuler, G.A., Nolan, M.P., Reynolds, A.E., and Hurst, W.C., 1999. Cleaning, Sanitizing, and Pest Control in Food Processing, Storage and Service Areas. The University of Georgia College of Agricultural and Environmental Sciences, Food Science Extension Program. Bulletin 927, September. http://www.ces.uga.edu/pubcd/b927-w.html. Accessed March 2, 2003.
15. Dauthy, M.E., 1995. Quality control/quality assurance and international trade; good manufacturing practices (GMP); hygiene requirements; hazard analysis and critical control points (HACCP), in Fruit and Vegetable Processing. FAO Agricultural Services Bulletin No. 119. Food and Agriculture Organization of the United Nations, Rome, Italy.
16. EPA, 1996a. Pesticides: Regulating Pesticides. The Food Quality Protection Act (FQPA) http://www.epa.gov/oppfead1/fqpa/backgrnd.htm. Accessed March 3, 2003.
17. EPA, 1996b. Federal Insecticide, Fungicide, and Rodenticide Act. http://www.epa.gov/region5/defs/html/fifra.htm. Accessed March 3, 2003.
18. EPA, 1976. Resource Conservation and Recovery Act. http://www.epa.gov/region5/defs/html/rcra.htm.
19. ASQ Food, Drug, and Cosmetic Division, 2002. History and overview of HACCP: primitive and modern food preservation methods, in *The Quality Auditor's HACCP Handbook*. American Society for Quality (ASQ), Milwaukee, WI.
20. Vasconcellos, J.A., 2002. Quality Assurance for the Food Industry. A Practical Approach, Personal Notes.

Chapter 8

PRODUCT QUALITY AUDITS AT THE RETAIL LEVEL

A product quality audit at the retail level, collected consistently and objectively, is designed to provide statistically valid data for actionable results.

On the basis of product codes and store visits by qualified individuals (field agents), product samples are collected at the "point of purchase"; complete sample and census information can be obtained that allow a manufacturing company to evaluate market conditions for its products and for those of its competitors through the consumers' eyes. An audit also assists the manufacturer in identifying possible improvement opportunities in both quality and profitability.

The products are evaluated for their quality characteristics: comprehensive product and package assessment; sensory evaluations; age and shelf-life studies; and overall product manufacturing performance, as well as marketing conditions such as promotion effectiveness, product distribution, and product penetration at the retail level, where the consumer makes his or her determination of quality. The manufacturing company can use all this information for long-term strategic planning and tactical decision making.

DEFINITION

A product quality audit at the retail level can be defined as the process of inspecting a sample that has previously been inspected and accepted by normal inspection methods, to determine the degree of compliance to established requirements and its quality performance at the retail level.

OBJECTIVES

The objectives of a product quality audit at the retail level are:

1. To determine the quality of the company's product available to the consumer.
2. To compare the results to the limits of the company's quality control (QC) specifications.
3. To compare the quality of the company's product to the quality of competitive brands.
4. To compare the quality of the company's product to that of the same product in previous years.
5. To compare the quality of the product, as manufactured by the company's different plants.

PROCEDURE

As part of the quality assurance (QA) department's annual program, a schedule for product quality audits should be established. The purpose is to select and set priorities, and assign product audit responsibilities among the QA department auditors.

Once the product audit program and the order of priorities are established, each auditor will have the responsibility of collecting the appropriate support information, establishing a time schedule, and coordinating with other persons from the various departments which may be involved (i.e., product development, manufacturing operations, packaging, marketing, etc.) for each of the various aspects of the audit.

PLANNING

Preliminary Review Meeting

Prior to the initiation of a product audit, the QA auditor should hold a preliminary review meeting, the purpose of which is to present an outline of the audit protocol for review and approval by the interested departments.

Protocol

The audit protocol should include:

a. Audit objectives
b. Sampling plan
c. Analytical tests to be performed
d. Sensory characteristics to be analyzed
e. Time schedules

Departments Involved

The review meeting should include, but not be limited to, representatives from:

a. Marketing/Sales
b. Processing operations
c. Product development
d. Sensory evaluation
e. Packaging
f. QC/Statistics

The QA auditor must make sure that all aspects of interest to the various departments are discussed and that all the representatives in attendance agree with the protocol in its entirety.

The representatives from those departments performing agreed-upon support functions (packaging, QC, sensory evaluation) should receive a written memorandum confirming the agreement and including a time schedule regarding initiation and completion of the work to be done. The other representatives in attendance should receive a copy of these memoranda.

Product Sampling

Prior to starting sample pick-up, the QA auditor should review and confirm the product sampling design with marketing.

By this time, marketing should have recommended and provided, as result of the preliminary review meeting, the following information:

1. Any sampling characteristic that would be appropriate to their needs.
2. A list of competitive brands that should be included in the audit for comparison to the company's product.
3. The cities where both the company's and the competitive brand products should be purchased, so as to properly reflect their national distribution.
4. Any other aspect that may be of interest, i.e., container sizes to be collected.
5. Unless otherwise agreed during the review meeting, sampling of the company's products should be designed to proportionally reflect actual production, both in terms of the plant's production and container sizes.

Product Pick-Up

1. Once the preliminary steps mentioned above have been approved, the QA auditor, with the assistance of marketing, will define the

Table 8.1 Cities Where Samples Should be Collected

Atlanta	Los Angeles	New York
Chicago	Miami	Sacramento
Cincinnati	Memphis	Saint Louis
Dallas	Minneapolis	Seattle
Detroit	New Orleans	Tucson

Size and Number of the Company's Product to be Collected per City

8 oz cans:	3 Production codes (01, 02, and 03). 5 cans per production code.
15 oz cans:	2 Production codes (11 and 12). 5 cans per production code.
Total:	5 Production codes

sampling protocol, the approximate pick-up dates, and the instructions to be sent to the field agents for proper pick-up.

Instructions should include the following detailed information:

a. Cities where products should be picked-up (example shown in Table 8.1)
b. Type of product and product brands requested
c. Stores to be visited in each city.
d. Number of sample codes, per store, per city
e. Number of containers, per sample, per city
f. Number of containers, per size, per sample, per city

2. The auditor shall keep a copy of the instructions sent to each field agent, making sure that the instructions are clear and specific. Any possible error must be corrected and further questions regarding the procedure to be used should be clarified.
3. Once the auditor is satisfied with the instructions, approval can be given for the initiation of product pick-up.

For each city, the auditor should send to every field agent an envelope containing sample labels. The labels should contain a sample I.D. number and container number. An example of the labels is shown in Table 8.2, describing the numerical code, which includes city code, sample size code, and number of containers per code.

If any of the field agents do not follow the instructions as written, resulting in confusion or errors in the audit protocol, report the situation to marketing. The auditor should take action for immediate correction and order new sample pick-ups to correct the erroneous ones.

Table 8.2 Samples to be Collected in Atlanta (City Code: 01)

8 oz **0101** 1	8 oz **0102** 1	8 oz **0103** 1
8 oz **0101** 2	8 oz **0102** 2	8 oz **0103** 2
8 oz **0101** 3	8 oz **0102** 3	8 oz **0103** 3
8 oz **0101** 4	8 oz **0102** 4	8 oz **0103** 4
8 oz **0101** 5	8 oz **0102** 5	8 oz **0103** 5
8 oz **01 01** 6	8 oz **0102** 6	8 oz **0103** 6

City code Size code Container Number
01 – 06 = 8 oz

4. Approximately 10 to 15 days after the initiation of pick-up, the samples will start to arrive. They should be entered in a receipt log (Table 8.3) with the following information:
   a. Sample #
   b. City of origin
   c. Number of samples received from each location (city)
   d. Date of receipt
   e. Condition of the cases containing the samples
   f. Condition of the samples

Table 8.2 (Continued) Samples to be Collected in Atlanta (City Code: 01)

15 oz **0111** 1	15 oz **0112** 1
15 oz **0111** 2	15 oz **0112** 2
15 oz **0111** 3	15 oz **0112** 3
15 oz **0111** 4	15 oz **0112** 4
15 oz **0111** 5	15 oz **0112** 5
15 oz **01 11** 6	15 oz **0112** 6

City code Size code Container Number
11 – 16 = 15 oz

5. It is important to include a record of the quality of the work done by each of the field agents. Special emphasis should be given as to how well he or she has packed the individual samples, to prevent damage in transit. This information will be important to pass on to marketing, so that they can advise the agents involved to improve packing during future audits.
6. The agents should include a slip in each shipped case, indicating the date of sample pick-up and the shipment date. This will give

Table 8.3 Samples Receiving Log. Product Audit

Product: _____

Sample #	*City*	*Codes*	*Date Rcvd*	*Date Sent*	*Case Condition*	*Containers Condition*
01	ATLANTA	0101				
		0102				
		0103				
		0111				
		0112				
02	CHICAGO	0201				
		0202				
		0203				
		0211				
		0212				
03	CINCINNATI	0301				
		0302				
		0303				
		0311				
		0312				
04	DALLAS	0401				
		0402				
		0403				
		0411				
		0412				

NOTES: _____

_____

_____

_____

_____

the auditor a general idea of the time needed to receive samples from each of the different cities and may be helpful in the future.

TESTING

Packaging Quality

Upon receipt, all individual containers should be properly identified and package quality evaluated according to the definitions of the company's package-quality document (Figure 8.1).

Eureka Foods, Inc.
R & D - Quality Assurance/Quality Control

PACKAGING-CONTAINER DEFECTS

Document: PACKAGING-CONTAINER DEFECTS	**Product Code: GP001**
Manuf. Plant: NAMPAHC	**Location: Orange, CA**
Revision: 1st Issue	**Issue Date: 09/17/00**
V. P. Operations. Approval: _____	**V.P. QA. Approval: _____**

Procedure for Cartons and Trays Inspection

A. When any hold situation is continuing, due to critical, major or minor defects, the Quality Control Inspector must continue rechecking the situation as often as possible until a recheck is acceptable. The first acceptable recheck marks the end of the hold situation.

B. Checks must be carried out on 10 samples per hour.

Disposition

The lots of cartons or trays failing the requirements of this General Manufacturing Procedure document may either be reworked, with defects eliminated or corrected, or disposition of the lot may be resolved in accordance to the company quality standards disposition and/or the appropriate regulations.

Defect Definitions

A. Carton Exterior

1. Critical Defects

a. Open Flaps. Any flap, top or bottom, unsealed, or malformed joint.

b. Wrong Container Count. Fewer items per carton than specified on carton print.

c. No Closing Film. Film missing that seals product into a tray.

2. Major Defects

a. Improper Flap Position. Flap on the bottom and top of carton must be glued with economy flaps in the exterior position. Side flaps in, front flap out on Convenience Cartons, must be locked into place.

b. Wrong Carton Any discontinued container.

c. Scuffs/Tears. Any scuff, tear, gouge, puncture or combination thereof which is greater than 1/4″ in any direction or which renders information illegible.

d. Defective Carton or Tray. Any material received from a supplier which does not conform to the applicable packaging material specification and established printing and color standards.

e. Stain/Foreign Material. Any discoloration, blemish or similar condition such as grease, dirt, paint or residues of any kind.

f. Out of Square Seal. Any glue flap projecting over 1/8″ beyond the flap edge

Figure 8.1 Packaging container defects (GMO Document).

g. **Poor Gluing.** Hot melt gun application. One stripe on each side of the economy flap. The length of the strip should be 5/8″.
h. **Defective Code.** Any illegible, blurred or incorrect code, wrong ink color, code partially or completely omitted, or wrong locations.
i. **Split Manufacturer's Joint.** Any split, separation or tear along the manufacturer's joint >1/2″.
j. **Improper Tray Closing.** Any tray closing film not sealed completely.
k. **Crushed Tray.** Tray crushed, bent, or torn more than 1/8″.
l. **Inverted Bag.** Top seal positioned at bottom of carton or tray.

3. Minor Defects
   a. **Scuffs/Tears.** Any scuff, tear, gouge, puncture or combination thereof which is less than 1/4″ in any direction.
   b. **Improper Folding.** Folding not occurring along score lines.
   c. **Heavy Glue.** Any glue outside the glue flaps of the carton, or under the economy flap (top only).
   d. **Glue on Sleeve.** Any glue in contact with contents of sleeve or sleeve adhering to case.
   e. **Color/Print Defects.** Any missing print or color. Any out-of-register print, color variations or print color defects which exceed standards, includes Universal Product Code (UPC).
   f. **Glue on Carton.** Any glue in contact with contents of carton or causing adhering to a case.
   g. **Crushed Tray.** Tray crushed, bent, or torn less than 1/8″.
   h. **Inverted Bag.** Top seal positioned at bottom of carton or tray.

Procedures for Cans Inspection

A. Checks must be carried out on 10 individual cans per hour.
B. The lots of cans failing the requirements of this General Manufacturing Procedure document may either be reworked, with defects eliminated or corrected, or disposition of the lot may be resolved in accordance to the company quality standards disposition and/or the appropriate regulations.

Defect Definitions

1. **Critical Defects (Unsaleable Defects)**
   a. **Leaker.** Any leaker, regardless of cause. Includes lifted pull-tabs and broken score lines.
   b. **Fractured Seam, Cutover.** Any fracture or torn seam. Any overhang of metal around top of countersink wall which is fractured.
   c. **False Seam.** Any failure of bodyhook and coverhook to engage.
   d. **Droop Lip.** A projection of double seam more than 0.016″ below the bottom of normal seam. Confirm droop or lip by seam teardown; see seam specification.
   e. **Deadhead. Spinner.** Double seam skid. Any indication of an incompletely rolled seam.

Figure 8.1 (Continued)

f. **Broken Chuck.** Any inward projection on countersink wall caused by a chipped or broken chuck.
g. **Rim Dent "V" Type.** Dent in double seam of can greater than 1/8″ deep. For aluminum cans greater than 1/16″ deep.
h. **Cable Cut.** Any fracture or penetration of double seam caused by a cable or similar conveying device that cuts through end plate.
i. **Buckled Cans.** Any container that has a distended can end where the metal has been pulled away from the counter sink.
j. **Mispackaged Product.** Any product that is mispackaged, in the wrong sleeve, wrong product mix, or that has the incorrect lid stock.
k. **Wrong/Missing Label.** Any wrong litho or label. Any missing label.

2. **Major "A" Defects (Unsaleable Defects)**
   a. **Flag Label.** Any label that has the potential of being separated from its container.
   b. **Label Adhesion.** Any label with less than 50% fiber tear (or 80% ink separation for universal label) of glue application area. Label testing must be done on at least 2 cans per hour per line. After glue is completely dry, test for fiber tears.
   c. **Separated Unit (Bi-Pack Tape).** Tape not holding two cans together as a unit.
   d. **Product on Can.** An observable amount of product on can or end.
   e. **Body Dent.** Dent in body of can greater than:
      202 - 211 diameter - 3/4″ long
      300 - 404 diameter - 1″ long
      502 - 603 diameter - 1-1/2″ long
   f. **Rim Dent Flat.** Flat dent in double seam of can greater than:
      202 - 404 diameter - 1/2″ long
      502 - 603 diameter - 3/4″ long
   g. **Tear (Bi-Pack Tape).** More than 4 individual tears along tape surface. Longest dimension tear of more than 1/8″.
   h. **Loose Edges (Bi-Pack Tape).** Any edge section not in contact with the can or label exceeding 1/2″.
   i. **No Copy (Bi-Pack Tape).** Any label declaration covered by tape making the label unreadable.
   j. **Defective Aluminum Pull-Tab.** Missing or weak pull-tab. Pull-Tab crooked, moved to left or right beyond positioning device.
   k. **Torn Label.** Any tear in any direction greater than:
      202 - 404 diameter - 1/4″ long
      502 - 603 diameter - 1/2″ long
   l. **Crooked Label.** Any crooked label that extends upon either double seam.
   m. **Loose Label.** Any air pocket under label which when pinched together causes label to fold away from can:
      202 - 404 diameter -> 1/8″ deep
      502 - 603 diameter -> 1/4″ deep

Figure 8.1 (Continued)

n. **Rim Dent "V" Type.** Dent in double seam less than 1/8" but greater than 1/16" in depth.
o. **Distorted Plastic Overcap.** Any out-of-round overcaps that cannot be run on equipment.
p. **Damaged Plastic Overcap.** Any holes, cracks, or splits.
q. **Foreign Material on Lid.** Any dirt, insects, etc. embedded in or adhered to lid.
r. **Folded/Creased Label.** Any label folded or creased (wrinkled) in any manner that detracts from the appearance.
s. **Product on Outside of Containers.** Any product that is on the outside of the container that may result in microbiological growth on the cups or lids.
t. **Scuff Label.** Any scuffing that materially detracts from the label appearance and would render the container Unsaleable.
u. **Unreadable UPC Code.** Any UPC code that cannot be read by Bar Code Verifier. (Multi-Pack shrink-wrap labels, only).

3. **Major "B" Defects**
   a. **Cable Scuff.** Any scuff or burn of double scam by a cable or similar conveying device, penetrating into the steel, allowing the possibility of rust to occur. Not deep enough to cut through end plate
   b. **Glue Voids**
      i. **Label Corners.** Any label corner not glued 1/4" along and 1/4" acrossoverlap glue stripe.
      ii. **Label Overlap.** Any glue void completely across lap area over 1" long, other than label corners.
   c. **Defective Pressure-sensitive Pull-Tab.** Pull-tab off center or blistered resulting in a good seal of less than 1/8" around radius of opening.
   d. **Defective Code.** Any illegible, incorrect, or missing code Any off-center code or heavy code which is judged to have fractured the inside enamel.
   e. **Warped Plastic Overcap.** Any warpage creating a gap greater than 1/8" between the external edge and a flat surface.
   f. **Defective Pressure-sensitive Pull-Tab.** Pull-tab off center or blistered, resulting in a good seal of less than 1/8" around radius of opening.
   g. **Wrong or Omitted Print.** Wrong or omitted print on the package
   h. **Stains.** Stains on the outside of the container that can not be removed.
   i. **Off Registration.** Any die cut that results in the loss of graphics
   j. **Product in Seal Area.** Any product that may be trapped in the seal of the cup.
   k. **Product Mix.** Any product that should not be in the cup, any product strings that carried over into the wrong cups, or any blending of two different products in the same cup
   l. **Rocker Bottoms.** Any misformed cup that rocks when set on the counter or that may affect the operation by causing severe down time.
   m. **Off Color.** Any product that is visually not the proper color.
   n. **Melted Bottles.** Any container that appears to have been melted or that is partially melted.

Figure 8.1 (Continued)

o. Scuff Label. Any scuffing greater than:
202 to 404 diameter > 1/8″ (0.125 sq. in.)
502 to 603 diameter > 1/4″ (0.250 sq. in.)

p. Body Dents. Body dents that are within the following criteria:
202 to 211 diameter > 1/2″ to ≤ 3/4″
300 to 404 diameter > 1/2″ to ≤ 1″
502 to 603 diameter >1" to ≤ l-1/2″

q. Abrasion. TFS, enamel or tinplate abrasion on end seam which penetrates into steel, allowing rust to occur. Total area limits for end seam abrasion are: chuck wall area, >10%: end scam chime area, >25%

3. Minor Defects

a. Color/Print Defects. Any missing print or color. Any out-of-register print, variation in color, or defects in print or color. Includes defective Universal Product Code (UPC).

b. Physical Defects. Any physical defect on the container or in the product that detracts from the product appearance but would not result in a consumer complaint.

c. Litho Scratch. Any litho scratch or accumulation of scratches, total area greater than:
202 - 404 diameter - 1/16 sq. in. (1/4″ x 1/4″)
502 - 603 diameter - 1/4 sq. in. (1/2″ x 1/2″)
Applies only to area greater than 1/4" away from double seams.

d. Excess Glue. Excess glue on label or can which detracts from the appearance of the package.

e. Abrasion. TFS, enamel or tinplate abrasion on end seam which penetrates into the steel, allowing rust to occur.

f. Knock-out Dent. Any dent in the end of can caused by knock-out rod. Actual end distortion.

g. Rim Dent "V" Type. Dent in double seam less than 1/16″ in depth.

h. Color (Bi-Pack Tape). Any wrong or off color

i. Wrinkles (Bi-Pack Tape). More than 12 wrinkles.

j. Scuff Label. Any scuffing that does not meet the criteria defined in the Major "B" category and falls within the following parameters:
202 to 404 diameter >0.015; ≤0.125″
502 to 603 diameter >0.032; <0.250″

k. Body Dents: (Litho cans only). Any dent not meeting the criteria defined in the Major B category and falls within the following parameters:
202 to 211 diameter >1/8″
300 to 603 diameter >1/4″

Figure 8.1 (Continued)

A detailed log should be kept regarding the type of defects found in each individual container for further detailed evaluation in the final report (Figure 8.2).

Eureka Foods, Inc.
R & D – Quality Assurance/Quality Control
PRODUCT AUDIT

		CONTAINER ID																			
DEFECTS	**LIMITS**	**0101-1**	**0101-2**	**0101-3**	**0101-4**	**0101-5**	**0102-1**	**0102-2**	**0102-3**	**0102-4**	**0102-5**	**0103-1**	**0103-2**	**0103-3**	**0103-4**	**0103-5**	**0111-1**	**0111-2**	**0111-3**	**0111-4**	**0111-5**
CRITICAL (Unsaleable Defects) Individual Limit = 0, Total Limit = 0																					
Leaker	**0**																				
Fractured seam, Cutover	**0**																				
False seam	**0**																				
Droop lip	**0**																				
Broken chuck	**0**																				
Rim dent "V" type	**0**																				
Buckled cans	**0**																				
Wrong/missing label	**0**																				
MAJOR "A" DEFECTS (Unsaleable Defects) Individual Limit = 1, Total Limit = 2																					
Flag label	**1**																				
Product on can	**1**																				
Body dent	**1**																				
Rim dent flat	**1**																				
Torn label	**1**																				
Crooked label	**1**																				
Loose label	**1**																				
Defective code	**1**																				
Body dent (masked by paper label)	**1**																				
Rim dent "V"	**1**																				
Foreign material on lid	**1**																				
Folded/creased label	**1**																				
Product on outside of containers	**1**																				
Scuff label	**1**																				
MAJOR "B" DEFECTS - Individual Limit = 1, Total Limit = 2																					
Cable scuff	**1**																				
Glue voids	**1**																				
Label corners	**1**																				
Label overlap	**1**																				
Defective code	**1**																				
Warped plastic overcap	**1**																				
Stains	**1**																				
Product in seal area	**1**																				
Off color	**1**																				
Scuff label	**1**																				
Body dents	**1**																				
Abrasion	**1**																				
MINOR DEFECTS - Individual Limit = 5, Total Limit = 8																					
Color/print defects																					
Physical defects																					
Litho scratch																					
Excess glue																					
Abrasion																					
Knock-out Dent																					
Rim dent "V" type																					
Scuff label																					

Figure 8.2 Container defects log.

Sensory Evaluation

To properly evaluate the flavor quality of the audited product, it is necessary to compare it to a representative reference product, selected from the same population as the audit samples, and which has the desired optimum-quality attributes. To find such a reference, a random selection has to be made from various product samples from the manufacturing records, which have already been qualified as a satisfactory grade at the time of production. The reference sample is selected from a group of satisfactory grade production codes, obtained from the plant where the product is manufactured.

To obtain the required samples, the QA auditor should request, by memorandum, a given number of samples randomly selected from production codes manufactured during an entire production period and having excellent analytical and sensory qualities. He should also obtain a copy of the QC data sheet corresponding to the requested samples.

The request should also include the number of cases needed per requested production code. This is calculated in consultation with the QC and sensory evaluation departments in charge of the audit analysis and will depend upon the number of audit samples to be evaluated.

As a rule of thumb, one reference sample helps in the evaluation of five to six audit samples. Therefore, if 200 audit samples are to be tested, normally 30 to 40 reference samples will be needed.

In the case reviewed, since two cases of the reference product will be needed, it would be wise to request two to three cases or production codes per plant.

Upon receipt of the samples for reference selection, place them under refrigeration until the selection and actual testing are initiated. Unless technically counterindicated, keeping the samples under refrigeration will help to prevent flavor changes in both the reference samples and in the audit samples.

The samples from which the reference will be selected will be evaluated by the corresponding Sensory Expert Panel, which will characterize and grade the samples for the different key attributes.

Each expert panelist will rate the selected reference sample on a numerical scale for each sensory attribute. The average of the scores will provide a base reference for the comparison of all the audit samples to be evaluated.

Analytical Testing

The audit samples will be analyzed according to the methodology required for quality control of the product studied. The results are entered in the form shown in Figure 8.3.

Eureka Foods, Inc.
QUALITY ASSURANCE PRODUCT AUDIT

Product: _____
Brand: _____
Date: _____

Can ID							
Production Code							
Date							
ANALYTICAL TESTS							
Vacuum, mm Hg							
Headspace, 1/16in.							
Drained wt, g							
Bostwick, cm							
pH							
Acidity							
°Brix							
Salt, %							
Color Agtron							

Figure 8.3 Product analytical tests log.

The auditor relies on the results obtained from the analysis carried out by the QC personnel in charge of the audit.

Upon finishing the analytical work, the QC manager should submit the results obtained for each product characteristic, for each sample, to the QA auditor, certifying the authenticity of the results and indicating any off-data, explaining reasons for errors, etc.

The QA auditor will statistically analyze the data obtained in order to compare characteristics between plants within the company or between the company's products as a whole, and against competitive products.

EXAMPLE OF A PRODUCT QUALITY AUDIT

Product Audited: Eureka Beef Stew
Eureka Food Products, Inc., Orange, California

Objectives

1. To determine the quality of Eureka beef stew, available at the national retail level.
2. To compare the quality of Eureka beef stew manufactured by Eureka Food Products, Inc., of Orange, CA to that of Classic beef stew, manufactured by CSU Food Processors, of Long Beach, CA.

Protocol

Samples of Eureka beef stew and of Classic beef stew were purchased in 15 cities throughout the U.S., during the period of July 1 to July 15, 2002. In each city, five cans per sample were obtained and sent to Orange by agents of Eureka Food Products, Inc., who were given special instructions on the procedures for acquisition, packaging, and sending of the products.

Once the samples were received at Eureka Food Products, the QA department personnel responsible for the product audit carried out the technical evaluation of the packaging of the products received, according to the specifications of the corresponding program for QC, in order to determine defects present in the product cans.

Determination of the physical and chemical quality attributes, as well as the sensory evaluation of the products, were carried out in the QC laboratories of Eureka Food Products, Inc. For sensory evaluation, samples of each product were evaluated by the beef stew expert panel, to determine the characteristics of flavor, texture, and appearance. The products were also evaluated for the presence of undesirable flavors and other undesirable attributes. The shelf-life of the audited products was calculated for July 8, the midpoint of the period for sample collection.

The results were then compared to the QC Program Limits for the manufacture of this product.

Comparison between Eureka and Classic Beef Stew Products

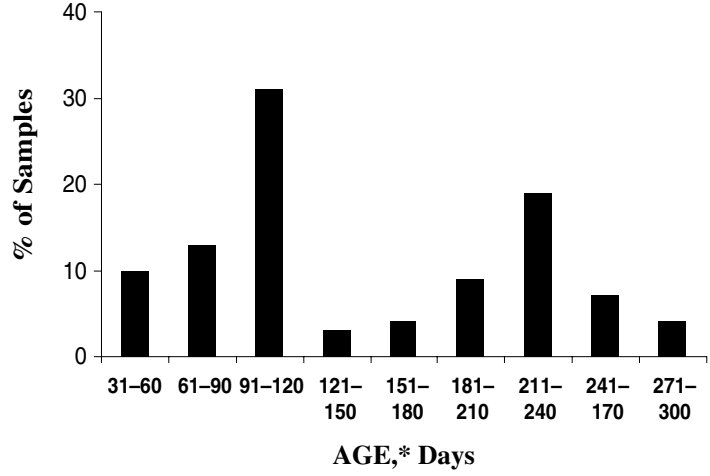
Age

The average age of the Eureka beef stew samples was 148 days, corresponding to production during the first half of March 2002. The age range of the samples was between 45 and 274 days. It was not possible to determine the age for the Classic product, as it was impossible to read its production code. Figure 8.4 shows the age distribution found at the retail level for the samples of Eureka beef stew.

Drained Weight

When the cans were opened and the product was spread on a tray, the Eureka beef stew samples appeared to be bigger and more compacted than those of the Classic product, which tended to crumble into small fragments.

The Eureka product had more meat than the Classic product, as shown by its drained weight of 24.7% and a range between 19.6 and 29.3%. The Classic product had a drained weight of 20.1% and a range of values



Product	Average	Range	No. of Samples
Eureka	148	45–274	30

*Age calculated from July 8, midpoint of the collection period.

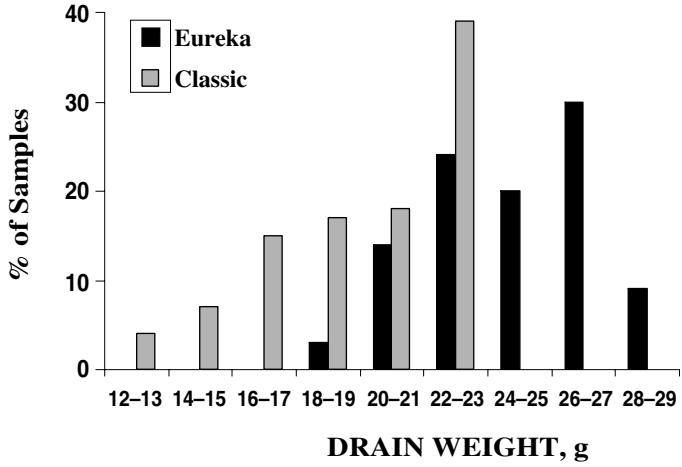
Figure 8.4 Age distribution of Eureka beef stew product.

between 12.7 and 23.8%, which was significantly lower. These values are illustrated in Figure 8.5.

The meat pieces in the Eureka product were irregular in size, with the texture and appearance of natural meat cuts. The meat in the Classic product, in comparison, consisted of cubic pieces of similar size, apparently consisting of processed meat — fractions of meat processed by pressure, formed into blocks and cut into small cubes

Bostwick Value

The Bostwick value of the Eureka beef stew product was 9.1 cm, within a range between 7.5 and 10.7 cm. The average Bostwick for the Classic product was 8.6, with a range between 5.6 and 11.0 cm. No significant differences existed between the Bostwick values of these two products. The distribution of values found for these products is shown in Figure 8.6.



Product	Average	Range	No. of Samples
Eureka	24.7	19.6–29.3	30
Classic	20.1[a]	12.7–23.8	27

*Significantly different.

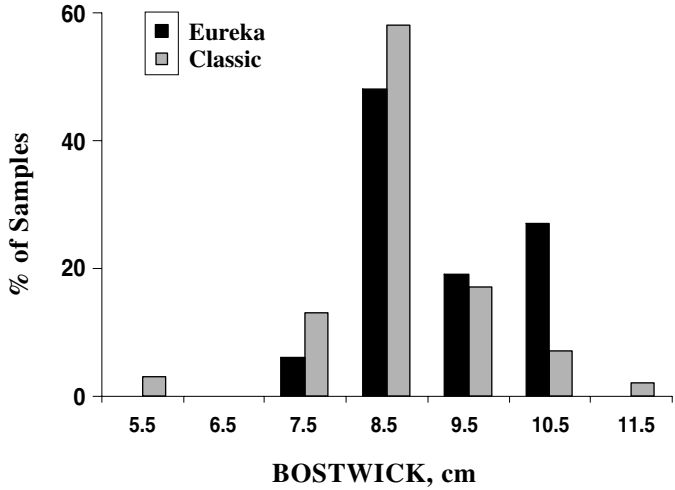
Figure 8.5 Drain weight of beef stew products.

pH

There were no significant differences in pH between the products evaluated. The average pH for both products was 5.9. The range of values for the Eureka product was 5.8 to 6.0 and the range of values for the Classic product was 5.6 to 6.0, as shown in Figure 8.7.

°Brix

The average value of the Eureka product was 12.7°, with a range between 11.6 and 14.0°, as shown in Figure 8.8. The Classic product had an average °Brix of 12.5°, significantly lower than that of the Eureka product. The range of values for the Classic product was between 12.1 and 12.6°.



Product	Average	Range	No. of Samples
Eureka	9.1	7.5–10.7	30
Classic	8.6	5.6–11.0	30

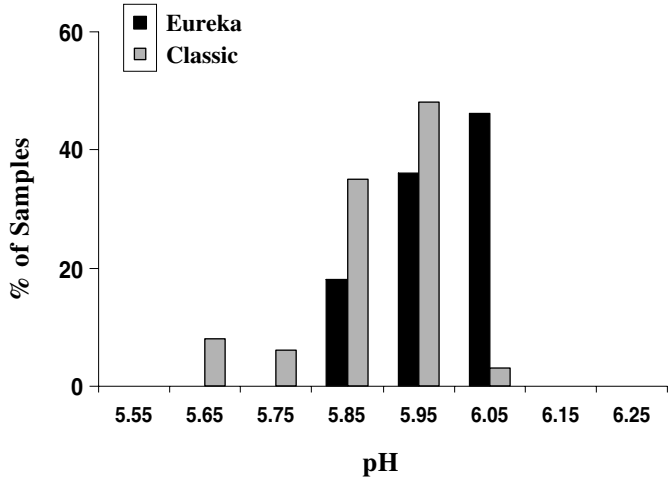
Figure 8.6 Bostwick consistency distribution of beef stew products.

Salt

The average salt level in the Eureka product was 1.7%, significantly lower than the 1.9% in the Classic product. The range of values for the Eureka product was narrow, i.e., 1.1 to 1.8%. In contrast, a range between 1.3 and 2.7% was found in the Classic product. Figure 8.9 shows the comparative distribution of values for the two brands studied.

Color Agtron

The average Agtron color of the gravy in the Eureka product was 12.3, within a range of 9.0 and 18.0, as shown in Figure 8.10; the average Agtron color for the Classic product was 8.4, significantly lower. The range of Agtron values for the Classic product was between 5.0 and 18.0, shown also in Figure 8.10.



Product	Average	Range	No. of Samples
Eureka	5.9	5.8–6.0	30
Classic	5.9	5.6–6.0	30

Figure 8.7 pH distribution of beef stew products.

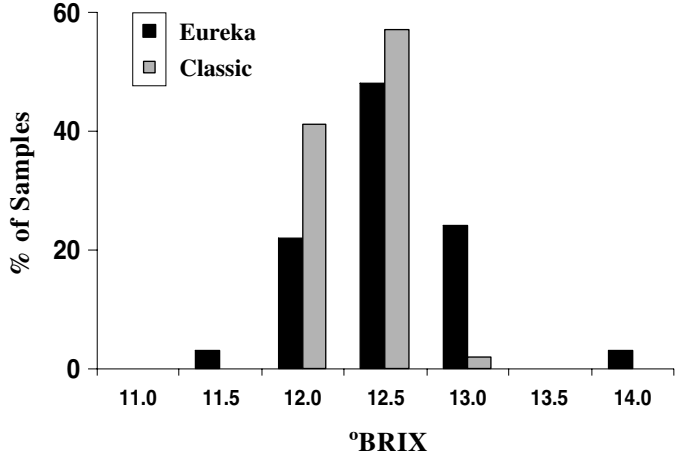
Visually, the gravy from the Eureka product had a light brown and somewhat translucent appearance, whereas the gravy from the Classic product had a dull brown-reddish appearance.

Sensory Evaluation

The sensory evaluation of these products was carried out on 10 samples. The samples were prepared as for normal consumption and served to the panelists at the normal consumption temperature (approximately 60°C). The results of the sensory evaluation were as follows:

Eureka Beef Stew

This product was characterized by a low taste of meat, moderate in spices and low in salt and sour flavors. In general, the vegetable components had a fresh appearance and excellent texture. A celery flavor was noticeable at a moderate level; a flavor of green bell peppers was characterized as low



Product	Average	Range	No. of Samples
Eureka	12.7	11.6–14.0	30
Classic	12.5[a]	12.1–13.1	30

[a]Significantly different

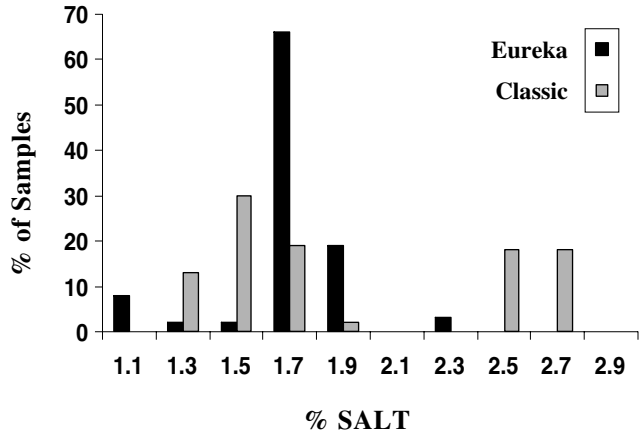
Figure 8.8 °Brix distribution of beef stew products.

to moderate, while sweet red peppers were found to be at a low level. The beef pieces were tender and described as having an acceptable flavor.

Classic Beef Stew

These samples had a low-to-moderate taste of beef, low in spices, and low in gravy and salt. The vegetables appeared somewhat brownish, indicating that they were probably not fresh when used, with a low-to-moderate taste of green bell peppers. A low carrot taste was also noticeable and flavor notes were characterized as a combination of a sweet/salty/sour taste. The texture of the meat pieces was tender, with some of the pieces appearing to crumble in the mouth. They had a moderate flavor of canned meat/beef bouillon.

The samples were inconsistent in appearance and texture, with a low overall flavor. Some of the undesirable flavor notes were described as low-to-moderate “dirt” and “metallic” flavors.



Product	Average	Range	No. of Samples
Eureka	1.7	1.1–1.8	30
Classic	1.9[a]	1.3–2.7	30

[a]Significantly different

Figure 8.9 Salt content distribution of beef stew products.

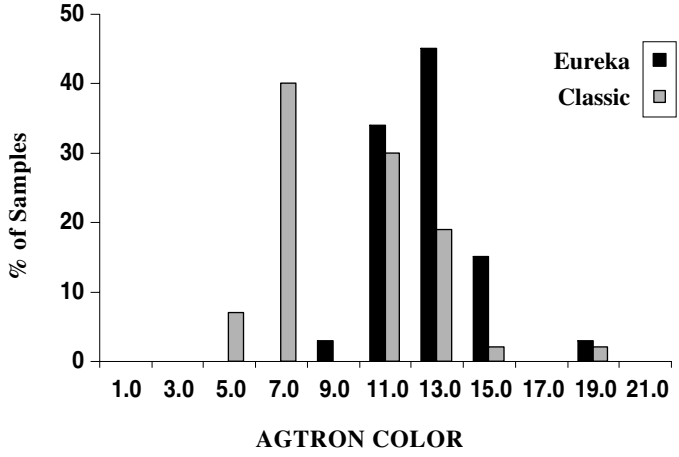
Cans: Vacuum and Headspace

One of the cans of the Classic product had a vacuum of 2.5 in Hg, which is below the required minimum 5 in. This can also had the lowest headspace of 3.5/16 in.

All other cans, of both brands, had vacuum and headspaces within the expected normal ranges.

Can Packaging Quality

The Classic product cans had a higher defect level, with a total of 123.8 defects per hundred units (DPHU), than did the Eureka product cans, whose total was 46.9 DPHU. In many cases, different types of defects appeared on the same can, one reason for the high number of defects found in the Classic product. Most of these defects were related to the label (79.7%), and consisted of nonaligned or loose labels, and excess



Product	Average	Range	No. of Samples
Eureka	12.3	9.0–18.0	30
Classic	8.4[a]	5.0–18.0	30

[a]Significantly different

Figure 8.10 Color Agtron distribution of beef stew products.

glue. Nonaligned labels were the most prevalent defect, at a level of 41.9 DPHU. The incident of dented cans was also high, at 14.5 DPHU.

Among the Eureka product cans, most of the defects consisted of nonaligned labels (25.3 DPHU) and dented cans (8.4 DPHU).

REFERENCE

1. Vasconcellos, J.A., 2002. Quality Assurance for the Food Industry. A Practical Approach, Personal Notes.

Chapter 9

HAZARD ANALYSIS AND CRITICAL CONTROL POINTS

INTRODUCTION

Acronyms such as TQM (Total Quality Management), ISO (International Organization for Standardization), and HACCP (Hazard Analysis and Critical Control Points) have become commonplace in the food industry. Everyone seems to have views on what should and should not be required of the industry. From food companies to regulatory agencies to academia, the debate continues. But, as much as differences exist regarding what should be adopted, and to what degree, the common denominator is the idea of public safety. The bottom line is: Food companies today cannot afford to operate without a comprehensive quality assurance (QA) program, which addresses the critical areas of food safety, and an HACCP program is essential in today's manufacturing climate.

Traditional quality control programs spot-checked manufacturing conditions, and randomly sampled and tested final products to ensure safe food. If the finished product met the specifications, it was approved; otherwise, the product was held, reprocessed, or destroyed. This approach of course was reactive rather than preventive, and was inefficient.

The ideas behind a QA program in general, and an HACCP program in particular, are about preventive systems — to eliminate a problem before it happens. The actions that these systems provoke are essentially preclusive — they are designed to prevent problems rather than solve them after they have occurred. Quality control (QC) checks occur during the process so that a finished product is deemed consistently safe.

THE HACCP CONCEPT

HACCP is an industry-wide effort approved by the scientific, as well as by the regulatory and industry communities, designed to focus on food safety, including food safety in retail establishments. A major focus of the HACCP program is "from farm to table." In this context HACCP is a concept as well as a method of operation, applied to all phases of food production, including agricultural production, food handling, food processing, food services, food distribution, and consumer use. In short, everyone is responsible for safe food products. When it comes to pathogens, "sight, smell, and taste" is not enough. It is necessary to have control over the process, the raw materials, the environment, and the people, beginning as early in the food production system as possible.

In the beginning there was great interest in this new method of food safety. The Food and Drug Administration (FDA) began to train its inspectors on the elements of HACCP and instituted special inspections of HACCP in food processing plants. There were a great number of conferences and meetings about HACCP, including a symposium during the 1974 Annual Meeting of the Institute of Food Technologists. During the 1970s, the FDA promulgated the regulations for thermally processed low-acid canned foods[1] and acidified foods.[2] Although these regulations did not mention HACCP, they were based on HACCP concepts.[3] Over the years, HACCP has been slowly accepted by the food industry and it has become a preventive system that guarantees the safety of food products. In practice, the HACCP program considers all types of hazards or potential hazard factors — biological, chemical, or physical — that could affect food safety and that occur naturally in the food or in the environment, or that are generated due to an error during food processing.

Although the description of the HACCP principles and concepts is relatively simple, the fact is that the development of an HACCP program is not, as will be seen later in this chapter. It takes time, expertise, common sense, and ability to develop an HACCP program.

In 1973, the FDA published the Low Acid Canned Food Regulations, developed using the principles of HACCP.[4] The FDA later published the Pasteurized Milk Ordinance, another set of regulations based on HACCP.[5] In 1985, The Food and Nutrition Board of the National Research Council recommended that HACCP be used as a product safety system to ensure the production of safe food.[6] Since then, HACCP has been incorporated into food regulations and customer purchasing requirements. Both the FDA and the U.S. Department of Agriculture (USDA) have embraced HACCP as an effective method to ensure farm-to-table food safety in the U.S. With the incorporation of the seven principles of HACCP into the United Nations Codex Alimentarius – Commission Food Hygiene, HACCP has also been embraced as an international standard for ensuring food

Table 9.1 Chronology of Development of HACCP as a Safety System in the Food Industry

1971. HACCP, as we presently know it, took form at the National Conference on Food Protection, where risk assessment was combined with the critical point concept.

Mid 1970s. Pillsbury first used HACCP for safety of foods in the U.S. Space Program and adopted it as a company-wide food-protection system. Pillsbury published the first comprehensive treatise on HACCP in 1973.

1973. An HACCP system was adopted for the Low-Acid Canned Food Regulations following the Bon Vivant Vichyssoise Soup botulism incident, in which several people died after eating the soup, due to botulism poisoning.

1985. The Food and Nutrition Board of the National Research Council/National Academy of Science published two books recommending that HACCP be used as a product safety system to ensure the production of safe food and for the broad application to various categories of noncanned food.

1989. The U.S. National Advisory Committee on Microbiological Criteria for Food (NACMCF) developed and approved a standardized and updated HACCP system, endorsed by federal regulatory agencies responsible for food safety.

1990s. The United Nations Codex Alimentarius Commission Food Hygiene standard embraced HACCP as an internationally accepted method for ensuring food safety by identifying hazards and monitoring their Critical Control Points in the process.

1997 December. FDA's Seafood HAACP program becomes mandatory.

1998 January. HACCP becomes mandatory for large meat and poultry manufacturers.

1999 January. HACCP becomes mandatory for small meat and poultry manufacturers.

1999 May. A voluntary pilot study to test the implementation, evaluation, monitoring, and enforcement of the proposed National Conference of Interstate Milk Shipment HACCP program.

1999 September. HACCP becomes mandatory for frozen dessert manufacturers in the state of Ohio.

2000 January. HACCP becomes mandatory for very small meat and poultry manufacturers.

2002 January. The juice HACCP regulation begins to be mandatory for processors, small businesses, and very small businesses.

Source: From Ohio State University Extension Bulletin 901, 2002.

safety.[7] Table 9.1 shows the chronology of development of HACCP in the food processing industry.[8] More recently, HACCP has expanded beyond the food industry. The FDA is evaluating pilot study results in the medical device industry, to determine whether HACCP should be incorporated into medical device regulations.

HACCP was a program originally developed as a microbiological system in the 1960s, to ensure the safety of food for astronauts.[9] The Pillsbury Company was asked to develop the first space foods as well as to design a system for controlling the safety of space foods used first for the Mercury flights and later for the Gemini and Apollo flights.[10,11] Working in collaboration

with the National Aeronautic and Space Administration (NASA), the U.S. Army Natick Laboratories and the U.S. Air Force Space Laboratory Project Group, Pillsbury pioneered its development, based on the "Failure, Mode and Effect Analysis" (FMEA) engineering system. This system looks at what could potentially go wrong at each stage in an operation, together with possible causes and the likely effects. But HACCP is more than a failure-mode-effect analysis for food. Essentially, HACCP is a product safety management system that identifies and monitors specific food-borne hazards — biological, chemical, or physical properties — that can adversely affect the safety of the food product, allowing food processors to take a proactive approach to prevent food-borne diseases.[10] This hazard analysis serves as the basis for establishing critical control points (CCPs) or steps in the process that must be controlled to ensure the safety of the food. Critical limits are then established that document the appropriate parameters that must be met at each CCP. Monitoring and verification steps are included in the system to ensure that potential risks are controlled. The hazard analysis, CCPs, critical limits, and monitoring and verification steps are documented in an HACCP plan. A properly implemented and functioning HACCP program minimizes the need for extensive product sampling and testing, since preventive measures are built into the production controls.

During the original development of HACCP, assurances of safety necessary for the space program required nearly totally destructive sampling with little product remaining for consumption. This was unacceptable for obvious reasons. In the Pillsbury-Natick program, a food processing operation was treated as an interlocking total system. Each facet was broken down and analyzed for its contribution to the overall level of risk associated with consumption of the product. Effective control mechanisms were then put in place to ensure that potential failures were prevented from occurring, focusing on preventing — rather than correcting — hazards that could cause food-borne illnesses, by applying science-based controls from raw material to finished products.[11] The program allowed the identification, prediction, and prevention of potential safety problems throughout the food-manufacturing process, setting up methods to control each possible hazard. A manufacturer then could keep records to make sure that the controls worked. With this program in place, testing the foods for safety was unnecessary.

This approach worked so well that the regulatory agencies began to adopt it as an approach to the control of microbiological hazards in the canning industry, beginning in about 1970. In 1971 the hazard analysis concepts were first introduced at the National Conference on Food Protection.[11] Extension to low-acid canned foods in general occurred in 1971 and 1972, and regulations pertaining to use for these foods were promulgated in 1973.[1,2,12] Gradual but incomplete acceptance of the program

within the food industry followed until 1980, when the U.S. regulatory agencies and the Natick Laboratories requested that the National Academy of Science study the application of microbiological control criteria to food manufacturing operations throughout the U.S. The report of the subcommittee convened with this purpose[14,15] was widely accepted and continues to be the preeminent reference on this subject. Since that time, numerous seminars and symposia, roundtables, and training courses offered by organizations and individuals have defined and redefined HACCP and its operating principles, excellent books have appeared on the topic,[15–17] and generic and specific computerized programs for HACCP management are being offered in the market. One of them, "Keller-Soft HACCP Compliance Software" offered by J.J. Keller & Associates, Neenah, WI, is an excellent program and is becoming widely used by manufacturing and food consultants. However, the plethora of information available on HACCP programs and their design and implementation in general tend to be unnecessarily complicated for those in the food industry who are responsible for HACCP development.

It is important to always remember that the establishment of effective HACCP programs involves primarily the application of good common sense and preventive considerations to address situations before they become problems. The emphasis is on prediction rather than reaction, on getting the process right initially rather than correcting it after problems have occurred. Many food companies operated in this manner long before 1971 because it made sense and it was cost-effective to do so. Only more recently have programs been formalized and honed to the point that they are effective tools, acceptable to both industry and regulators.

Professionals seeking additional information on HACCP programs and their implementation are directed to the publication of the HACCP working group of the National Advisory Committee on Microbiological Criteria for Foods.[18] This document provides a detailed explanation of HACCP principles and includes a decision tree, which may be of assistance in identifying CCPs.

By using HACCP, the manufacturer will no longer need to rely solely on routine inspections to spot potential food safety hazards. An HACCP program makes inspections more useful by concentrating only on potential problems and on critical areas and thus saves time. Once problems are identified, they can easily be corrected. Records produced for the HACCP system also have benefits. Tracking food temperatures and other data allows workers to become interested in food safety, leading to better food handling, improved food quality, and increased pride in their work.

An HACCP program should cover all foods. For most foods, this requires knowledge of basic food-manufacturing practices and common sense. For multi-ingredient foods, technical assistance is recommended.

The HACCP program for each food product being manufactured in a plant make up the HACCP program of that plant.

The FDA has adopted the HACCP system and intends to eventually use it for much of the U.S. food supply. Many of its principles are already in place in the FDA-regulated low-acid canned food industry. In a 1995 final rule, which took effect in December 1997, the FDA established HACCP for the seafood industry.[19] Also, the FDA has incorporated HACCP into its Food Code, a document that gives guidance to and serves as model legislation for state and territorial agencies that license and inspect food service establishments, retail food stores, and food vending operations in the U.S.

Under the Pathogen Reduction and HACCP systems regulations,[20] the USDA required that HACCP be implemented first in the largest meat and poultry plants, with 75% of slaughter production under HACCP-based process control systems by January 26, 1998. Plants are required to develop HACCP programs to monitor and control production operations. Most of these establishments were required to start using HACCP by January 1999. Very small plants had until January 25, 2000 (USDA regulates meat and poultry; FDA all other foods).

In April 1998, the FDA proposed requiring HACCP controls for fruit and vegetable juices[21] and in January 2001 published the final rules for mandatory HACCP of all manufacturers of fruit and vegetable juice and juice products.[22] The final rule for the juice industry took effect on January 22, 2002 for large and medium businesses, January 21, 2003 for small businesses, and will take effect on January 20, 2004 for very small businesses. The FDA is also considering developing regulations that would establish HACCP as the food safety standard throughout other areas of the food industry, including both domestic and imported food products.

To determine the degree to which such regulations would be feasible, the agency is conducting pilot HACCP programs with volunteer food companies. The programs involve cheese, frozen dough, breakfast cereals, salad dressing, fresh and pasteurized juices, bread, flour, and other products.

HACCP has been endorsed by the National Academy of Sciences, the Codex Alimentarius Commission (an international food standard-setting organization), and the National Advisory Committee on Microbiological Criteria for Foods. Today, many U.S. food companies already use the HACCP system in their manufacturing processes, to make sure their products are safe. The system is also in use in other countries, including Mexico and Canada, and within the European Community (member countries of the European Union), where HACCP is propitiated by the directive 93/43 in effect since December 1995.

While there is no official document that states exactly what is critical, a thorough HACCP program identifies the critical areas of an operation and provides methods of monitoring, recording, and handling those areas.

THE IMPORTANCE OF HACCP

New challenges to the U.S. food supply have prompted the FDA to consider adopting an HACCP-based food safety system on a wider basis. One of the most important challenges is the increasing number of new food pathogens. For example, between 1973 and 1988, bacteria not previously recognized as important causes of food-borne illness, such as *Escherichia coli* O157:H7 and *Salmonella enteritis*, became more widespread. There are also increasing public health concerns about chemical contamination of food, for example, the effects of lead and other heavy metals present in food on the nervous system. Other important factors are that the size of the food industry and the diversity of products and processes have grown tremendously — in the amount of domestic food manufactured and the number and kinds of foods imported. At the same time, the FDA and state and local agencies have the same limited level of resources to ensure food safety.

The need for HACCP in the United States, particularly in the seafood industry, is further fueled by the growing trend in international trade for worldwide equivalence of food products and the Codex Alimentarius Commission's adoption of HACCP as the international standard for food safety.[7,23]

ADVANTAGES

HACCP offers a number of advantages. Most important, the program:

1. Focuses on identifying and preventing hazards from contaminating food, based on sound science.
2. Permits more efficient and effective government oversight, primarily because record keeping allows investigators to see how well a firm is complying with food safety laws over a period, rather than how well it is doing on any given day.
3. Places responsibility for ensuring food safety on the food manufacturer or distributor.
4. Helps food companies to compete more effectively in the world market.
5. Reduces barriers to international trade.

In the application of HACCP, the use of microbiological testing is seldom an effective means of monitoring CCPs, because of the time required to obtain results. In most instances, monitoring of CCPs can best be accomplished through the use of physical and chemical tests, and through visual observations. Microbiological criteria do, however, play a role in verifying that the overall HACCP system is working.

For a successful HACCP program to be properly implemented, management must be committed; this indicates an awareness of the benefits and costs of HACCP, and will include education and training of all employees. Benefits, in addition to enhanced assurance of food safety, are better use of resources and timely response to problems.

THE HACCP PROGRAM

Guidelines for Application of the HACCP Principles

HACCP has become a technical management program in which food safety is addressed through the control of biological, chemical, and physical hazards in all segments of the food industry from growing, harvesting, processing, manufacturing, and distributing to preparing food for consumption. For the successful implementation of an HACCP program, management must be strongly committed to the HACCP concept. A firm commitment to HACCP by top management provides company employees with a sense of the importance of producing safe food.

Prerequisite programs such as current Good Manufacturing Practices (cGMPs) are essential for the development and implementation of successful HACCP programs. Food safety systems based on the seven principles of HACCP have been universally accepted by government agencies, trade associations, and the food industry and are being successfully applied in food processing plants, retail food stores, and food service operations around the world. The development of effective HACCP programs should be appropriately implemented in each manufacturing stage of the food industry under consideration.

HACCP Program Prerequisites

The production of safe food products requires that an HACCP program be built upon important prerequisites. The following are examples of common prerequisites.

Facilities. The establishment should be located, constructed, and maintained according to sanitary design principles. There should be linear product flow and traffic control to minimize cross-contamination from raw to cooked materials.

Supplier Control. Each facility should assure that its suppliers have in place effective GMP and food safety programs. These may be the subject of continuing supplier guarantee and supplier HACCP system verification.

Specifications. There should be written specifications for all ingredients, products, and packaging materials.

Production Equipment. All equipment should be constructed and installed according to sanitary design principles. Preventive maintenance and calibration schedules should be established and documented.

Cleaning and Sanitation. All procedures for cleaning and sanitation of the equipment and the facility should be written and followed. A master sanitation schedule should be in place.

Personal Hygiene. All employees and other persons who enter the manufacturing plant should follow the requirements for personal hygiene.

Training. All employees should receive documented training in personal hygiene, GMPs, cleaning and sanitation procedures, personal safety, and their role in the HACCP program.

Chemical Control. Documented procedures must be in place to assure the segregation and proper use of nonfood chemicals in the plant. These include cleaning chemicals, fumigants, and pesticides or baits used in or around the plant.

Receiving, Storage, and Shipping. All raw materials and products should be stored under sanitary conditions and the proper environmental conditions, such as temperature and humidity, to assure their safety and wholesomeness.

Traceability and Recall. All raw materials and products should be lot-coded and a recall system in place so that rapid and complete traces and recalls can be done when a product retrieval is necessary.

Pest Control. Effective pest control programs should be in place.

Other prerequisite programs include:

- Quality assurance procedures
- Standard operating procedures for sanitation, processing, product formulations and recipes
- Glass control
- Procedures for receiving, storage, and shipping
- Labeling
- Employee food and ingredient handling practices

Each stage of the manufacturing process must provide the conditions necessary to protect food while it is within that stage. This has traditionally been accomplished through the application of cGMPs, now considered to be prerequisite to the development and implementation of effective HACCP programs.

Prerequisites provide the environment and conditions necessary for the production of safe, wholesome food. Many of the conditions and

practices are specified in federal, state, and local regulations and guidelines (e.g., cGMPs and Food Code). At the international level, the Codex Alimentarius General Principles of Food Hygiene describes the basic conditions and practices expected for foods intended for international trade. In addition to regulatory requirements, industry often adopts policies and procedures specific to their operations.

The existence and effectiveness of prerequisites should be assessed during the design and implementation of an HACCP program. All prerequisites should be established, documented, regularly audited, and managed separately from the HACCP program. Certain aspects, however, may be incorporated into the program. For example, many establishments have preventive maintenance procedures for processing equipment to avoid unexpected equipment failure and loss of production. During the development of an HACCP program, the team may decide that the routine maintenance and calibration of an oven should be included in the plan as a verification activity. This would further ensure that all the food in the oven is cooked to the minimum internal temperature necessary for food safety.

Education and Training

The success of an HACCP program depends upon educating and training management and employees in the importance of their role in producing safe foods. Employees and operators must understand what HACCP is and learn the skills necessary to make it function properly. This should include information about the control of foodborne hazards in all stages of food manufacturing. Specific training should include working instructions and procedures outlining the tasks of those employees monitoring CCPs. Personnel must be given the materials and equipment necessary to perform their required tasks; management must provide the time for a thorough education and training of their personnel.

Formal training in QA and quality management is not readily available at many major universities.[24] The results of a survey by the Institute of Food Technologists, however, indicates that several food science departments are currently planning or commencing courses of this type. In addition, one of the most promising avenues for increasing the amount of training in QA and QC is the use of postgraduate or continuing education programs.

One of the reasons that the first formal HACCP programs pertaining to low-acid canned foods were so successful[25] was the emphasis that was placed on training the operators who controlled the equipment and were responsible for its maintenance. Regulatory personnel also were required to attend training courses on HACCP implementation. In this way, a

common starting point was established for hazard assessment and control in that portion of the food industry.

Training programs should include various aspects of food microbiology and epidemiology.[26] In these programs, data should be presented that increase understanding of how processes work, as well as how HACCP can reduce or eliminate risks that might be present in these processes. Practical examples relating to hypothetical food plants may be helpful in relating the material to "real world" situations.

DEVELOPMENT OF AN HACCP PROGRAM

The format of HACCP programs varies depending upon several circumstances. In many cases, the program will be product and process specific. In other cases, the programs may use a unit operations approach. Generic HACCP programs can serve as useful guides in the development of process and product HACCP programs; however, it is essential that the unique conditions within each facility or plant be considered.

In the development of an HACCP program, five preliminary tasks need to be accomplished before the application of the HACCP principles to a specific product and process.[12]

The Preliminary Tasks of an HACCP Program

As Sperber[27] notes, there were originally three principles; however, expansion and better definition of the HACCP concept has enlarged this number to provide for the operation of a more comprehensive program. The preliminary tasks in the development of an HACCP plan are summarized below. The identification, analysis, and control of significant hazards are described in somewhat greater detail when reviewing the seven principles of an HACCP program.

Choosing the HACCP Team

The team's responsibility is to develop the HACCP program. The HACCP team must be composed of individuals with specific knowledge of the product characteristics and expertise appropriate to its manufacturing process, and its variability and limitations, including individuals from areas such as engineering, production, sanitation, QA, analytical/food microbiology, and personnel involved in the manufacturing operation itself. This fosters a sense of ownership among those who must implement the program.

Due to the technical nature of the information required for hazard analysis, it may also be necessary that outside experts, knowledgeable in the food process, either participate in or verify the completeness of the

hazard analysis and the HACCP program, evaluating the potential biological, chemical, and physical hazards associated with the product and the process. The HACCP team must consider, however, that a plan which is totally developed by outside sources may turn out to be erroneous, incomplete, and lacking in support at the local level. Outside experts should have the knowledge and experience to correctly:

- Conduct a hazard analysis
- Identify potential hazards
- Identify hazards which must be controlled
- Recommend controls, critical limits, and procedures for monitoring and verification
- Recommend appropriate corrective actions when a deviation occurs
- Recommend research related to the HACCP program if important information is not known
- Validate the HACCP program

Description of the Food Product and Its Distribution

The HACCP team must be able to describe the food product. This includes a general characterization of it, its ingredients, and the processing and manufacturing methods. The method of the product distribution should also be described, along with information on whether the food is to be distributed frozen, refrigerated, or at ambient temperature, as well as the storage requirements.

Description of the Intended Use and Consumers of the Product

A description of the normal expected use of the food product should be outlined. The intended consumers may be the general public or a particular segment of the population, e.g., infants, immunocompromised individuals, the elderly, etc.

Development of a Flow Diagram Describing a Food Product Manufacturing Process

A flow diagram provides a clear, simple outline of the steps involved in the manufacturing process. The flow diagram should cover all the steps in the manufacturing process, which are directly under the control of the manufacturing plant. It can also include steps in the food chain, before and after processing, which occur in the plant. The flow diagram need not be complex. A block-type flow diagram such as the one shown in Figure 9.1, describing the production of frozen cooked beef patties, is simple, easy to understand, and sufficiently descriptive.

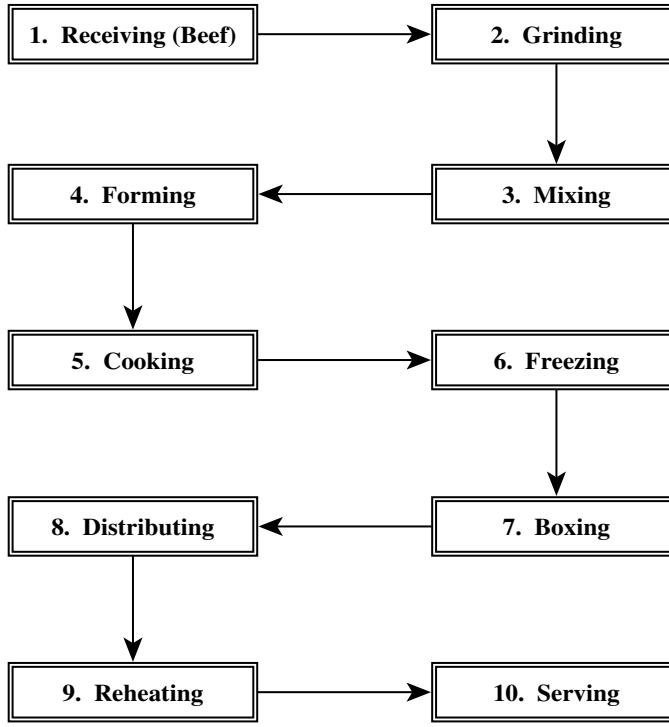


Figure 9.1 Flow diagram of frozen cooked beef patties manufacturing process. (From U.S. National Advisory Committee on Microbiological Criteria for Foods (NACMCF), 1998.)

The archives of the microbiology and QA groups may contain data gathered in the past on the effectiveness of control steps in eliminating or controlling the growth of potential foodborne pathogens. Such data can be of much value to the HACCP team. Should this information not exist, it can easily be obtained, in replicate, over a period of time.

Verification of the Flow Diagram

Once the previous tasks have been completed, the HACCP team should perform an on-site review of the manufacturing operation to verify the accuracy and completeness of the flow diagram. For example, where there are considerable amounts of raw materials, processing equipment such as receiving stations or conveyors, or inspection and testing prior to processing, it may be wise to break out that processing step into a separate flow diagram for clarity and accuracy in hazard analysis review.[12] Modifications should then be made, as necessary, and the flow diagram documented.

Failing to include a process step in the HACCP plan can result in an inaccurate representation of the process and this could lead to disastrous consequences. The omission of a processing step means that the step is not subjected to the required scientific analysis for biological, chemical, and physical hazards. Once the process flow diagram is properly modified, it should be signed and dated to serve as a record that it has been reviewed and accepted for the product, process, and site being analyzed.[12]

THE SEVEN HACCP PRINCIPLES

After these five preliminary tasks have been completed, the seven principles of HACCP are applied.

Principle 1: Conduct a Hazard Analysis

After addressing the preliminary tasks discussed above, the HACCP team must conduct an analysis with the purpose of developing a list of hazards — biological, chemical, or physical — reasonably likely to cause injury or illness if not effectively controlled. When conducting a hazard analysis, considered by many to be the foundation of an HACCP plan, *safety* concerns must be differentiated from *quality* concerns. The word hazard, as used in this context, is related to safety. A thorough hazard analysis is key in the preparation of an effective HACCP program. If the hazard analysis is not done correctly and the hazards warranting control within the HACCP system are not identified, the plan will not be effective regardless of how well it is followed.

The hazard analysis and identification of associated control measures accomplish two objectives:

- Potential hazards and associated control measures are identified.
- The identified hazards are evaluated and modified, if necessary, so that product safety is further assured or improved. The completed analysis provides a basis for determining CCPs in Principle 2.

In the first objective, hazard identification, the HACCP team reviews the ingredients used in the product, the activities required at each step in the process, the equipment used and its characteristics, the final product and the methods for its handling, storage, and distribution, the intended use, and the product consumers. Based on this "brainstorm" review, the team develops a list of potential biological, chemical, or physical hazards, which may occur, increase, or are necessary to control, at each step of the manufacturing process. Table 9.2 provides examples of the type of

Table 9.2 Examples of Practices that Increase Potential Food Safety Hazards

CROSS-CONTAMINATION
Storage of raw foods and ingredients with manufactured and ready-to-eat foods
Poor employee sanitation practices
Failure to clean equipment properly
Failure to protect food adequately from contamination
Improper storage of refuse in food manufacturing areas
IMPROPER STORAGE
Food storage at improper temperatures
Use of coolers and other processing units without thermometers
Use of poor cooling practices; overloading of refrigeration units
Storage of food in improperly labeled containers
OTHER HAZARDS (BIOLOGICAL, CHEMICAL, PHYSICAL)
Use of improper or inadequate cleaning and sanitation practices
Use of poor food manufacturing and handling practices
Use of utensils or food contact surfaces made from improper materials
Inadequate maintenance of documentation and records
Improper storage of chemicals and personal items

practices that may be helpful to consider when identifying potential hazards. Knowledge of any adverse health-related events historically associated with the product will be of value in the identification process.

After the list of potential hazards is completed, the second objective, hazard evaluation, is conducted.

An important part of the HACCP evaluation is the HACCP flowchart. A flowchart positions process components in the actual sequence in which they exist within the plant, beginning with raw materials and ending with the packaging operation and storage of the finished product. It will include details of critical process steps such as temperature, pH levels, and dwell times. Frequently, standard flowcharts do not include certain aspects of the overall process that are vital to its safety. Among such "hidden" risk points are things such as consumer abuse, storage, and transport of the product. These should be added at the time that the HACCP chart is formulated, and thus may differ substantially from traditional charts formulated by engineering and plant groups. The flowcharts should include not only process elements or steps, but also what the steps entail. For example,

an aseptic process step noted and drawn on the flow chart should include time of heating, the temperature attained, and details of cooling.

An analysis is then carried out in which each process step shown on the flow chart (Figure 9.1) is evaluated for potential risk. Addressing each process point, the potential hazard is listed followed by whatever measures are present for its control. The characterization of each individual process point is the task of the HACCP team and will rely heavily on the team members with microbiological background. Hazards relegated to the low-risk category are essentially deleted from further consideration and the focus of the team turns toward significant hazards.

Categories of Hazards

Biological hazards in food processing include bacterial, viral, or enteric and parasitic organisms.[28] Chemical hazards include naturally occurring chemicals, such as mycotoxins from mold, toxic mushrooms, and plant toxins, as well as chemicals added during food production and processing, such as pesticides, food additives, and lubricants. Physical hazards may appear as glass, stones, or metal fragments, with the most likely outcomes ranging from a chipped tooth to choking.[28–32]

In 1992, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) defined a hazard to be "any chemical, physical or biological property that could cause an unacceptable consumer health risk."[28] The group also introduced a food-risk categorization process that forms a basis for the first HACCP principle.[18] It suggested the following six categories for risk assessment:

A. Food intended for consumption by at-risk population. This accounts for the risk factors introduced when consumers are very young or old, immunocompromised, or otherwise unusually susceptible to the potential hazards of the evaluated food product.

B. Product containing sensitive ingredients. This is intended to account for any ingredient that may be a source of a hazard or that might be a good carrier of a microbiological hazard, i.e., eggs.

C. No process step to eliminate hazard. Raw milk is still sold and consumed in America today. The removal of the pasteurizing step is a good example of this factor.

D. Recontamination potential before packaging. Aseptic packaging has an obvious hazard control advantage over other forms of packaging because it significantly reduces the potential for recontamination of product.

E. Potential for product abuse. This applies if there is a real potential for abuse to the product during distribution or consumer handling that could lead to an unsafe product.

F. No terminal heat process. This is intended to account for ready-to-eat foods that typically do not require reheating. In other words, we cannot depend on adequate consumer cooking to eliminate the remaining microbiological hazards.

Based on the above risk factors, food risk categories are assigned as 0–VI with VI as the highest risk. Foods that fall into risk factor A, such as infant formula or baby food, automatically become a risk category VI, while foods with none of the risk factors are assigned to the 0 risk category. Foods with one of the risk factors other than A are risk category I. Those with two factors other than A are category II, and so on for categories III, IV, and V.

Food risk categories can also be assigned to ingredients, incoming raw materials, in-process foods, and finished products. These risk factors and food risk categories help in identifying and classifying high-hazard foods for microbiological hazards, but they still do not aid in identification of chemical or physical hazards, or of CCPs for HACCP.[32]

Biological Hazards

Biological hazards are living organisms, including microorganisms that can put human health at risk. Biological hazards include bacteria, parasites, protozoa, viruses, their toxins, etc. (Table 9.3).

Agricultural products and food animals carry a wide range of bacteria. From a public health standpoint, most bacteria are harmless. Others — the pathogenic microorganisms — can cause illness or even death in humans. The numbers and types of bacteria vary from one food or animal species to another, from one geographic region to another, and with production and slaughter or harvesting methods. During production, processing, packaging, transportation, preparation, storage, and service, any food may be exposed to pathogenic bacterial contamination or allow development of microbial toxins that can cause mild to severe illness or death. The most common biological hazards in meat and poultry are microbiological. Biological hazards, however, may also be due to parasites or zoonotic disease processes.

Some of the major pathogenic bacterial organisms that can cause foodborne illness from eating meat or poultry are: *Salmonella, Clostridium perfringens, Listeria monocytogenes, Staphylococcus aureus, Campylobacter jejuni, Yersinia enterocolitica, Bacillus cereus, Clostridium botulinum,* and *Escherichia coli* 0157:H7.

Table 9.3 Examples of Biological Hazards in Food

Pathogenic Bacteria

Aeromonas hydrophila and other spp.
Bacillus cereus
Brucella abortis
Brucella suis
Campylobacter spp.
Clostridium botulinum
Clostridium perfringens
Escherichia coli
- *E. coli* 01 57:H7-enterohemorrhagic (EHEC)
- *E. coli*-enteroinvasive (EIEC)
- *E. coli*-enteropathogenic (EPEC)
- *E. coli*-enterotoxigenic (ETEC)
- Enterovirulent *E. coli* Group (EEC Group)

Listeria monocytogenes
Plesiornonas shigelloides
Salmonella spp.
Shigella spp.
Staphylococcus aureus
Streptococcus pyogenes
Vibrio cholerae
Vibrio parahaemolyticus and other vibrios
Vibrio vulnificus
Yersinia enterocolitica
Yersinia pseudotuberculosis

Viruses

Hepatitis A virus
Hepatitis E virus
Norwalk virus group
Rotavirus

Parasitic Protozoa and Worms

Acanthamoeba
Anisakis sp. and related worms
Ascaris lumbricoides
Cryptosporidium parvum
Diphyllobothrium spp.
Enteramoeba histolytica
Eustrongylides sp.
Giardia lamblia

Table 9.3 (Continued) Examples of Biological Hazards in Food

Nanophyetus spp.
Taenia solium
Taenia saginata
Trichinella spiralis
Trichuris trichiura

Sources: Adapted from Ohio State University Ext. Bull. 901, 2002. Ensuring Safe Food, Columbus, OH; FAO, 1998. Food Quality and Safety Systems, Food and Agricultural Organization of the United Nations, Rome; Riswadkar, A.V., 2000. Quality Corner, Food Quality, January/February.

Table 9.4 Minimum Growth Temperatures for Foodborne Pathogens

Microorganism	*Minimum Temperature (°C)*
Listeria monocytogenes	1
Yersinia enterocolitica	–2
Enterotoxigenic Escherichia coli	3
Vibrio vulnificus	5
Aeromonas hydrophila	0–5
Nonproteolytic *Clostridium botulinum*	3.3
Vibrio parahaemolyticus	5–7
Salmonella	7–10
Bacillus cereus	6–10
Staphylococcus aureus	7–10
Proteolytic *C. botulinum*	10
Clostridium perfringens	12

Source: FAO, 1998. Food Quality and Safety Systems, Food and Agricultural Organization of the United Nations, Rome.

In most cases, pathogens must grow to appropriate levels in foods to cause foodborne disease. For this to occur, the food must contain the nutrients required by the microorganism to grow; the microorganism must have enough water; the pH must be in the favorable range; the food must be free from substances that prevent growth of the pathogen (preservatives, etc.); the food must be at a temperature allowing growth (Table 9.4), and the organism must be given time to multiply. A number of

foodborne pathogens however, are psychrotrophic, i.e., capable of growth at refrigeration temperatures.

Chemical Hazards

Chemical hazards fall into two categories:

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

In general, there is a low likelihood of occurrence of chemical hazards in foods and the best method of control is prerequisite programs. In certain instances, however, a chemical hazard may be recognized as a CCP and thus controlled as such.[12] Examples of this are chemical substances such as allergens present in foods, that can cause an adverse reaction in some individuals; it may be necessary to establish CCPs in the manufacture of certain specific foods. Table 9.5 shows a list of the chemical hazards that can be normally be found in foods. Table 9.6 gives examples of chemicals used in food production, the points for their control during processing, and the control measures usually taken.

To identify any chemical hazards, it is necessary first to identify any chemical residues that might still be present in the animal tissue. To do this, the following should be kept in mind:

- The types of drugs and pesticides routinely used in raising animals, source of meat and poultry ingredients.
- Feeds and supplements fed to the animals.
- Environmental contaminants the animals may have come into contact with, including both naturally occurring and added contaminants.
- Pesticides used on plants that may end up as residues in the animal.
- The source of the water the animals drink.

The following preventive measures help to ensure that animals entering the establishment are free of harmful residues:

Table 9.5 Examples of Chemical Hazards in Foods

Naturally Occurring Chemicals

Allergens
Mycotoxins (for example, aflatoxin)
Scombrotoxin (histamine)
Ciguatoxin
Mushroom toxins
Shellfish toxins
- Paralytic shellfish poisoning (PSP)
- Diarrheic shellfish poisoning (DSP)
- Neurotoxic shellfish poisoning (NSP)
- Amnesic shellfish poisoning (ASP)
- Pyrrolizidine alkaloids

Phytohaemagglutinin
Grayanotoxin (Honey intoxication)
Phytohaemagglutinin (Red kidney bean poisoning)
Tetrodotoxin (Pufferfish)

Added Chemicals

Polychlorinated biphenyls (PCBs)
Agricultural chemicals
Pesticides
Fertilizers
Antibiotics
Growth hormones
Prohibited substances

Toxic Elements and Compounds

Lead
Zinc
Cadmium
Mercury
Arsenic
Cyanide

Food Additives

Vitamins
Minerals

Contaminants

Lubricants
Cleaners
Sanitizers

Table 9.5 (Continued) Examples of Chemical Hazards in Foods

Coatings
Paints
Refrigerants
Water or steam treatment chemicals
Pest control chemicals
From Packaging Materials
Plasticizers
Vinyl chloride
Printing/coding inks
Adhesives
Lead
Tin

- Requirement that the animals have been raised in conjunction with the January 1994 FDA Compliance Policy Guidelines.
- Written assurances from suppliers for each lot of animals, stating that the animals are free of illegal residues.
- Setting maximum allowable residue limits for specific drugs, pesticides, and environmental contaminants in animal urine or tissues as targets to ensure that FDA and Environmental Protection Agency (EPA) tolerances are met.
- Assurance that trucks used to ship the animals do not have chemical hazards that could result in contamination.

Most establishments use chemicals during processing to keep their operations sanitary. Yet it is necessary to be aware that chemical hazards can occur at any of the following points:

- Prior to receiving chemicals at the processing plant
- Upon receiving chemicals
- At any point where a chemical is used during processing
- During storage of chemicals
- During the use of any cleaning agents, sanitizers, lubricants, or other maintenance chemicals
- Prior to shipment of finished product
- In trucks used to ship finished product

Physical Hazards

A physical hazard is any physical material not normally found in a food, which causes illness or injury to the individual using the product or, if

Table 9.6 Examples of Chemicals Used in Food Production and Control Measures

Chemical	*Point of Control*	*Control Measure*
	Raw Materials	
Pesticides, toxins, hormones, antibiotics, hazardous chemicals	Prior to receipt	Specifications, letters of guarantee, vendor certification, approved uses
	Upon receipt	Vehicle inspection, tests, controlled storage conditions
Color additives, inks, indirect additives, prohibited substances in packaged ingredients and packaging materials	Prior to receipt	Specifications, letter of guarantee, vendor certification, approved uses
	Upon receipt	Vehicle inspection, proper storage
	Processing	
Direct food additives	Prior to receipt	Review purpose, purity, formulations
	Point of use	Handling practices
Color additives	Prior to receipt	Review purposes, exempt/certified, labeling requirements
	Point of use	Handling practices, quantities used
Water additives	Boiler/water treatment systems	Approved chemicals, handling practices, quantities used
	Building and Equipment Maintenance	
Indirect food additives, paints, coatings, lubricants, chemicals.	Prior to use	Specifications, letters of guarantee, approved
	Point of use	Handling practices, quantities used, proper storage
	Sanitation	
Pesticides	Prior to use	Approved chemicals, procedures/uses
	Point of use	Handling practices, label instructions, surfaces protected, cleaned after application
Cleaners, sanitizers	Prior to use	Approved chemicals, procedures
	Point of use	Procedures, adequate rinsing

Source: Stevenson, K.E. and Bernard, D.T., 1995. *HACCP. Establishing Hazard Analysis Critical Control Programs. A Workshop Manual,* 2nd ed., The Food Processors Institute (FPI), Washington, D.C. With permission.

Table 9.7 Common Physical Hazards Found in Food

Material	*Injury Potential*	*Sources*
Glass	Cuts, bleeding; may require surgery to find and remove	Bottles, jars, light fixtures, utensils, gauge covers, etc.
Wood	Cuts, infection, choking; may require surgery to remove	Field sources, pallets, boxes, building materials
Stones	Choking, broken teeth	Fields, buildings
Metal	Cuts, infection; may require surgery to remove	Machinery, fields, wire, employees
Insulation	Choking; long term if asbestos	Building materials
Bones	Choking	Improper processing
Plastic	Choking, cuts, infection; may require surgery to remove	Packaging, pallets, equipment
Personal effects	Choking, cuts, broken teeth; may require surgery to remove	Employees

found naturally as part of a product, is to be removed, i.e., bones in meat. Physical hazards include a variety of foreign materials or objects, such as glass, wood, metal, and plastic that can be inadvertently introduced into a product during the manufacturing process. Foreign objects that cannot or do not cause illness or injury are not considered hazards, even though they may not be aesthetically pleasing to the customers. Table 9.7 list some of the most common physical hazards found in foods.

A number of situations can result in physical hazards in finished products. They include, but are not limited to:

- Contaminated raw materials.
- Poorly designed or poorly maintained facilities and equipment. For example, paint chips falling from overhead structures onto exposed product, or pieces of metal from worn or improperly maintained equipment that is in contact with or near the product.
- Improper procedures or improper employee training and practices. For example, glass jars, broken by improper loading on the line by employees, or improper or inadequate condition examination; glass pieces from broken or chipped jars when filling product containers.
- The sanitation standard operating procedures (SSOPs) can be used to identify and control cross-contamination due to employee practices.

Preventive Measures

Once all significant biological, chemical, and physical hazards for each processing step and each ingredient have been identified, measures to

HAZARD ANALYSIS/IDENTIF1CATION/PREVENTIVE MEASURES

PRODUCT/PROCESS: _____ **Page 1 of ___**

INGREDIENTS/ PROCESS STAGE	HAZARD B, C, P*	PREVENTIVE MEASURE(S)

***B = Biological; C = Chemical; P = Physical**

DATE: _____ **APPROVED BY:** _____

Figure 9.2 Hazard analysis/identification/preventive measures.

prevent hazards from compromising the safety of the finished product also have to be identified and implemented. Information should be entered in the preventive measure(s) column of the Hazard Analysis/Identification/ Preventive Measures Form (Figure 9.2). HACCP defines a preventive measure as a "physical, chemical, or other means that can be used to control an identified food safety hazard."

Some of the measures used to prevent chemical hazards are:

- Using approved chemicals only
- Having detailed product specifications for chemicals entering the plant
- Maintaining letters of guarantee from suppliers
- Inspecting trucks used to ship finished product
- Properly labeling and storing all chemicals
- Properly training employees who handle chemicals

Measures used to prevent physical hazards include, but are not limited to:

- Making sure that the plant specifications for building design and operation are accurate and updated regularly
- Making sure that the letters of guarantee for ingredients and product supplies are accurate and updated regularly

- Performing random visual examinations of incoming product and materials
- Using magnets and metal detectors to help find metal fragments that could be a physical hazard
- Using stone traps and bone separators to remove potential physical hazards
- Keeping equipment well maintained
- Training employees to identify potential problems

Table 9.8 offers a guide to potential microbiological, chemical, and physical hazards in foods and food processing operations.

Questions to Consider when Conducting a Hazard Analysis[12]

The hazard analysis consists of asking a series of questions which are appropriate to the process under consideration. The purpose of the questions is to assist in the identification of potential hazards in different aspects or areas of the manufacturing process. The following shows an example.

Ingredients

- Does the food contain any sensitive ingredients that may represent microbiological (e.g., *Salmonella, Staphylococcus aureus*), chemical (e.g., aflatoxin, antibiotic or pesticide residues), or physical (stones, glass, metal) hazards?
- Are potable water, ice, and steam used in formulating or in handling the food?
- What are the sources (e.g., geographical region, specific supplier)?

Intrinsic Factors

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

- What hazards may result if the food composition is not controlled?
- Does the food permit survival or multiplication of pathogens or toxin formation in the food during processing?
- Will the food permit survival or multiplication of pathogens or toxin formation during subsequent steps in the food chain?
- Are there similar products in the marketplace? What has been the safety record for such products? What hazards have been associated with them?

Table 9.8 Guide to Potential Microbiological, Chemical, and Physical Hazards*

Material or Ingredient	*Hazard or Complaint-Related Spoilage*		
	*Microbiological***	*Chemical*	*Physical*
Bread crumbs ingredients such as natural spices or dried cheese	NU unless there are sensitive	NU	Metal (wire), glass, FOs[2]
Canned foods (low acid, pH above 4.6) from improper preprocess handling	Botulism from underprocessing or leakage, staph enterotoxin	Pesticides, heavy metals, cleaning chem., food chemicals, lubricants	Metal, stones, glass, FOs
Coconut (dry, shredded; coconut milk)	Could have *Salmonella* sp. and other pathogens	Pesticides, heavy metals, cleaning chem., food chemicals	Metal, glass, FOs
Coffee (beans) flavus in moldy beans Cleaning chem., rope, wood, other	Could have mycotoxins	Pesticides, contamination with fumigants, or from shipping	Metal (wire), stones, glass,
Condiments (high acid, salt or sugar) pickles, relish, hot sauce	Spoilage from yeast or mold, sometimes causing a container explosion hazard	Excess acid, leached metals, pesticides, cleaners	Metal, glass, FOs
Dehydrated milk, cheese, egg, meat, poultry, dry powders	*Salmonella* sp. *Listeria* monocyt., *E. coli, Staph. aureus*	Pesticides, antibiotics, hormones, heavy metals, cleaning chem., food additives	Metal (wire), glass, FOs
Dried vegetables (garnishes and powders); and spices	*Salmonella* sp., *Listeria* monocyt., *E. coli, Staph. aureus*	Pesticides, fumigants, heavy metals, food additives, cleaning chem.	Metal (wire), glass, FOs
Essences and spice oils, resins	NU	Toxic if in high concent. or contaminated with toxic chem.	NU (unless dry)
Food chemicals (acids, ingredients, flavors, salt antioxidants, vitamins)	NU	Toxic if in high concent. or contaminated with toxic chem.	Metal (wire), glass, FOs
Food preservatives (benzoates, sorbates)	NU	Toxic if in high concen. or contaminated with toxic chem.	Metal (wire), glass, FOs

Table 9.8 (Continued) Guide to Potential Microbiological, Chemical, and Physical Hazards*

Material or Ingredient	*Hazard or Complaint-Related Spoilage*		
	*Microbiological***	*Chemical*	*Physical*
Fruit oils (e.g., lemon oil)	Spoilage flora (depends on system)	Pesticides, high concentrations of common chem.	NU
Fruit pectin	NU	Pesticides, heavy metals, cleaning chem.	Metal, glass, FOs
Fruit pulp (dry powder)	Spoilage flora, mold	As above	Metal fragments, FOs
Juice concentrates, fruit pulp	Spoilage flora & mold (in acidic juice products); heat resist. and preservative resist. microorg.	Pesticides, cleaning chem., lubricants, preservatives, food chemicals, heavy metals	Metal, glass, wood, FOs
Nuts and nut meats	Mycotoxins, *Salmonella* sp., *E. coli, Staph. aureus*	Pesticides, fumigants, heavy metals, food additives, cleaning chem.	Metal (wire), rocks, glass, other
Packaging	Spoilage flora; leakage and recontamination with harmful microorganisms	Toxic chemicals from: inks, paint, packaging films, adhesives, lubricants, etc.	Misc.
Product-related	Any hazardous microorganisms from process system, environment (dust, air, floor, drains, etc.), and ingredients	Chemicals from ingredients or environment	Many sources: ingredients, systems, environment people
Prepared or pasteurized refrigerated milk, cheese, egg, meat, poultry, fish, soya products (tofu)	Possibility of insufficient cook or cross-contamination: *Listeria* monocyt., *E. coli, Staph. aureus* and other micro. pathogens	Antibiotics, hormones, heavy metals, cleaning chem., food additives	Wire, glass, FOs
Raw meats, poultry, fish, shellfish, raw eggs, raw milk	*Salmonella* sp., *Listeria* monocyt., *E. coli* (pathogenic types; 0157:H7), *Staph. aureus*, other bacteria and viral pathogens, parasites	Pesticides, antibiotics, hormones, heavy metals, cleaning chem., natural chem.	Metal, glass, bone, FOs

Table 9.8 (Continued) Guide to Potential Microbiological, Chemical, and Physical Hazards*

Material or Ingredient	*Hazard or Complaint-Related Spoilage*		
	*Microbiological***	*Chemical*	*Physical*
Raw vegetables and fruits, particularly, melons; juices	*Salmonella* sp., *Listeria* monocyt., *E. coli* (pathogenic types; 0157:H7), *Staph. aureus*, other bacteria and viral pathogens, parasites	Pesticides, fertilizers, heavy metals, fuel/lubricants, cleaning chem., toxic chemicals of various origin	Metal, rocks, wood, glass, FOs
Rice	*Bacillus cereus*	Pesticides, agricultural chemicals, mold toxins	Metal (wire), glass, stones
Starch (dry), flours	May contain some bacterial pathogens	Mold toxins, pesticides	Metal (wire), FOs
Sugar(s) (dry)	Spoilage flora	Caustic contaminants from shipping Some sugars toxic if in high concent.	FOs, metal
Water	Bacterial and viral pathogens, protozoan parasites	Environ. chem., heavy metals, nitrates, etc.	NU
Xanthan gum, carrageenan, other natural gums, thickeners	*Salmonella* sp. and other microbial pathogens	Contamination with toxic chem.	Metal (wire), FOs

NU = Not usually; FOs = foreign objects.

* The hazard lists do not necessarily include all possible or specific hazards characteristic of a particular food material, locality, or source.

** The reader should assume that most ingredients may contain heat-resistant spores of *Clostridium botulinum* that could be a hazard in improperly processed canned food or if a partially processed food is held at abusive refrigeration temperatures (generally considered to be >4.4°C/40°F). Also, heat-resistant sporeformers such as *C. perfringens* and *Bacillus cereus* may be present in various ingredients and may multiply under food abuse conditions.

Source: Corlett, D., 1998. *HACCP User's Manual,* Aspen Publishers, Gaithersburg, MD. With permission.

Procedures Used for Processing

- Does the process include a controllable step that destroys pathogens? If so, which pathogens? Consider both vegetative cells and spores.
- If the product is subject to recontamination between processing (e.g., cooking, pasteurizing) and packaging, which biological, chemical, or physical hazards are likely to occur?

Microbial Content of the Food

- What is the normal microbial content of the food?
- Does the microbial population change during the normal time the food is stored prior to consumption?
- Does the subsequent change in microbial population alter the safety of the food?
- Do the answers to the above questions indicate a high likelihood of certain biological hazards?

Facility Design

- Does the layout of the facility provide an adequate separation of raw materials from ready-to-eat (RTE) foods if this is important to food safety? If not, what hazards should be considered as possible contaminants of the RTE products?
- Is positive air pressure maintained in product packaging areas? Is this essential for product safety?
- Is the traffic pattern for people and moving equipment a significant source of contamination?

Equipment Design and Use

- Will the equipment provide the time–temperature control that is necessary for safe food?
- Is the equipment properly sized for the volume of food that will be processed?
- Can the equipment be sufficiently controlled so that variation in performance will be within the tolerances required to produce a safe food?
- Is the equipment reliable or is it prone to frequent breakdowns?
- Is the equipment designed so that it can be easily cleaned and sanitized?
- Is there a chance for product contamination with hazardous substances, such as glass?

- What product safety devices (metal detectors, magnets, sifters, filters, screens, thermometers, bone removal devices, dud detectors) are used to enhance consumer safety?
- To what degree will normal equipment wear affect the likely occurrence of a physical hazard in the product?
- Are allergen protocols needed in using equipment for different products?

Packaging

- Does the method of packaging affect the multiplication of microbial pathogens or the formation of toxins?
- Is the package clearly labeled "Keep Refrigerated" if this is required for safety?
- Does the package include instructions for the safe handling and preparation of the food by the end user?
- Is the packaging material resistant to damage, thereby preventing the entrance of microbial contamination?
- Are tamper-evident packaging features used?
- Is each package and case legibly and accurately coded?
- Does each package contain the proper label?
- Are potential allergens included in the list of ingredients on the label?

Sanitation

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

Employee Health, Hygiene, and Education

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

Conditions of Storage between Packaging and the End User

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

Intended Use

- Will the food be heated by the consumer?
- Will there likely be leftovers?

Intended Consumer

- Is the food intended for the general public?
- Is the food intended for consumption by a population with increased susceptibility to illness, e.g., infants, the aged, the infirmed, or immunocompromised individuals?
- Is the food to be used for institutional feeding or for the home?

Hazard Identification

The Raw Materials

As all the questions are evaluated in the hazard analysis stage, potential hazards are identified based on the safety nature and history of each material, particularly raw materials that are likely to contain pathogen microorganisms or toxins, or that allow the growth of any pathogens. One example is milk and other dairy products, which have an inherent microbial risk that must be controlled. Milk is a neutral pH product that contains protein and sugars; these factors make milk a product that can be easily contaminated by pathogenic microorganisms. Without proper treatment to destroy these microorganisms, there is an increased probability that consumers who drink untreated milk will get food poisoning.[12]

All the potential risks in raw materials for a product — nature of the materials, their intrinsic factors, their suppliers, their function in the finished product, how they are manufactured, packaged, and distributed — must be identified. Each of these factors have an impact on the safety or risk potential of the finished product, and must be described and documented in enough detail so that anyone reading the documentation has a clear understanding of exactly what the materials are.

One important aspect for understanding the nature of and evaluating the raw material used in manufacturing a product is to conduct a site audit of the supplier(s). A site audit is the best approach for a complete

understanding of the quality system of all suppliers of raw materials; they should be audited before entering into a contract and receiving any material. It is important to be assured that the suppliers have effective GMPs and product safety in place. Ideally, all suppliers should be using an HACCP program as well. Table 9.9 provides an example of documentation for raw material hazard analysis and potential hazard identification.

The Manufacturing Process

After all materials to be used in making the product have been evaluated and any potential hazard that they may contribute have been identified, the next step is to evaluate the process and identify all potential points where hazards can exist or be introduced. These include facility design, equipment design, processing steps, personnel hygiene, traffic flow, etc. Each step of the process must be considered as a potential point for introducing or eliminating a hazard, and it is very important to have an answer to questions such as who is doing what, with what, why, when, where, and how is it done. In this sense, HACCP allows the manufacturer to focus hazard control efforts on specific critical points in a process. The manufacturer gains efficiency and a greater assurance of food safety.

Control Measures

When a hazard is identified, control measures must be recommended and explained. Not all control measures, however, are within a manufacturer's control. At the consumer level, the question is how the consumer is protected from this hazard; the HACCP team must answer this.

In many instances, it is the consumer's responsibility to control the hazard. In such cases, the manufacturer's duty is to inform the consumer of any potential risks and include, in or on the product, instructions for its safe use. Directions such as "keep refrigerated" on dairy products and shell eggs are examples of statements provided by the manufacturer on product packaging to ensure that the products are used/stored properly. Another common example is the statement declaring that the product must be used before a certain date. Control measures must have an identified scientific basis for being effective.

Risk Categories

After hazards and their appropriate control measures are in place, they must be evaluated for severity and probability of risk.

The severity of a risk is often classified on a scale of high, moderate, or low. High risks are life-threatening conditions or conditions resulting in irreversible damage; low risks are minor conditions or conditions

Table 9.9 Hazard Analysis and Potential Hazard Identification in Raw Materials

Ingredient	*Description*	*Determine Likelihood of Potential Hazards Associated with Material*	*Storage of Health Consequences if Potential Hazard is Not Properly Controlled*	*Determine*	*Assess Severity Occurrence of Potential Hazard if Not Properly Controlled*
Pasteurized liquid whole egg	Liquid whole eggs are made up of both the yolk and the white from chicken eggs. The eggs are washed, checked for quality, and mechanically cracked. The liquid egg is then pumped into a large tank through a 60-mesh filter and held at 45°F until enough material is accumulated for pasteurization. It is then pasteurized at 190°F for 10 sec and rapdly cooled to 40°F. It is shipped in tanks that are held at <42°F. Material is liquid, with a neutral pH. It contains fermentable carbohydrates and is an excellent growth medium for microorganisms.	After pasteurization, eggs must be held at no greater than 45°F for no greater than 5 days.	Microbiological: *Salmonella* in finished product	Salmonellosis is a foodborne infection causing a moderate to severe illness that can be caused by ingestion of only a few cells of *Salmonella*.	Product is made with liquid eggs, which have been associated with past outbreaks of Salmonellosis. Recent problems with *Salmonella* serotype enteritidis in eggs cause increased concern. Probability of *Salmonella* in raw eggs cannot be ruled out. If not effectively controlled, some consumers are likely to be exposed to *Salmonella* from this food.

Chemical: Eggs are known food allergen.	Egg allergic individuals can suffer health consequences from mild to severe. There have been documented cases of death caused from severe allergic reactions to eggs.	As an ingredient in the finished product, unless properly identified in the ingredient statement, there is a probability of the product being consumed by a food allergic individual.
Physical: Eggshells	There are no documented cases of severe injuries caused by eggshells. There are cases of minor mouth abrasions.	There is a low probability of any injury from eggshells as the liquid eggs are filtered through a 50-mesh screen and the shells are brittle.

Source: ASQ Food, Drug, and Cosmetic Division, 2002. *The Quality Auditor's HACCP Handbo*ok, ASQ Quality Press, Milwaukee, WI. Reprinted with permission.

resulting in reversible and treatable injuries. The most severe risk of any hazard is death, but, in general, the most common reactions to a hazard are low to moderate. However, in certain individuals or population groups — the aged, infirm, immunocompromised, or infants — the consequences may be life threatening.

A number of factors must be considered in assessing the potential safety risks if a hazard is not controlled. When considering the severity of a hazard, questions must be answered such as: What are the consequences (mild to severe) if exposed to the hazard? What is the potential duration of the illness or injury? If the HACCP team cannot answer these questions, it should seek assistance through state and federal regulatory agencies.

The most difficult part of the hazard analysis is the assessment of the probability of risk. One of the factors to be considered when trying to establish this is the product history. If the hazard has been found in the product/material before, it is necessary to identify the source of contamination and to determine whether patterns exist, or if the problem appears to be random. The frequency of past occurrences should also be identified.

If the product that the HACCP plan is being designed for is either a new product or a product with no clear history, the HACCP team should look at other similar products in the market. Have hazards been found in similar products? Products undergoing similar manufacturing processes and products containing common raw materials should be examined.

One way to determine whether the hazard is common and the risk is severe is to look at the regulations, both domestic and worldwide, for the industry. In general, if a regulatory body has addressed the hazard and prescribed a specific control measure, then it has been done with forethought and is, in most cases, based on scientific evidence. Another source of information is product safety actions taken by companies or regulatory agencies. Product recalls are also a validation of the probability of occurrence, especially if it happens more than once and to more than one company. The FDA regularly publishes notices of food recalls. A review of those recalls can indicate if similar products have been recalled and may help to establish a probability of occurrence.

Many industry trade associations and regulatory bodies are developing model HACCP plans to assist companies. Since many smaller organizations do not have the internal resources to perform an HACCP analysis, model plans provide a good starting point for information on what type of hazards can be expected in a product. There are, however, significant risks and limitations to the direct adoption of any model HACCP plan; it is very important to keep in mind that every HACCP plan is product- and production-line specific. They are one-of-a-kind and must be reviewed with each change in raw material or the process. One minor change in the product or process can introduce a significant hazard that may not

be controlled. Model HACCP plans are developed to be generic; they do not and cannot take into account the specifics that make up any finished product, or the intrinsic factors for any specific product. It is necessary to keep in mind that HACCP is not about being perfect; it is the proactive identification of hazards far in advance of incidents of injury or illness.

Hazard evaluation is probability vs. possibility. From a practical point of view, it is necessary to ask and answer the questions: It is possible for anything to happen, but is it probable? Is this hazard reasonably likely to occur under the given conditions of the process? If it is unreasonable to expect the hazard to occur, then it is a mere possibility.

Documentation

The final HACCP plan should list and contain all of the supporting documentation, including, but not limited to, the complete hazard analysis documentation for each material and processing step, references, audit reports, and scientific evidence. The complete hazard analysis, with all the supporting documents, must be complete, clear, and should be kept on file in one central location, readily available to the company when necessary. It is not uncommon for the same information to be used for multiple HACCP plans throughout the company.

One final aspect of the hazard analysis is that it must be done on the actual product, at the actual production location, with the actual people who best know the product and the potential hazards. The hazard analysis is based on facts, not assumptions. It requires research and a variety of technical knowledge about many different topics.[12]

Special Considerations when Conducting a Hazard Analysis

- Hazards identified in one manufacturing step, process operation, or plant may not be significant in another plant producing the same or similar product.

  Due to differences in equipment or an effective maintenance program, the probability of metal contamination may be significant in one facility but not in another. Part of the HACCP team identification and evaluation objectives is to keep a summary of the discussions and the rationale developed during the hazard analysis for future reference. Such information will be useful during future reviews and updates of the hazard analysis and the HACCP program.
- Hazards associated with each step in the production should be listed along with any measures used to control them.

  The term “control” is used because not all hazards can be prevented, but virtually all can be controlled. More than one control

may be required for a specific hazard while, on the other hand, in certain cases more than one hazard may be addressed by a specific control measure. Table 9.10 is an example of using a logic sequence in conducting a hazard analysis for the production of frozen cooked beef patties. Enteric pathogens — e.g., *Salmonella* and verotoxin-producing *Escherichia coli* — in raw meat would be identified as hazards. Cooking is a control measure, which can be used to eliminate these hazards.

- Considerations of common dietary choices, which lie outside of HACCP, are not included during the evaluation of each potential hazard.

  However, the product, its method of preparation, transportation, storage, and the persons likely to consume it, should be considered; this will help to determine how each of these factors may influence the potential occurrence and severity of the hazard being controlled. The team must consider the influence of the procedures for food preparation and storage, and whether the intended consumers are susceptible to a potential hazard. Differences of opinion, even among experts, may occur, as to the likely occurrence and severity of a hazard. The HACCP team may have to rely upon the experts' opinion in the development of the HACCP program.

  While the examples used relate only to biological hazards, chemical and physical hazards are equally important. The examples explain the steps for identifying hazards, which may be assisted by risk assessment addressing specific hazards or control factors. The HACCP team should take risk assessments into consideration, as they become available. Risk assessment[29] is a significantly different process than hazard analysis, and the identification of hazards of concern and their evaluation may be facilitated by the information gathered. Risk assessment gives HACCP programs the versatility and dynamic which make them so valuable to the food industry (see section on Risk Categories).

Deciding which Potential Hazards Must be Addressed in the HACCP Program

When conducting the hazard evaluation, each potential hazard is evaluated based on its likelihood of exposure, occurrence, and severity, and the potential consequences if the hazard is not properly controlled. In addition, consideration should be given to the effects of short-term as well as long-term exposure. Severity is the seriousness of the consequences of exposure to the hazard. Considerations of severity, e.g., magnitude and duration of illness or injury, are helpful in understanding the public health impact of

Table 9.10 Process Hazard Analysis, Hazard Evaluation, and Risk Assessment in the Manufacture of Frozen Beef Patties*

The product contains eggs prepared for foodservice, and commercial frozen precooked, boned chicken for further processing.

Step 1. Potential Hazard Identification

Hazards associated with the product:

- Enteric pathogens (i.e., *E. coli* O157:H7 and *Salmonella*)

Product containing eggs:

- *Salmonella* in finished product

Commercial frozen precooked boned chicken for further processing:

- *Staphylococcus aureus* in finished product

Step 2. Hazards Evaluation

Assess severity of health consequences if potential hazard is not properly controlled

Hazards associated with the product:

- Epidemiological evidence indicates that *E. coli* and *Salmonella* cause severe health effects including death among children and elderly.
- Undercooked beef patties have been linked to disease from these pathogens.
  - *E. coli* O157:H7 is of very low probability and salmonella is of moderate probability in raw meat.
- Product may be contaminated with *S. aureus* due to human handling during boning of cooked chicken. Enterotoxin capable of causing illness will only occur as *S. aureus* multiplies to about 1,000,000/g.
  Operating procedures during boning and subsequent freezing prevent growth of *S. aureus*; the potential for enterotoxin formation is very low.

Product containing eggs:

- Salmonellosis is a foodborne infection resulting in a moderate to severe illness due to ingestion of only a few cells of *Salmonella*.
- Product is made with liquid eggs, which have been associated with past outbreaks of salmonellosis. Recent problems with *Salmonella* serotype enteritidis in eggs cause increased concern. Probability of *Salmonella* in raw eggs cannot be ruled out.
- If not effectively controlled, some consumers are likely to be exposed to *Salmonella* from this food.

Commercial frozen precooked boned chicken for further processing:

- Certain strains of *S. aureus* produce an enterotoxin, which can cause a moderate foodborne illness.
  Determine likelihood of occurrence of potential hazard if not properly controlled.

Using the information above, determine if this potential hazard is to be addressed in the HACCP program.

Hazards associated with the product:

- The HACCP team decides that enteric pathogens are hazards for this product. *Hazards must be addressed in the plan*

Table 9.10 (Continued) Process Hazard Analysis, Hazard Evaluation, and Risk Assessment in the Manufacture of Frozen Beef Patties*

Product containing eggs:

- HACCP team determines that if the potential hazard is not properly controlled, consumption of product is likely to result in an unacceptable health risk.
  Hazard must be addressed in the plan

Commercial frozen precooked boned chicken for further processing:

- The HACCP team determines that the potential for *S. aureus* enterotoxin formation is very low. It is still desirable to keep the initial number of *S. aureus* organisms low. Employee practices that minimize contamination, rapid carbon dioxide freezing, and handling instructions have been adequate to control this potential hazard.
  Potential hazard does not need to be addressed in plan.

* For illustrative purposes only. The potential hazards identified may not be the only hazards associated with the products listed. The responses may be different for different establishments.

Source: U.S. National Advisory Committee on Microbiological Criteria for Foods (NACMCF), 1998.

the hazard. The likely occurrence is evaluated on the basis of experience, epidemiological data, and technical literature information.

Principle 2: CCP Identification

In addition to determining potential hazards, HACCP programs identify the points in the food-manufacturing process where these hazards can best be controlled. Potential hazards that are reasonably likely to cause illness or injury in the absence of their control must be addressed in determining CCPs. Complete and accurate identification of CCPs is fundamental to controlling food safety hazards.

A CCP is defined as a point, step, or procedure in a food manufacturing process at which:

- Control that is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level can be applied; and where,
- Later processing steps won't correct these safety problems.

Examples of CCPs include:

- Raw materials receiving, testing ingredients for chemical residues or other contaminants/adulterants, mixing ingredients, other food-handling operations.

- Batching, thawing, product formulation (ingredient weight/volume, pH, A_w, homogenicity, verification test), thermal processing, reprocessing, hot-holding steps, cooling, metal detection.
- Refrigeration, refrigerated-storage, packaging, handling of refrigerated foods and ingredients.

This definition differs from that of a control point (CP) in that a CP is any step in the process at which biological, chemical, or physical risks or hazards can be controlled, and usually is related to quality or production issues and not to product safety, unless the control point supports a CCP. For example, in preparing a dry ingredient mix, screens, magnets, and a metal detector are placed in the production line to prevent metal contamination of the finished product. The screen and magnets are CPs, but the metal detector is a CCP.[12]

The information developed during the hazard analysis is essential for the HACCP team in identifying which steps in the process are CCPs. One strategy to facilitate the identification of each CCP is the use of a CCP decision tree as shown in Figure 9.3 and Figure 9.4. However, it is necessary to keep in mind that although a decision tree can be helpful in determining if a particular step is a CCP for a previously identified hazard, it is merely a tool and not a mandatory element of an HACCP program. A CCP decision tree is in no way a substitute for expert knowledge.

The CCPs relevant to significant hazards are then identified with emphasis on whether preventive measures are adequate. This hazard analysis step is one of the most critical in establishing the HACCP program.

Any number of means may achieve control. In the case of microorganisms, factors such as pH, water activity, temperature, control of ingredients, sanitation, and other factors may be involved, singly or in combination, to control health hazards. In the case of a hazard relating to tramp metal following a screening operation, control may be achieved by magnets, metal detectors, or sifters.

During this analysis and identification process, the HACCP team evaluates and often debates the relative hazards involved, with the aim of reaching a consensus. Agreement may not be needed, and may not even be desirable in many cases. Disagreement at this point is evidence that the issue under discussion is not clearly defined as a control. Later on, during the verification step of HACCP, it will become clear if the point is, in fact, a control point, and agreement can be reached.

The table described in Figure 9.2 includes the process steps, hazards that have been identified, and the preventive measures that assure that the food is safe. Only CCPs should be listed on this chart and only measures that definitively prevent the growth of the organism or destroy it should be listed. A number of preventive control measures that might

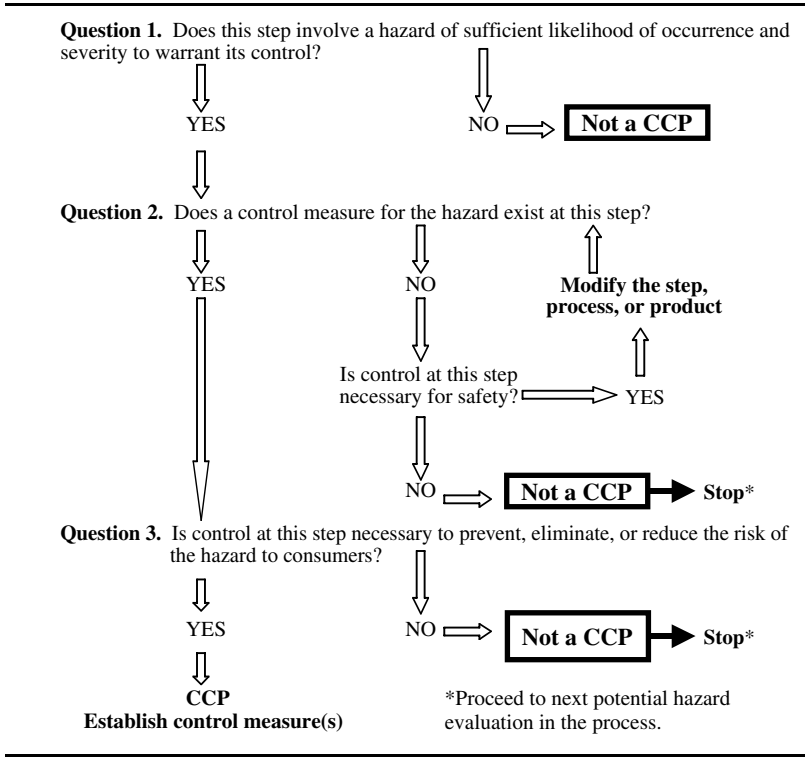


Figure 9.3 Critical control points decision tree, example I. (From U.S. National Advisory Committee on Microbiological Criteria for Foods (NACMCF), 1998.)

be relevant are shown below. Frequently, these control measures can be evaluated by experiments designed to assure that a specific control is effective. For example, the presence of organisms subsequent to a heat processing step, or the existence in a process of organisms related to human skin might indicate that employee hygiene control procedures are not being followed. These control measures should apply only to product safety.

Preventive Critical Control Measures (Microbiological)

- Temperature extremes
- Chemical preservatives
- Sterilization

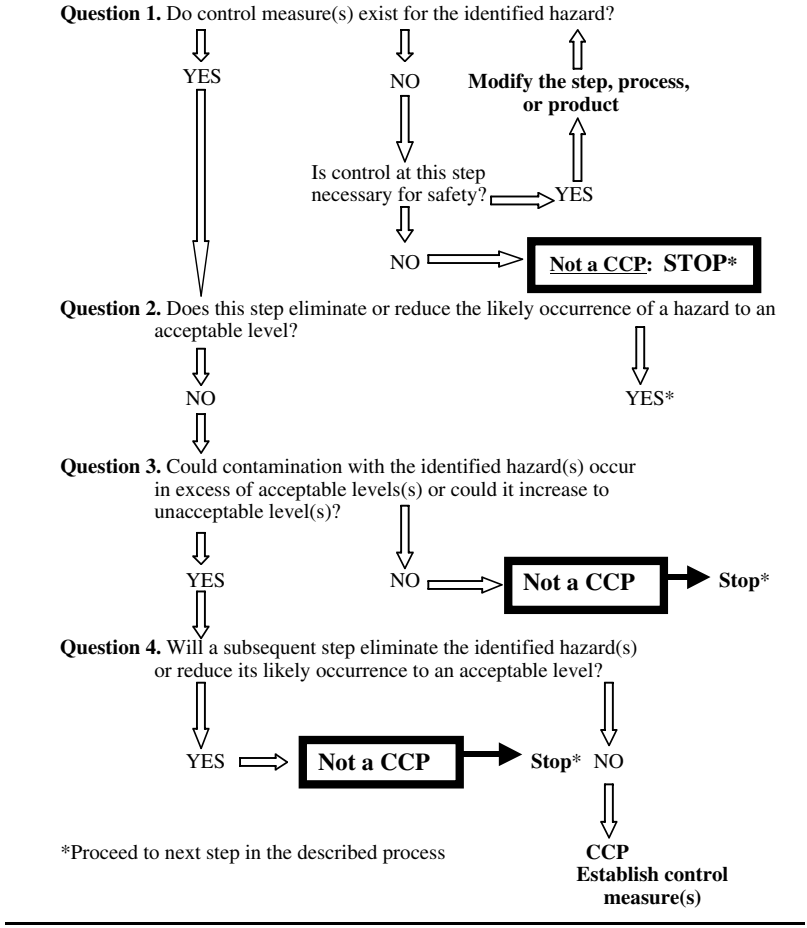


Figure 9.4 Critical control points decision tree, example II. (From U.S. National Advisory Committee on Microbiological Criteria for Foods (NACMCF), 1998.)

- pH, water activity
- Prevention of contamination
- Personal hygiene
- Packaging
- Raw materials control
- Process sanitation
- Process design
- Modified atmospheres

CCP Decision Tree

Important considerations when using the decision tree:

- The decision tree is used after the hazard analysis has been completed.
- The decision tree is used at the steps where a hazard that must be addressed in the HACCP program has been identified.
- A subsequent step in the process, which may be more effective for controlling a hazard, may be the preferred CCP.
- More than one step in a process may be involved in controlling a hazard.
- More than one hazard may be controlled by a single specific control measure.

CCPs must be carefully developed and documented. Table 9.11 shows a CCP determination form, a model for documentation summary of CCPs in a process. The CCPs can be sequentially numbered on the process flow diagram, on the CCP determination form, and in the HACCP plan. A good idea, for convenience, is to qualify the CCPs by adding to the number the letters B (biological), C (chemical), and P (physical). CCPs must be used only for purposes of product safety. For example, a specified heat process, at a given time and temperature designed to destroy a specific microbiological pathogen, could be a CCP. Likewise, refrigeration of a precooked food to prevent hazardous microorganisms from multiplying, or the adjustment of a food to a pH necessary to prevent toxin formation, could also be CCPs.

As expressed previously, different manufacturing plants preparing similar food items can differ in the hazards identified and the steps that are designated CCPs. This can be due to differences in each plant's layout, equipment, selection of ingredients, manufacturing processes, etc.

Principle 3: Establish Critical Limits for Each CCP

Once CCPs are identified, critical limits are determined to reduce or eliminate potential hazards.

A critical limit is defined as a maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level, the occurrence of a food safety hazard.[29] A critical limit is used to distinguish between safe and unsafe operating conditions at a CCP.

Each CCP has one or more control measures to assure that the identified hazards are prevented, eliminated, or reduced to acceptable levels. Each control measure has one or more associated critical limits. Critical limits

Table 9.11 Critical Control Point Determination Form

Process step	Is this hazard of sufficient likelihood of occurrence and severity to warrant its control? Yes: Proceed to next question. No: Not a CCP	Is this hazard fully controlled by a prerequisite program? Yes: Not a CCP No: Proceed to next question.	Q1. Do control measures exist for the identified hazard? Yes: Proceed to next question. No: Either not a CCP or need to modify step, process, or product.	Q2. Is this process step specifically designed to eliminate or reduce the likely occurrence of this identified hazard to an acceptable level? Yes: CCP No: Proceed to next question	Q3. Could contamination with the identified hazard(s) occur in excess of acceptable level(s) or increase to unacceptable level(s)? Yes: Proceed to next question. No: Not a CCP	Q4. Will a subsequent step eliminate the identified hazard(s) or reduce its likely occurrence to an acceptable level? Yes: Not a CCP- Identify subsequent step. No: CCP	CCP Number

Source: ASQ Food, Drug and Cosmetic Division, *The Quality Auditor's HACCP Handbook*, ASQ Quality Press, Miwukee, WI. With permission. 2002.

may be based upon factors such as temperature, time, physical dimensions, humidity, moisture level, water activity (a_w), pH, titratable acidity, salt concentration, available chlorine, viscosity, preservatives, or sensory information (i.e., aroma, texture, visual appearance). Critical limits must have a technological and scientific basis.

CCP, as noted earlier, must be controlled by one or more preventive measures that maintain the hazard source below critical limits. These limits may be obtained experimentally from regulatory sources, expert opinions, industry standards, research studies, equipment manufacturers, and surveys of the literature pertaining to a particular product. No matter how the limits are set, a competent authority well versed in food microbiology and safety matters should review them.

Once critical limits are established for a CCP, processing limits can be developed. It should be remembered that critical limits define unacceptable processing conditions related primarily to safety issues, and that critical limits that prevent the growth or presence of food-borne pathogens may have little effect on spoilage organisms. It is also important to remember that a critical parameter or limit may change with changes in the process. For example, a pH limit set at one process temperature may not be limiting at another. Similarly, changes in the configuration of the process equipment may significantly change the critical limits of a process point, possibly resulting in a hazardous product. Table 9.12 provides examples of critical limits to be considered for the reduction or elimination of potential hazards at CCPs. Figure 9.5 shows the forms that can be used to summarize in tabulated form the CCPs, their critical limits, monitoring, corrective actions, and verification procedures.

Sampling of the product for microbiological testing is inefficient and is therefore seldom used for determining critical limits, mostly because of the time factor between sampling and test results. This is particularly important when the pathogen is present at low levels or is not randomly distributed through the production lot. To control and ensure microbiological safety, it is better to define the time/temperature processing conditions at which the microbiological reduction or elimination and, thus, food safety, are met. An example is the specific lethality of a cooking process such as the USDA/Food Safety and Inspection Service (FSIS) performance standard of 6.5 $\log_{10}$ reduction of *Salmonella* for cooked poultry product that ensures that the product no longer causes a food-borne illness due to *Salmonella*.[12]

Critical limits and criteria for food safety may be derived from sources such as regulatory standards and guidelines, literature surveys, experimental results, and expert recommendations.

In the example for production of frozen cooked beef patties (Table 9.10), the process is designed to ensure the production of a safe product.[29]

Table 9.12 Examples of Critical Limits to Reduce or Eliminate Potential Hazards at CCPs

A.	CCPs: Receiving
	Potentially hazardous foods must be at or below 40ºF.
	Frozen foods must not have thawed.
	There must be no evidence of spoilage, abuse, foreign objects, or contamination of foods and ingredients.
B.	CCPs: Cooking, Reheating, and Hot Holding
	Cook poultry to at least 165ºF.
	Cook pork to at least 150ºF.
	Cook roast beef to at least 130ºF.
	Reheat all foods rapidly to at least 165ºF.
	Hold all hot foods at 140ºF or higher.
C.	CCPs: Refrigeration and Refrigerated Storage
	Chill roast beef from 120ºF to 55ºF in less than 6 hours. Continue to chill to 40ºF.
	Chill all other foods from 130ºF to 80ºF in 1-1/2 hr, and from 80ºF to 40ºF in 6 hr.
	Do not leave potentially hazardous foods or ingredients at room temperature.
	Do not overload or stack containers in coolers.
	Do not cover hot foods tightly in the cooler until chilled.
	Chill and store foods in shallow pans 2–3 in. deep.
D.	CCPs: Food Handling (Covered by sanitation SOPs and GMPs)
	Wash vegetables thoroughly in clean cold water.
	Use proper hand-washing techniques.
	Use proper dishwashing and sanitizing techniques.
	Cover and protect open cuts and scratches.
	Handle processed foods only with clean gloves or utensils.
	Use clean and sanitized equipment and utensils.
	Stay home when sick.

Source: Adapted from Riswadkar, A.V., 2000. Quality Corner, *Food Quality,* January/February.

The hazard analysis identified enteric pathogens (e.g., verotoxigenic *E. coli* O157:H7 and salmonellae) as significant biological hazards. Furthermore, cooking was identified as the step in the process at which control may be applied to reduce the pathogens to an acceptable level.

To ensure that an acceptable level is consistently achieved, accurate information is needed regarding:

- The probable number of the pathogens in the raw patties
- Their heat resistance
- The factors that influence the heating of the patties
- The area of the patty that heats at the slowest rate

Product:_____ Page #__

Operational or Process Step	CCP		Hazards	Critical Limits		Monitoring		
	#	Description		#	Description	Procedure	Frequency	Person(s) Responsible

Product:_____ **Page #** __

CCP & CL	Corrective Actions for Line if Limit Exceeded & Person(s) Responsible	Corrective Actions for Product Lot(s) if Limit Exceeded & Person(s) Responsible	Verification Procedure and Frequency	Person Responsible for Verification	HACCP Records Where Located, and Person(s) Responsible

CCP = Critical Control Point; CL = Critical Limit

Figure 9.5 HACCP plan summary table. (From Corlett, D., 1998. *HACCP User's Manual*, Aspen Publishers, Gaithersburg, MD. With permission.)

Collectively, this information forms the technical and scientific basis upon which critical limits are established.

Process Step	*CCP*	*Critical Limits*
5. Cooking	YES	Oven temperature: ___ °F Time; rate of heating and cooling (belt speed in ft/min): ____ ft/min Patty thickness: ____ in. Patty composition: (e.g., all beef) Oven humidity: ____% RH

In the previous example for beef patties,[29] it was assumed that the HACCP team determined that the factors that may affect the thermal destruction of enteric pathogens are those listed in Table 9.12, and that a thermal process equivalent to 155°F for 16 sec was necessary to assure the safety of the product.

To ensure that this time and temperature are attained, it was determined that it would be necessary to establish critical limits for oven temperature and humidity, belt speed (time in oven), patty thickness, and patty composition (e.g., all beef, beef and other ingredients). The control of these factors will make it possible to produce a wide variety of cooked patties, all of which will be processed to a minimum internal temperature of 155°F for 16 sec.

At another facility, manufacturing the same product, the HACCP team determined that the best approach was also to use an internal patty temperature of 155°F and hold for 16 sec as critical limits. However, in this facility, the internal temperature and hold time control of the patties were monitored at a given frequency to ensure that the critical limits were constantly met as the product exited the oven. In this case, the exit temperature of the patties has to be carefully monitored and clearly documented in the corresponding record form for verification purposes.

Process Step	*CCP*	*Critical Limits*
5. Cooking	YES	Oven temperature: ___ °F Time; rate of heating and cooling (belt speed in ft/min): ____ ft/min Patty thickness: ____ in. Patty composition: (e.g., all beef) Patty temperature at exit: ____ °F

Chemical hazards, such as lead, mercury, etc. can be the result of a contaminated environment. Control of this situation basically depends

upon letters of guarantee by the suppliers together with a critical limit that specifies "no lead as provided by a supplier source guarantee." Chemical hazards such as pesticides, hormones, antibiotics, preservatives, colors, vitamins, and nitrites must be controlled through GMPs, good agricultural practices (GAPs), and prerequisite programs.[12]

Equipment such as magnets, metal detectors, sifters, and screens remove physical hazards. For a magnet, the critical limit could be described as "no hazardous metal"; for a metal detector, the critical limit is based on the detector's capability to find ferrous, nonferrous, and stainless steel material. The functioning of the kick-out mechanism must be defined and monitored. All kick-outs should be carefully checked to determine the source of the metal.

Once the critical limits are established, operational limits can be established to prevent deviations of the critical limits. Operational limits must be set tighter than the critical limits, so that a safety factor exists for the benefit of the processor. These limits must take into account factors such as accuracy and precision of the measurements, process and product variation, and limits needed to achieve quality requirements. Operational limits must provide the processor with the opportunity to adjust the process and bring it back into control prior to the production of out-of-spec product.

Principle 4: Establish CCP Monitoring Procedures

Monitoring consists of a planned sequence of observations or physical measurements that can be readily recorded at each CCP to ensure that the process is under control without imposing unrealistic time delays or costs in production. Monitoring provides an early warning that a process is either losing control or is, in fact, out of control. Monitoring procedures can be carried out continuously, using many types of physical and chemical instruments such as temperature recorders, pressure recorders, or pH recorders that will provide information upon which decisions and appropriate actions are taken when critical limits are exceeded. For example, temperature and time for a scheduled thermal process of low-acid canned foods can be recorded continuously on temperature recording charts. If the temperature falls below the scheduled temperature or the time is insufficient, as recorded on the chart, the product is retained and the disposition determined as in Principle 5 of the HACCP program. Likewise, pH measurement may be performed continually in fluids or by testing each batch before processing. There are many ways to monitor critical limits on a continuous or batch basis and record the data on charts. Continuous monitoring, always preferred when feasible, requires carefully calibrated. monitoring equipment for accuracy. Because of the potentially serious consequences of a critical limit deviation, monitoring procedures must be effective. An unsafe food may result if a process is not properly controlled and a deviation occurs.

When dealing with noncontinuous monitoring, the question of when to monitor becomes extremely important. It is necessary to establish a reliable enough monitoring frequency and procedure to indicate that the CCP and the hazard are under control. Intermittent monitoring quickly leads to a discussion on statistics. Random testing at a CCP or statistically based sampling may be utilized to verify effectiveness of the CCP, critical limit, and monitoring activities. If monitoring is on a per-lot basis, i.e., raw material, it is necessary to consider what the size of the sample should be. If a production line is monitored, the question is how often to sample. Statistically designed data collection or sampling systems lend themselves to this purpose. Management must decide on the amount of risk it is willing to accept by consulting literature or competent statistical authorities, so that appropriate time intervals can be incorporated into the development of a sampling plan.

The Food Safety and Inspection Service (FSIS) requires that each monitoring procedure and its frequency be listed in the HACCP program and accurate records be kept for future use in verification. The monitoring procedures used for each CCP must be specific and designed to monitor each hazard identified. All records and documents associated with CCP monitoring should be dated and signed by the person doing the monitoring. The form illustrated in Figure 9.5A (HACCP Plan Summary Table) is used for registering monitoring activities for each of the CCPs identified in the manufacturing process.

Monitoring serves three main purposes:

1. It facilitates tracking of the operation. If monitoring indicates that there is a trend toward loss of control, then action can be taken to bring the process back into control before a deviation from a critical limit occurs. In this sense, monitoring is essential to food safety management.
2. It determines when there is loss of control and a deviation occurring at a CCP. When a deviation occurs, an appropriate corrective action must be taken.
3. It provides written documentation for use in verification.

Some examples of monitoring procedures include:

- Raw materials sampling and inspection
- Process control specifications (time/temperature checking and documenting)
- Dry storage room temperature and humidity checking and inspection
- Cold room storage temperature
- Amounts of additives/ingredients used for each batch/lot checking and documenting

- Product sampling for bacterial analysis
- Net weight checking and documenting

When done properly, monitoring can help to prevent or minimize loss of product when a process or handling deviation occurs. It can also help to pinpoint the cause of a problem.

Assignment of the responsibility for monitoring is an important consideration for each CCP. Specific assignments will depend on the number of CCPs and control measures, and the complexity of the monitoring. Personnel who monitor CCPs should be associated with production, e.g., line supervisors, selected line workers, and maintenance personnel, and QC personnel. Monitoring activities include, for example, determining how and by whom cooking time and temperature should be controlled.

The American Society for Quality (ASQ) describes the following 10 steps in monitoring activity:[12]

1. **Ask the right questions.** The questions must relate to the specific information needed.
2. **Conduct appropriate information analysis.** What analysis must be done to get from raw data to a comparison with the critical limit(s)?
3. **Define where to collect information.** Where are the specific locations for data collection?
4. **Ensure unbiased information.** If the information is biased, it will not describe the process conditions and cannot be compared to the critical limits.
5. **Understand the needs of the person collecting the information.** This may include special environment requirements, training, and experience.
6. **Design simple but effective data forms.** Forms used to record data must be self-explanatory, permitting recording of all appropriate data, and designed to reduce opportunity for error.
7. **Prepare instructions.** Appropriate and clear operating instructions are powerful tools. They help employees monitor the process in a consistent manner.
8. **Test the forms and instructions and revise as necessary.** The person or employee who develops a form may think it is easy to use; however, it may prove difficult to use by the operator under production conditions.
9. **Train the person(s) collecting the information.** Personnel must be trained in the monitoring techniques for which they are responsible, fully understand the purpose and importance of monitoring, be unbiased in monitoring and reporting, and accurately report the

results. Operators need to know how, where, and when to collect the information, and how, where, and when to properly record it.

10. **Audit the information collection process and validate the results.** Audits provide a tool to ensure that an HACCP system is (1) operating as planned and (2) operating in an effective and efficient manner.

In addition, production personnel in general should be trained in procedures to follow when there is a trend toward loss of control, so that adjustments can be made in a timely manner. Monitoring personnel must immediately report a process or product that does not meet critical limits.

Most monitoring procedures need to be rapid because they relate to on-line, "real-time" processes and there will not be time for lengthy analytical testing. Once limits for potential hazards have been established, methods should be set and followed.

Monitoring can be done by either observation or measurement at the CCPs. In general, an observation gives a qualitative index of control, while a measurement results in a quantitative index. The choice of whether the monitoring will be an observation or a measurement, or both, depends upon the established critical limit and available methods of monitoring. Potential time delays and costs need to be considered.

Four types of monitoring are employed:[33] visual observations, sensory evaluations, physicochemical evaluations, and microbiological analysis.

- Visual observations — watching workers' practices, raw materials inspection
- Sensory evaluations — checks for off-odors, off-colors, off-flavors, product texture
- Physicochemical evaluations — pH or acidity, viscosity, solids content, salt content, water activity, time, temperature, pressure
- Microbiological analysis

Visual Observations

This type of monitoring is the most basic means of data collection and the most simple to carry out; therefore, emphasis must be placed on doing it correctly. Extreme care must be taken when selecting, training, and standardizing observers.

The most important factor to remember in visual observations is that it is the process point that is being checked and not the product being manufactured. For example, to determine if a continuous pH monitor is operating correctly, a simple observation of a continuous process chart should suffice to be sure that the correct pH level has been attained.

Sensory Evaluations

In cases such as organoleptic determination of decomposition or chemical or microbiological analyses, the person must have a high level of training and experience. The odor, taste, and feel of a product leaving a CCP can often tell much about how well a given hazard has been controlled. Tasting a product is usually not advised if it has an off-odor or if it has been exposed to conditions known to promote growth or toxin production. The smell of a product passing through a process point may be extremely helpful. For example, a musty odor could indicate the presence of mold growth and thereby the absence of mold control steps in the process. It also should be noted that off-odors associated with refrigerated or stored products may go undetected. The person(s) carrying out sensory evaluation as a quality tool should be unbiased. He/she should be someone in whom the company can place its trust.

Physicochemical Evaluations

Physicochemical measurement can include physical, chemical, or microbiological tests. The major advantage of these types of tests is that they are often rapid and, in some cases, adaptable to continuous monitoring. This is valuable because continuous or semicontinuous monitoring represents a large number of sample points, hence an extraordinary amount of confidence can be placed in these results. The most common physicochemical process measurements are time, temperature, and pH. For raw materials, chemical tests for toxins, food additives, contaminants; and microbiological tests for coliforms, *E. coli*, *Salmonella*, and other microorganisms are used.

Physicochemical tests require extra care. Instruments must be calibrated, as monitoring with noncalibrated instruments can do more harm than good. Physicochemical analyses are always preferred over other types of evaluations, although they may be used effectively in combination with other monitoring techniques.

Microbiological Analysis

As noted earlier, these types of determinations require extensive periods of time to complete and for this reason are less desirable than the monitors already mentioned. They are, however, useful in situations where the microbiological quality of raw materials may be critical; in such instances, the control point can be sampled at some period before it is incorporated in the product, and the analysis completed before production begins. Thus, the time constraints normally applying to microbiological testing are reduced.

Microbiological tests are seldom effective for monitoring due to their time-consuming nature and problems with assuring detection of contaminants. Physical and chemical measurements are often preferred because they are rapid and usually more effective for assuring control of microbiological hazards. For example, the safety of pasteurized milk is based upon measurements of time and temperature of heating rather than testing the heated milk to assure the absence of surviving pathogens.

With certain foods, processes, ingredients, or imports, there may be no alternative to microbiological testing. However, it is important to recognize that a sampling protocol, which is adequate to reliably detect low levels of pathogens, is seldom possible because of the large number of samples needed. This sampling limitation could result in a false sense of security by those who use an inadequate sampling protocol. In addition, there are technical limitations in many laboratory procedures for detecting and quantifying pathogens or their toxins.

It is equally important to state clearly who will do the necessary monitoring. This person must have knowledge of the procedures to be used, especially if physicochemical procedures are involved. In many plants, supervisory personnel take over this task, reasoning that if adjustments to the critical process points are required, these individuals are able to make them. It also should be noted that the HACCP tables shown in Figure 9.5A and B should contain columns for the CCP to be monitored and the person responsible for doing the monitoring.

Principle 5: Establish Corrective Actions Procedures

Regardless of how well the HACCP system has been designed and implemented, critical limits established by the procedures already discussed may be exceeded, which by HACCP definition could result in a hazard to the consumer. Once hazards have been identified, critical limits determined, and monitoring procedures set up, it is important to have pre-established corrective actions to eliminate the deviations and permit production to proceed. Corrective actions are defined as "actions to be taken when the results of monitoring at the CCPs indicate a loss of control." The HACCP plan must be designed so that deviations from the critical limits can be discovered quickly, allowing for detection and subsequent elimination or reduction of deviations by corrective actions taken as early as possible. Corrective actions help to correct and eliminate the cause of a deviation, as well as to determine the scope of the problem so that out-of-spec product can be identified and disposed of. The result is restoration of control of the process.

It is generally considered that there are four general steps to any corrective action.[12]

Identifying Causes of Deviations

Involves some form of root cause analysis defined as "a fundamental deficiency that results in a nonconformance and must be corrected to prevent recurrence of the same or similar nonconformance."[12] Misidentification of the root cause could lead to an improper corrective action.

Determining Product Disposition

To address a problem correctly, the manufacturer needs to identify the hazards and their causes. The company must improve the manufacturing processes, revise company procedures, and train employees to follow the new procedures.

Determining the appropriate method for disposing of nonconforming product is important. Product destruction should be witnessed and documented, but this practice is a short-term correction designed to contain a problem. Long-term corrections are valuable because they address the underlying cause and are expected to solve a problem permanently. The processes used to determine short- and long-term solutions should be included in the corrective action plan.

Recording the Corrective Action

Corrective actions must be documented and recorded to assist in the identification of problems and to determine if the HACCP plan requires modification. The documentation should identify the product, describe the deviation, detail the corrective action taken (including the final disposition of the affected product), and state the name and job title of the person responsible for making the correction. The second page of the HACCP Plan Summary Table (Figure 9.5B) is used to enter the information on corrective action for each CCP.

The ASQ recommends that one additional record, the so-called "Notice of Unusual Occurrence and Corrective Action" (NUOCA)[12] be used for corrective actions. NUOCA is designed for use in situations where a predetermined corrective action is not available for a given scenario. However, NUOCA often is used to mean any corrective action report, supporting the position that corrective actions should be unusual occurrences.

Independent of the corrective action taken, it is necessary to keep records that include:

- The deviation identified.
- Reason for holding a product.
  - Time and date of occurrence.
  - Amount of product involved.

- Disposition and/or release of the product.
  - Name of the person making the disposition decision.
- Actions taken to prevent the deviation from occurring. This may require reevaluation of the HACCP plan.

Corlett[13] suggests the form illustrated in Figure 9.7 as a deviation report form based on the requirements listed above.

Reevaluating The HACCP Plan

One important step involved in corrective action is the reevaluation of the HACCP plan. Reevaluation can be used to:[25]

- Identify gaps in the HACCP plan
- Identify hazards that may have been overlooked
- Determine whether the corrective actions taken are sufficient to correct deviations
- Establish whether critical limits are properly set
- Determine if monitoring activities are adequate
- Determine if available new technologies could reduce the occurrence of a hazard
- Determine if new hazards must be addressed in the HACCP plan

An HACCP program for food safety management is designed to identify health hazards and to establish strategies to prevent, eliminate, or reduce their occurrence. Specific corrective action plans should be developed for each CCP since variations result from many causes. Actions that would be considered corrective include: isolating and holding product for safety evaluation, diverting the affected product or ingredients to another line where deviation would not be considered critical, reprocessing, rejecting raw material, and destroying product.

In practice, corrective actions may be automatic and self-correcting. For example, when level controllers read an insufficient level of hydrogen peroxide solution for sterilizing aseptic packaging attached electronically to relays and switching circuits, these will automatically shut the packaging machine down and divert the flow of the product, and the machine ceases operation in response to the deviation. The operation will only be resumed when an acceptable corrective action is taken. For this reason, automatic systems are preferred. Unfortunately, many systems are not amenable to automatic control and human intervention is necessary. When this is the case, warning systems consisting of audible devices such as horns, or visual alerts such as flashing lights or a message flashed on a computer screen to alert an operator to a problem that requires correction.

Until some response to a deviation is forthcoming, the product will continue through the system without interruption. It is important, therefore, that manual checking for CCP deviations, where no alternatives exist, be done frequently and recorded on a log chart. The product manufactured during a period of deviation should be identified, segregated, and held pending a decision on its disposition. The purpose of an HACCP program is to prevent events such as these from occurring. Should a consumer safety issue be identified, the appropriate regulatory agencies must be notified if the product has entered interstate commerce.

Corrective actions should include the following elements:

- Determine and correct the cause of noncompliance
- Determine the disposition of noncompliant product
- Record the corrective actions that have been taken

An HACCP program requires that specific corrective actions be developed in advance for each CCP, and outlines the steps to be taken if the critical limit is not met. The HACCP program should specify what is to be done when a deviation occurs, who will be responsible for implementing the corrective actions, and that a record be developed and maintained of the actions taken. Examples of corrective actions include:

- Rejection of raw materials and ingredients that do not meet buying specifications
- Adjusting a cooler's thermostat to obtain the proper temperature
- Extending cooking time
- Reprocessing or reheating a product to the proper temperature
- Modifying food-handling procedures
- Discarding products

Principle 6: Establish Procedures for HACCP Verification and Validation

Verification

Although verification appears to consist simply of checking for instrument calibration and the reviewing of records, this process embodies additional activities that ensure the validity of an HACCP program and includes review of CCP records, critical limits, and microbial sampling and analysis procedures. Once the HACCP program is established, it is important that the critical limits surrounding each CCP are verified with regard to the overall effectiveness of the program; periodic verification audits should also be performed.

The importance of the verification procedure relies on the fact that it assists a company in accomplishing three objectives.

1. To ensure that the HACCP plan works: Verification confirms that the written plan is implemented, and that the implemented plan is identical to the written plan.
2. To ensure that the HACCP plan is valid: When used in this manner, the verification procedure constitutes a scientific review of the rationale behind each part of the plan.
3. To ensure that the HACCP plan is relevant: Since the HACCP plan is not intended to be static once developed and implemented, it must be reviewed periodically to ensure that it remains current and effective. At a minimum, it is recommended that the verification of the entire HACCP system should take place annually. The annual review assesses whether the plan is functioning as designed, and that it continues to accurately reflect the company's product and operational requirements. This was emphasized and clarified in the 1997 HACCP Principles and Application Guidelines of the NACMCF.[28]

The National Academy of Sciences[34] pointed out that the major infusion of science in an HACCP system centers on proper identification of the hazards, CCPs, and critical limits, and instituting proper verification and validation procedures. These processes should take place during the development and implementation of the HACCP programs and maintenance of the system.

One aspect of verification is evaluating whether the facility's HACCP plan functions according to the established program. An effective plan requires little end-product testing, since sufficient validated safeguards are built in early in the process. Therefore, rather than relying on end-product testing, firms should rely on frequent reviews of their HACCP plan, verification that the plan is being correctly followed, and review of CCP monitoring and corrective action records.

Individuals within a company, third-party experts, and regulatory agencies carry out verification activities. It is important that individuals doing verification have appropriate technical expertise and knowledge to perform this function and establish the effectiveness of the plan in protecting the product. Each individual control point is evaluated to be sure that it is operating and that the limits for its operation are correct. A summarizing or inclusive evaluation of the entire HACCP plan also is undertaken during the verification process to be sure that all aspects of the program are being followed. The role of regulatory and industry in HACCP was further described by the NACMCF as shown in the following sections:[35]

Events that May Require Verification Inspection of the HACCP Plan

- New information concerning safety of the product, or process, or the manner in which the consumer uses a product.
- When foods have been implicated in food-borne disease.
- When established criteria have not been met.
- To verify that changes have been made correctly following a modification in the HACCP program.
- Following significant modification to process points that are critical.

HACCP Verification Protocol and Activities — Information in Verification Reports

- Initial validation of the HACCP plan.
- Subsequent validation of the HACCP plan.
- The person(s) responsible for administering and updating the HACCP program.
- Review of the HACCP program for completeness. Records should include the company's name and location, date and time of activity, initials of the operator, identity of the product, and product code.
- Confirming the accuracy of the flow diagram.
- Checking for the presence of prerequisite programs.
- Certification that monitoring instruments are properly calibrated and in working order (thermometers and other critical measuring instruments).
- Verification of CCP monitoring as described in the plan.
- Review of personnel records to determine amount of training and knowledge of individuals responsible for monitoring CCPs.
- Records associated with CCP monitoring.
- Confirming direct recording of monitoring data of CCPs while in operation.
- Visually inspecting operations to observe if CCPs are under control.
- Sampling and analytical test methods (audit of procedures) used to verify that CCPs are under control.
- Randomly collecting and analyzing samples of in-process or finished product.
- Sampling for environmental and other concerns.
- Review of monitoring, deviations, corrective action records, and disposition of finished product to show compliance with the plan.
- Review of written records of verification inspections that certify compliance with the plan.
- Review of consumer or customer complaints related to the performance of the CCPs or reveal the existence of unidentified CCPs.
- Review of modifications to the plan.

Table 9.13 Example of a Company Established HACCP Verification Schedule

Activity	*Frequency*	*Responsibility*	*Reviewer*
Verification activities scheduling	Yearly or upon HACCP program change	HACCP coordinator	Plant manager
Initial validation of HACCP program	Prior to and during initial implementation of plan	Independent expert(s)[a]	HACCP team
Subsequent validation of HACCP program	When critical limits changed, significant changes in process, equipment changed, after system failure, etc.	Independent expert(s)[a]	HACCP team
Verification of CCP monitoring as described in the plan (e.g., monitoring of patty cooking temperature)	According to HACCP program (e.g., once per shift)	According to HACCP program (e.g., line supervisor)	According to HACCP program (e.g., quality control)
Review of monitoring, corrective action records to show compliance with the program	Monthly	Quality assurance	HACCP team
Comprehensive HACCP system verification	Yearly	Independent expert(s)[a]	Plant manager

[a] Done by people other than the team writing and implementing the plan. May require additional technical expertise as well as laboratory and plant test studies.

- Validation activities.
- Comprehensive HACCP system verification.

Verification Schedules

Table 9.13 illustrates an example of an established HACCP verification schedule, which can be carried out on the following bases.

- Routinely, or on an unannounced basis, to assure CCPs are under control.
- When there are emerging concerns about the safety of the product.
- When foods have been implicated as a vehicle of food-borne disease.
- To confirm that changes have been implemented correctly after an HACCP program has been modified.
- To assess whether an HACCP program should be modified due to a change in the process, equipment, ingredients, etc.

The information obtained from the verification procedures is entered in the HACCP Plan Summary Table (Figure 9.5B) for each CCP and its

critical limits, including frequency of verification, person(s) responsible for verification, and HACCP records, records location, and person(s) responsible for such records.

Validation

Another important aspect of verification is the initial validation of the HACCP program to determine that it is scientifically and technically sound, that all hazards have been identified, and that if the program is properly implemented, these hazards will be effectively controlled. This may require the assistance of external resources to identify the biological, chemical, or physical hazards that are intrinsic to raw materials, ingredients, or processes.

Validation ensures that the program does what it was designed to do; i.e., succeed in ensuring the production of a safe product. A scientific or technical review of the critical limits is necessary to verify that the specifications that are set are adequate to control the hazards that are likely to occur, and in some cases that the specifications comply with regulatory requirements. Food manufacturing plants are required to validate their own HACCP programs. The FSIS does not approve an HACCP program in advance, but will review it for conformance with the final rule.

Information needed to validate the HACCP program often includes:

- Expert advice and scientific studies
- In-plant observations, measurements, and evaluations

For example, validation of the cooking process for beef patties, previously presented, should include the scientific justification of the heating times and temperatures needed to obtain an appropriate destruction of pathogenic microorganisms, i.e., enteric pathogens, and studies to confirm that the conditions of cooking will deliver the required time and temperature to each beef patty.

Subsequent validations are performed and documented by an HACCP team or an independent expert as needed. For example, validations are conducted when there is an unexplained system failure; when a significant product, process, or packaging change occurs; or when new hazards are recognized.

In addition, an unbiased, independent authority should conduct a periodic comprehensive verification of the HACCP program. Such authority can be internal or external to the food operation. This should include a technical evaluation of the hazard analysis and each element of the program, as well as on-site review of all flow diagrams and appropriate records from the operation of the plan. A comprehensive verification is independent of other verification procedures and must be performed to ensure that the program is resulting in the control of hazards. If the results

of the comprehensive verification identify deficiencies, the HACCP team modifies the program as necessary.

Principle 7: Document the HACCP Program. Establishment of Record-Keeping Procedures

An HACCP program should be thoroughly documented and implemented establishing procedures for the identification, storage, retrieval, maintenance, protection, and disposition of documents. The documentation generated must be formal written records providing factual evidence that an activity has been performed in a timely manner in accordance with established procedures. Information contained in corrective action records provides a description of the deviation and an evaluation of the corrective action taken, as well as a notation as to final disposition of the affected product. The name of the individual responsible for taking the corrective action should be included. A sample corrective action report is shown in Figure 9.6.

Records should be available to each plant manager, who should be familiar with their content. Alterations of the manufacturing program or of the HACCP program should be recorded in supplements to the program, especially if they involve CCPs. This is very important, as the records may be demanded by regulatory inspectors making routine inspections; therefore, they should be complete and easily available at all times.

The HACCP regulations require all plants to maintain a written copy of their program, records documenting the monitoring of CCPs, critical limits, handling of process deviations, and verification activities. Monitoring results for each CCP must be recorded for review by management and should indicate that the manufactured foods and ingredients have been properly evaluated, handled, and processed.

To ensure that controls are working, that proper information is being recorded, and that the workers handle foods properly, management should conduct a daily record review. If records indicate potential problems, an investigation must begin immediately and findings must be documented, in detail, of the corrective action taken.

The Food, Drug, and Cosmetic Division of the ASQ[12] offers some examples of record forms, illustrated in Figure 9.6 through Figure 9.9. Generally, the records maintained for an HACCP program should include the information indicated below.

- **A written copy of the HACCP program.** This requires the preparation and maintenance of a written HACCP program by the food manufacturing plant. The program must detail the hazards of each individual or categorical product covered by the program. It must clearly identify the CCPs and critical limits for each. CCP monitoring and record-keeping procedures must be shown in the plant's

Name of Company
Address

HACCP PROGRAM RECORDS

Corrective Action Report

Date:_____ Product:_____

Batch/Lot ID:_____ P.O. number:_____

Problem:_____

Action taken:_____

Present status:_____

Supervisor:_____ Date:_____

Reviewed by:_____ Date:_____

Figure 9.6 Corrective action report form (HACCP Program). (From ASQ Food, Drug and Cosmetic Division, 2002. *The Quality Auditor's HACCP Handbook*, ASQ, Milwaukee, WI. Reprinted with permission.)

program. Program implementation strategy should be provided as part of the plant's documentation. The approved HACCP program and associated records must be on file at the plant.

- **Listing of the HACCP team members.** Names, positions, qualifications, and assigned responsibilities.
- **Employee training.** Records pertinent to CCPs and to the HACCP program (Figure 9.11).
- **Description of the food.** Its distribution, intended use, and consumer.

HACCP System Deviation Report
(A Deviation is a Failure to Meet a Critical Limit)

Product: _____ Line: _____

Facility: _____ Establishment Number: _____

IDENTIFY THE DEVIATION — Occurred at CCP number: _____

What was the deviation? _____

_____

When did the deviation occur? Date: _____

Time: _____ A.M.: _____ P.M.: Shift: _____

Reported by: _____ Initial: _____

REASON FOR HOLDING THE PRODUCT:
Why was the product held? _____

Amount of product held? _____

Person placing product on hold: _____ Initial: _____

DISPOSITION AND/OR RELEASE OF PRODUCT:
What is the decision on disposition of this product? _____

Person making product disposition: _____ Date: _____

Signature: _____

ACTIONS TO PREVENT THE DEVIATION FROM RECURRING:
What was done to prevent the failure of this critical limit? _____

_____

Person making recommendation: _____ Initial: _____

Date: _____

Date: _____ Approved By: _____

Date: _____ Initial: _____

Date: Approved By _____

Figure 9.7 HACCP system deviation report form.

- **Ingredients.** Those for which critical limits have been established (including letters of guarantee, Figure 9.8).
- **Documents supporting the HACCP program and hazard analysis.** Documentation of the adequacy of the program from a knowledgeable HACCP expert, including an outline of prerequisite programs and preliminary steps. Such documents include:
  - **Record-keeping.** The maintenance of records generated during the operation of the program. Recording events at CCPs on a regular basis ensures that preventive monitoring occurs systematically and ultimately makes the program work. Correcting problems

Name of Supplier Company
Address of Supplier Company

Supplier Company Letter of Guarantee

Date

Name of receiving company
Address of receiving company

Dear _____

This letter is sent to you to certify that in accordance with your purchasing order of (date), this shipment of (product) (lot number _____) conforms to the specifications for the hazards specified in your purchase order.

Sincerely,

J. C. Powers
QC Director

Reviewed by: _____ Date: _____

Figure 9.8 Example of a supplier letter of guarantee. (From FAO/WHO, Codex Alimentarius Commission, 1993.)

without record keeping almost guarantees that problems will recur. The level of sophistication of the record keeping necessary depends upon the complexity of the food processing operation. A *sous vidé* process or cook-chill operation, for a large institution, requires more record keeping than a limited menu cook-serve operation. The simplest effective record-keeping system that lends itself well to integration within the existing operation is the best.

- **Verified manufacturing process for the products under the program.** Includes:
  - Flow diagrams
  - Written SSOPs

Name of Company
Address of Company

Processing Record

Date: _____ Product: _____

Critical Limits: _____ Shift: _____

Operator: _____

Batch #	Time	Temp MIG	Temp. Recorder	Comments

Reviewed by: _____ **Date:** _____

Figure 9.9 Example of a processing record form. (From ASQ Food, Drug, and Cosmetic Division, 2002. *The Quality Auditor's HACCP Handbook*, ASQ Quality Press, Milwaukee, WI. Reprinted with permission.)

- Manufacturing Standard Procedures, GMPs
- Analytical Control Procedures

- **Supplier guarantees.** Certificates of Compliance/importer verification (Figure 9.8)
- **Monitoring records** and monitoring procedures, including the rationale for determining hazards and control measures.
- **Processing, storage, and distribution records**
  - Product formulation records.
  - Batch preparation logs.

Name of Company
Address of Company

Temperature Instruments Calibration Record

Instrument: _____

Model number: _____ Serial number: _____

Location: _____

Calibration date scheduled: _____

Date Calibrated	Calibration Results	Method of Calibration	Performed by	Comments

Reviewed by:_____ **Date:**_____

Figure 9.10 Example of an instrument calibration record form. (From ASQ Food, Drug, and Cosmetic Division, 2002. *The Quality Auditor's HACCP Handbook*, ASQ Quality Press, Milwaukee, WI. Reprinted with permission.)

- Cooking procedure logs.
- Thermal processing logs.
- Thermal processing equipment validation records.
- Equipment calibration records.
- Instrument calibration record.
- Information that establishes the efficacy of a CCP to maintain product safety.

Name of Company
Address of Company

Employee Training Record

Employee Name: _____

Training Course	Date(s) of Course

Reviewed by: _____ **Date:** _____

Figure 9.11 Example of an employee training record form. (From ASQ Food, Drug, and Cosmetic Division, 2002. *The Quality Auditor's HACCP Handbook*, ASQ Quality Press, Milwaukee, WI. Reprinted with permission.)

- All CCPs.
- Critical limit(s). Data supporting critical limits, including laboratory analyses.
- Data establishing the safe shelf life of the product, if age of product can affect safety. Records of laboratory analyses, i.e., salt, pH, microbial challenge studies, etc.
- Shelf life studies.

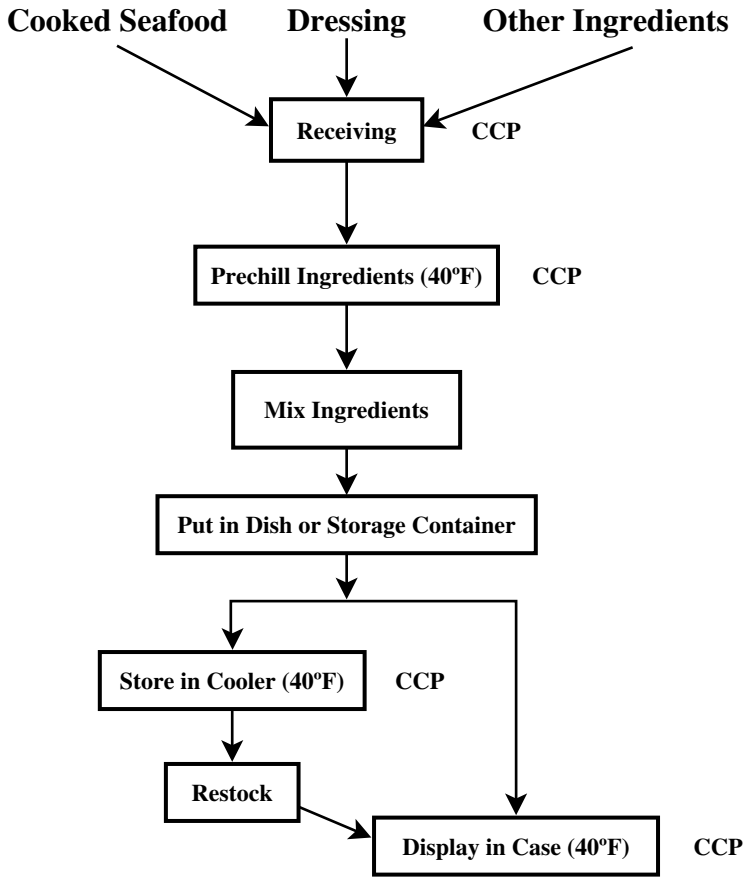


Figure 9.12 Flowchart showing the stages in the manufacturing and storage of seafood salads and the critical control points in the process.

- Consultant reports.
- Packaging design and validation records. Records indicating compliance with critical limits when packaging materials, labeling, or sealing specifications are necessary for food safety.
- Other documents directly related to the product manufactured.

- **Deviation and corrective action records** (Figure 9.7).
  - Corrective action reports
- **Verification records and procedures.** Verification records document that the HACCP system is valid and is consistently implemented. Verification of records should be conducted periodically and on a predetermined schedule. Verification records include:

- The HACCP plan and modifications to the plan, i.e., changes in ingredients, formulations, processing, packaging, and distribution.
- Processor records verifying supplier compliance with letters of guarantee or certificates.
- Calibration records to verify the accuracy and calibration of all monitoring instruments.
- Analytical records, microbiological challenge tests, environmental tests, periodic in-line tests, and finished-product testing.
- Audit records of in-house, on-site inspections. Figure 9.9 through Figure 9.11 are samples of potential HACCP verification records. For the meat and poultry industry, USDA/FSIS has specific format, review, and signature requirements.

- **Validation records of equipment-evaluation tests.**

The USDA/FSIS offers a guidebook for preparation of HACCP plans, including those for several meat and poultry products available from FSIS Public Outreach.[36]

Format for HACCP Information

In addition to listing the HACCP team, product description and uses, and providing a flow diagram, other information in the HACCP program can be tabulated as follows:

Process Step	*CCP*	*Chemical Physical Biological Hazards*	*Critical Limit*	*Monitoring Procedures/ Frequency Person(s) Responsible*	*Corrective Action Person(s) Responsible*	*HACCP Records Person(s) Responsible*	*Verification Procedures/*

The following chart is an example of an HACCP program documentation for a product cooling step in a retail level food establishment.

PROCESS STEP *CCP*	*COOLING* *Critical Control Point #8*
Criteria or Critical Limit Establish Monitoring	Cool foods rapidly in small quantities to 5°C (41°F) Department personnel break down food into small quantities and monitor the cooling process
Corrective/Preventive Action	Modify cooling procedures/discard
HACCP Records	Deli cooking/cooling log
HACCP System Verification	Deli safety audit by store manager

Examples of Records Required during Operation of the HACCP Program

- Ingredients
  - Supplier certification documenting compliance of an ingredient with the manufacturer's specifications and critical limits.
  - The manufacturing plant audit records verifying supplier compliance.
  - Storage temperature record for temperature-sensitive ingredients, when ingredient storage is a CCP.
  - Storage time records of limited shelf-life ingredients, when ingredient storage is a CCP.
- Preparation
  - Records from all monitored CCPs.
  - Records verifying the continued adequacy of the food preparation procedures.
- Packaging
  - Records indicating compliance with specifications of packaging materials.
  - Records indicating compliance with sealing specifications.
- Finished Product
  - Sufficient data and records to establish the efficacy of barriers in maintaining product safety.
  - Sufficient data and records establishing the safe shelf life of the product if age of product can affect safety.
  - Documentation of the adequacy of the HACCP procedures from an authority knowledgeable of the hazards involved and necessary controls.
- Storage and Distribution
  - Storage temperature records.
  - Refrigerated shipment records.
  - Records showing no product shipped after shelf-life date on temperature-sensitive products.

- Deviation and Corrective Action
  - Validation records and modification to the HACCP program indicating approved revisions and changes in ingredients, formulations, preparation, packaging, and distribution control, as needed.
- Employee Training
  - Records of employee training programs.
  - Records indicating that food employees responsible for implementation of the HACCP program understand the hazards, controls, and procedures.

IMPLEMENTATION AND MAINTENANCE OF AN HACCP PROGRAM

The successful implementation of an HACCP program is facilitated by commitment from top management. The next step is to establish a plan that describes the individuals responsible for developing, implementing, and maintaining the program.

The team is then responsible for developing the initial plan and coordinating its implementation. Product teams can be appointed to develop programs for specific products.

An important aspect in developing these teams is to ensure that they have appropriate training. Upon completion of the HACCP program, procedures and forms for operating, for monitoring, and for taking corrective action are developed. Often it is a good idea to develop a timeline for the activities involved in the initial implementation of the program. Implementation involves the continual application of the monitoring, record keeping, corrective action procedures, and other activities as described in the program.

Maintaining an effective system depends largely on regularly scheduled verification activities. The program should be updated and revised as needed. An important aspect of maintaining the HACCP system is to assure that all individuals involved are properly trained so they understand their roles and can effectively fulfill their responsibilities.

Practical Example: HACCP Plan Model for Refrigerated Stick and Sliced Celery[13]

The following pages illustrate, in diagrammatic format, an HACCP plan for refrigerated stick and sliced celery. They are an example of this scientific/technical tool for safety control in food manufacturing operations.

HACCP Plan Model for Refrigerated Stick and Sliced Celery

Parts:			
1.0	HAACP plan identification page	4.0	Raw materials and ingredient list and information
2.0	Assemble the HACCP team	5.0	Develop and verify flow diagram
3.0	Describe food and its distribution and identify intended use and consumers of the food	6.0	Hazard analysis
		7.0	Flow diagram with CCP and SSOP
		8.0	HACCP plan summary table

Part 1.0
Form 1.0 HACCP Worksheet Forms

Worksheets: Hazard Analysis and Critical Control Point System for Development of the HACCP Plan	
HACCP Plan Identification Page	
Products: Class model for: Refrigerated Fresh Celery Sticks and Celery Slices*	
Product Codes: 5″ Sticks - CFCS 1; 3/8″ Slices - CFCS 2.	
	Company: Corlett Food Consulting Service
	Company Location: Concord, California
Company Contact(s):	Name: Don Corlett Phone: _____ Title: QA Manager Fax: _____ (& Class instructor)
Manufacturing Location: _____	
Manufacturing Contact:	Name: Carol Wright Phone: _____
	Title: General Manager Fax: _____
Date HACCP Plan Prepared: August 15, 1996	
Date HACCP Plan Revised: _____	
Date HACCP Plan Approved: August 20, 1996	

*__NOTE:__ This class model is intended only as a teaching example and is based on a hypothetical food operation. It is not suitable for use for commercial products or processing operations. The development of the HACCP plan for an actual commercial product and processing operation must be based on developing the HACCP plan and system based on hazard analysis for the specific food and specific processing conditions.

Part 2.0
Form 2.0 HACCP Worksheet Forms

Preliminary Step 1. Assemble the HACCP Team

Product: Model: Celery

Facility: Amaranth Place

Date: August 15, 1996

	Name	Title
HACCP Team Leader/Coordinator:	Don Corlett	QA Manager
HACCP Team Members	Riggs Firstlook	Receiving
	Bradley Heater	Processing
	Phil Product	Packaging
	Fred Fix	Maintenance
	Hecter McClean	Sanitation
	Jane Quality	Quality Control
	Samantha Sample	Laboratory
	Hugh Stack	Distribution
	Lydia Newit	Product Development

Part 3.0 Form 3.0 HACCP Worksheet Forms
Preliminary Step 2.
Describe Food and its Distribution: Common or usual name? (Please attach recipe/formulation) Raw, precooked? Ready-to-eat or must it be cooked before consumption Preservation method? Type of package? Method of distribution? Is product distributed frozen, refrigerated, or is it shelf stable? Length of shelf-life? At? Temperature? Label instructions? Are special distribution controls needed?
Refrigerated Fresh Celery Sticks and Slices Refrigerated fresh celery sticks and slices are ready-to-eat, are packed in 12-oz plastic pouches, and are sold in the refrigerated produce case in the grocery store. This celery stick product is intended for snacks and the sliced celery pieces may be used in salads or cooked for dinner or made into soup, etc. The product is made from fresh-cut field celery that is harvested and shipped under refrigeration to the processing facility. The celery is washed, trimmed, cut or sliced, and placed in sealed plastic bags. Finished product is refrigerated during storage, distribution, and retail display. The product has a best-used-by refrigerated shelf-life of 15 days from the date of processing. Product is stored at 40°F or lower, but is not frozen.

Part 3.0 Form 3.0 HACCP Worksheet Forms
Preliminary Step 3.
Identify the intended use and consumer of the food What is the normal use of the food by intended consumers? Who will consume the food? Is the food intended for high-risk populations (infants, elderly, immunocompromised)? Is the food intended for retail or food service? Is food held refrigerated, frozen, or hot before consumption?
Refrigerated Fresh Celery Sticks and Slices The product is intended for consumption by the general population, either at home or in a food service environment. It is not specifically processed for high-risk populations. Refrigerated fresh celery sticks and slices must be held at refrigerated temperatures of 40°F or lower before consumption. Unused portions should be refrigerated. This product should not be frozen because freezing will damage the texture and quality.

Part 4.0
Form 4.0 HACCP Worksheet Forms

Preliminary Step 3.1 Raw Materials and Ingredients List and Information						
Product: Refrigerated Celery Sticks/Slices					Date: August 15, 1996	
Product Codes: Sticks: CFCS - 1; Slices: CFCS - 2 Page: 1 of 1						
Name of Raw Material or Ingredient (Also Packaging)	Spec. Number	Form Powder, Diced, etc.	Preservation Method: Dry, Refrigerated, Frozen, etc.	Packaging Bags, Drums Bulk, etc.	Size Package or Lots	Other Information
Fresh whole celery bunches; may use stalks if necessary	001	Whole	Refrigerated 33–40°F	Corrugated boxes; wood boxes	Totes; some boxes approximately 60 lb	Trucked
Water for processing				Plant water system		Source: city
Plastic Pouches (12 oz size)	002	Roll stock		Corrugated	100 lb	Trucked

Part 5.0
Form 5.0 HACCP Worksheet Forms

(page 1)

Preliminary Steps 4. and 5.

4. Develop flow diagram for the specific product or group of products. Possible parts of sequence:

Raw materials and ingredients
Shipping
Receiving
In-process steps
Combination of in-process streams
Fabrication and further processing
Product
Packaging
Storage
Distribution
Point-of-sale display
Consumer use

5. Verification of the flow diagram to insure accuracy and completeness.

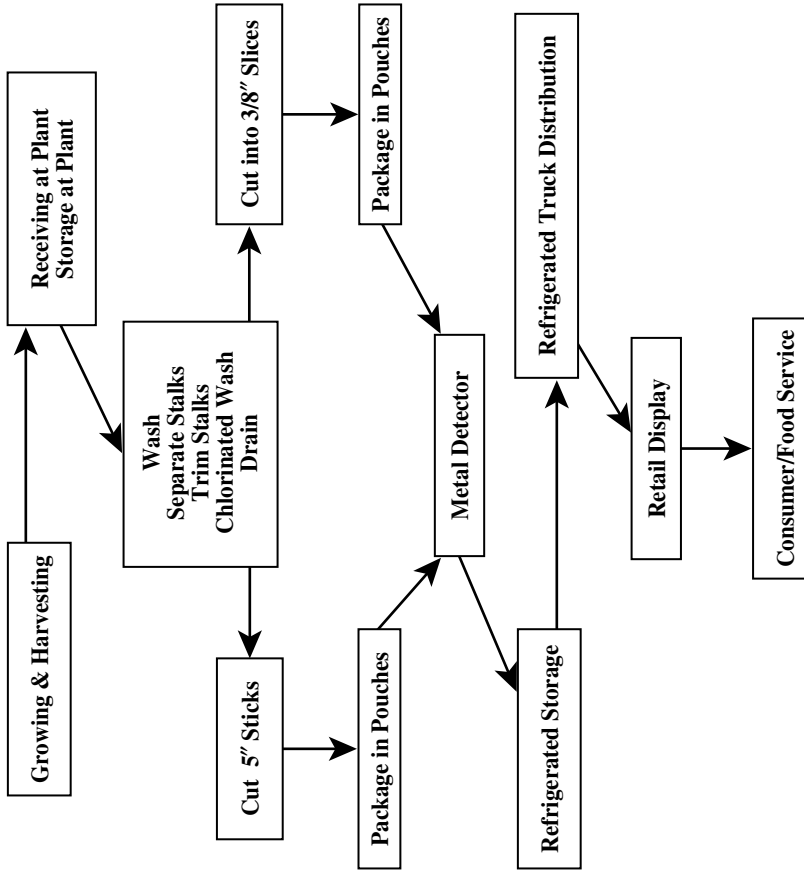
Did the HACCP team inspect the operation to verify the accuracy and completeness of the flow diagram?

Yes: XX HACCP Team Coordinator: D. A. Corlett Date: August 15, 1996

Refrigerated Fresh Celery Sticks and Slices
(Class example; for class use only)

Please refer to the following diagram

Part 5.0
Flow Diagram for 5″ and 3/8″ Sliced Refrigerated Celery



Part 6.0
Hazard Analysis Work Sheet

Firm Name:
Firm Address:

Product Name: Refrigerated Fresh Celery Sticks/Slices
Product Description: Refrigerated fresh-cut product
Method of Distribution and Storage: Refrigerated truck
Intended Use and Consumer: Snacks/salad; general population

Date: August 15, 1996
Name of Preparer: Donald A. Corlett

(1)	(2)	(3)	(4)	(5)	(6)	(7)
Ingredient/ Processing Step	**Identify Potential Hazard(s) Introduced, Controlled, or Enhanced at This Step**	**Are Any Potential Food Safety Hazards Significant? (Yes or No)**	**Justify Your Decision for Column 3**	**What Preventive Measure(s) can be Applied for the Significant Hazards?**	**Is this Step a Critical Control Point (CCP)? (Yes/No)**	**CCP #**
Growing & harvesting (bunches of celery)	Biological	Yes	Microbiol. contam. from field, water, worker	Field sanitation and cooling of product	Yes; Field	Cert.?
	Chemical	Yes	Pesticide residues from field application	Auditing of pesticide applic. before harvest	Yes; Field	Cert.?
	Physical	No	Nuisance and quality matter. Use SSOPs.		No	—
Receiving & storage at processing plant	Biological	Yes	Microbial from field and truck	Preapprove vendor for field sanitat. program	Yes	1
	Chemical	Yes	Pesticide residues from field spraying	Preshipment record and tolerance approval	Yes	1
	Physical	No	Application of GMPs and SSOPs		No	—
Prepare: wash, trim; chlori-nated wash Drain Cool	Biological	Yes	Microbial from field and truck	Trim and wash product. Chlorinated water rinse and drain. Keep product at temp. 32–40°F	Yes	2
	Chemical	No	Application of GMPs and SSOPs		No	—
	Physical	No	Application of GMPs and SSOPs. In-line magnets to remove metal		No	—

Part 6.0
Hazard Analysis Work Sheet, continued

Firm Name: CFCS Product Name: Refrigerated Fresh Celery Sticks/Slices Date: Aug. 15, 1996

(1)	(2)	(3)	(4)	(5)	(6)	(7)
Ingredient/ Processing Step	**Identify Potential Hazard(s) Introduced Controlled, or Enhanced at this Step**	**Are Any Potential Food Safety Hazard Significant? (Yes or No)**	**Justify Your decision for Column 3**	**What Preventive Measure(s) can be Applied for the Significant Hazards?**	**Is this Step a Critical Control Point? (CCP) (Yes/No)**	**CCP #**
Cut 5″ sticks or cut 3/8″ slices	Biological	No	SSOPs for the cutter and area		No	—
	Chemical	No	GMPs		No	—
	Physical	Yes	Possible broken cutter blades	Install downstream elect. metal detector	No	—
Package in pouches and code pouches	Biological	Yes	Lack of refrigeration allow growth of microorg. pathogens	Maintain product temp. at <40°F	Yes	3
		Yes	Growth of low temp. microorg. pathogens	Storage by shelf-life code	Yes	4
						—
	Chemical	No	In storage		No	—
	Physical	No			No	
Electronic metal detector	Biological	No			No	—
	Chemical	No			No	—
	Physical	Yes	Prevent metal (broken blades, wire, etc.) from contamin. finished product	In-line electronic metal detector for sealed packages	Yes	5

Part 6.0
Hazard Analysis Work Sheet, continued

Firm Name: CFCS Product Name: Refrigerated Fresh Celery Sticks/Slices Date: Aug. 15, 1996

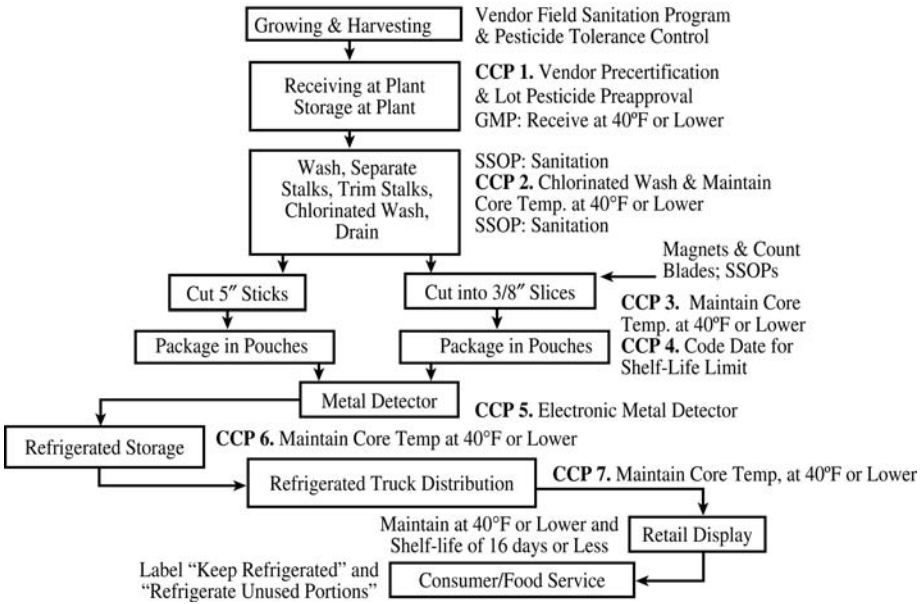
(1)	(2)	(3)	(4)	(5)	(6)	(7)
Ingredient/ Processing Step	**Identify Potential Hazard(s) Introduced Controlled, or Enhanced at this Step**	**Are Any Potential Food Safety Hazards Significant? (Yes or No)**	**Justify Your Decision for Column 3**	**What Preventive Measure(s) can be Applied for the Significant Hazards?**	**Is this Step a Critical Control Point? (CCP) (Yes/No)**	**CCP #**
Refrigerated storage of pouched product	Biological	Yes	Prevent growth of microorg. pathogens including *Listeria*	Temp. 32-40ºF; code/ <16 day shelf-life	Yes	6
	Chemical	No	Packaged product		No	—
	Physical	No	Packaged product		No	—
Refrigerated truck distribution	Biological	Yes	Prevent growth of pathogenic microorganisms	Truck compartment air temp. at 40ºF or less in distribution	Yes	7
	Chemical	No	SSOPs apply to truck refer. compartment	SSOPs also apply to truck. compartment	No	—
	Physical	No	SSOPs apply to truck refer. compartment		No	—
Retail display	Biological	Yes	Microorg. growth from high temp. or over shelf-life	40ºF or less temp. <16-day shelf-life	Yes	Groc. CCP?
	Chemical	No	Packaged product		No	—
	Physical	No	Packaged product		No	—

Part 6.0
Hazard Analysis Work Sheet, continued

Firm Name: CFCS Product Name: Refrigerated Fresh Celery Sticks/Slices Date: Aug. 15, 1996

(1)	(2)	(3)	(4)	(5)	(6)	(7)
Ingredient/ Processing Step	**Identify Potential Hazard(s) Introduced Controlled, or Enhanced at this Step**	**Are Any Potential Food Safety Hazards Significant? (Yes or No)**	**Justify your decision for Column 3**	**What Preventive Measure(s) can be Applied for the Significant Hazards?**	**Is This Step a Critical Control Point? (CCP) (Yes/No)**	**CCP #**
Consumer/food service	Biological	Yes	Growth of microrg. pathogens if not refrigerated	"Keep refrigerated" and "Refrigerate unused portions" on the label	CCP or a Standard Operating Procedure (SOP)	?
	Chemical	No	Remote: Tampering	Tamper-evident package or instructions	SOP	—
	Physical	No	Remote: Tampering	Tamper-evident package or instructions	SOP	—
	Biological					
	Chemical					
	Physical					

Part 7.0
Flow Diagram with CCP for 5″ Stick and 3/8″ Sliced Refrigerated Celery



Part 8.0
HACCP Plan Tabulation for Product or Process
Refrigerated Fresh Celery Sticks/Slices
Page 1 of 8

Operational or Process Step	Hazard Type MCP?	CCP		Critical Limits		Monitoring		Person(s) Responsible
		#	Description	#	Description	What & How	Frequency	
Receiving & storage at processing plant (bunches of celery)	Microbial: Pathogens from field water & workers; pesticide residues from spraying	1	Vendor pre-certification and pre-shipment record-review program	1.1	Vendor meets requirements for field sanitation, potable water, and employee hygiene. Vendor monitors with microbiolog. test program to verify compliance.	Approve vendor. Use vendor approval SOP 1.1 Examine incoming lot: - Proper tag. - Approved vendor - No damage or abnormal conditions	Before season or before shipment Each lot	Purchasing mgr. and QA mgr. Receiving warehouse person.
				1.2	Vendor provides accurate records of correct application and tests indicating that residues meet government tolerances	Review and approve pesticide application records before approval to ship to plant. Lot must be properly tagged.	Each incoming lot	Purchasing mgr. and QA mgr.

CCP = Critical Control Point

Part 8.0
HACCP Plan Tabulation for Product or Process
Refrigerated Fresh Celery Sticks/Slices

CCP & CL #	Corrective Actions for Line if Limit Exceeded & Person(s) Responsible	Corrective Actions for Product Lot(s) if Limit Exceeded & Person(s) Responsible	HACCP Records, Where Located and Person(s) Responsible	Verification Procedure and Frequency	Persons Responsible for Verification
1.1	Withdraw vendor certification. Approve new vendors and arrange for alternative supply.* Purchasing and QA.	Discontinue shipping. Reject lot(s) at Receiving Department. If in plant, place on QC hold/isolate.* Purchasing and QA.	Daily records located in the Receiving Department Person designated provides his/her initials on monitoring documents and on corrective action documents Supervisor reviews records at end of each shift for completeness and accuracy, and signs and dates records	Compare records for compliance to HACCP plan. Use NACMCF92/97 company HACCP verification procedure. Audit every two weeks. Conduct external HACCP verification audit on quarterly basis.	HACCP team (Internal HACCP verification) Corporate Quality Assurance: HACCP team from another food plant, consultant, etc.
1.2	Advise Production Department if ingredient lot(s) not shipped. Arrange for alternative supply. Purchasing and QA.	Discontinue shipping. Reject lot(s) at Receiving Department. If in plant, place on QC hold/isolate.* Purchasing and QA.			
NOTE: Prepare deviation report describing corrective action taken and product hold information. All deviations must be reviewed and handled by QA.					

CCP = Critical Control Point, CL = Critical Limit

* Daily records are maintained in the corresponding manufacturing area or department.

Part 8.0
HACCP Plan Tabulation for Product or Process
Refrigerated Fresh Celery Sticks/Slices

Operational or Process Step	Hazard Type MCP?	CCP* #	CCP* Description	Critical Limits #	Critical Limits Description	Monitoring What & How	Monitoring Frequency	Person(s) Responsible
Prepare: Wash Trim Chlorinated wash Drain Cool of 40°F or less	Microbiol: pathogens	2	Wash trimmed produce with chlorinated water, and maintain core product temp. (range 32-40°F)	2.1	Residual free chlorine in wash water: 0.5 ppm-minimum; 2.0 ppm-maximum. Water pH: 6.0-7.0	Chlorine test of incoming water with Cl test kit. Test water pH. Chlorine test of post-contact water with Cl test kit. Test water pH.	Every 30 min Every 30 min	Prep. room supervisor
Note: sanitation covered by SSOPs				2.2	Maintain product core temperature at 40°F or less	Measure celery core temperature with a calibrated thermometer. Use SOP 2.2	Every 15 min	Prep. room supervisor
Package in pouches	Growth of microbiol. pathogens if temp. excessive	3	Maintain core temperature at 40°F or less	3	Maintain core temperature at 40°F or less (range 32–40°F)	Measure celery core temperature with calibrated thermometer. Use SOP 3.0	Every 15 min	Packaging machine operator

Part 8.0
HACCP Plan Tabulation for Product or Process
Refrigerated Fresh Celery Sticks/Slices

CCP & CL #	Corrective Actions for Line if Limit Exceeded & Person(s) Responsible	Corrective Actions for Product Lot(s) if Limit Exceeded & Person(s) Responsible	HACCP Records, Where Located and Person(s) Responsible	Verification Procedure and Frequency	Persons Responsible for Verification
2.1	Stop the line. Correct Cl and/or pH of water as required. Test for correct level and start line.* Prep. Room Supplier & QA	Hold product from last inspection reading. QA to evaluate held product for action (rerun; destroy).* QA Mgr.	Daily records located in the designated area.* Person designated provides his/her initials on monitoring documents; and on corrective action documents. Supervisor reviews records at end of each shift for completeness and accuracy, and signs and dates records.	Compare records for compliance to HACCP plan. Use NACMCF92/97 company HACCP verification procedure. Audit every two weeks Conduct external HACCP verification audit on quarterly basis. Conduct microbiol. testing each week as environmental sanitation check.	HACCP teams (Internal HACCP verification) Corporate QA; HACCP team from another food plant; Consultant; etc.
2.2	Stop the line. Correct temperature problem and restart line* Prep. Room Supplies & QA	Hold product from last inspection reading. QA to evaluate held product for action (release, rerun, destroy)* QA Mgr.			
3	Stop the line. Correct temperature problem and restart line* Prep. Room Supplies & QA	Hold product from last inspection reading. QA to evaluate held product for action (release, rerun, destroy)* QA Mgr.			
NOTE: Prepare deviation report describing corrective action taken and product hold information. All deviations must be reviewed and handled by QA.					

CCP = Critical Control Point; CL = Critical Limit
* Daily records for CCP 2.1–2.2 are in Prep. Dept. Daily records for CCP 3 are in Packaging Dept.

Part 8.0
HACCP Plan Tabulation for Product or Process
Refrigerated Fresh Celery Sticks/Slices

Operational or Process Step	Hazard Type MCP?	CCP		Critical Limits		Monitoring		Person(s) Responsible
		#	Description	#	Description	What & How	Frequency	
Package in pouches – application of	Microbial hazard *Listeria*	4	Provide a refrigerated shelf-life code	4.1	Apply 14 day shelf-life date from pack date	Visually inspect code at start-up	Each shift	QC technician
				4.2	Code must be present on each pouch and also include product ID, plant, loc., etc.	Visually inspect code on pouches	Continuous	Pouch line operator & box packers
In-line electronic metal detector	Physical: Metal	5	Detect metal in celery pouches; kick out possible metal-containing pouches.	5.1	Reject pouches indicating metal ≥1/32″	Run pouches on on-line detector	Continuous	Pouch filler operator
				5.2	Calibrate electronic metal detector	Test blanks must be rejected	Each hour	QC technician
				5.3	Examine reject pouches/product for metal. Use information to correct upstream metal contamination problem (e.g., broken cutter blades). Place on QC hold.	Open pouch and screen mixture for metal fragments. Determine if fragments are magnetic	Each hour	QC technician

CCP = Critical Control Point

Part 8.0
HACCP Plan Tabulation for Product or Process
Refrigerated Fresh Celery Sticks/Slices

CCP & CL #	Corrective Actions for Line if Limit Exceeded & Person(s) Responsible	Corrective Actions for Product Lot(s) if Limit Exceeded & Person(s) Responsible	HACCP Records, Where Located and Person(s) Responsible	Verification Procedure and Frequency	Persons Responsible for Verification
4.1	Stop line. Correct the code and restart line. QA Technician.*	Place lot(s) on hold until they can be given the correct code. QA*	Daily records located in the Production Dept. Person designated provides his/her initials on monitoring documents and on correct. action documents. Supervisor reviews records at end of each shift for completeness and accuracy and signs and dates record.	Compare records for compliance to HACCP plan. Use NACMCF92/97 company HACCP verification procedure. Audit every 2 weeks. Conduct external HACCP verification audit on quarterly basis.	HACCP team (Internal HACCP verification) Corporate QA; HACCP team from another food plant; consultant; etc.
4.2	Stop line. Correct. Start line. Package Operator, QA Technician.*	As above. Apply code to packages. Package Superv.*			
5.1	Stop line if reject rate excessive. Correct/start. QA.*	Determine if wire, metal splinters, etc. could be in the pouches. Put all pouches on hold up to previous negative monitoring check. Held pouches to be examined for safety by QA to determine release or destruction of lot(s).			
5.2	Stop line. Calibrate detector. Start line. QA.*				
5.3	Stop line if metal found. Immediately call QA for help.*				

NOTE: Prepare deviation report describing corrective action taken and product hold information. All deviations must be reviewed and handled by QA.

CCP = Critical Control Point; CL = Critical Limit
* Daily records for CCP 2.1–2.2 are in Prep. Dept. Daily records for CCP 3 are in Packaging Dept.

Part 8.0
HACCP Plan Tabulation for Product or Process
Refrigerated Fresh Celery Sticks/Slices

Operational or Process Step	Hazard Type MCP?	CCP*		Critical Limits		Monitoring		Person(s) Responsible
		#	Description	#	Description	What & How	Frequency	
Refrigerated storage of pouched product	Growth of microb. pathogens if temp. or time excessive	6	Maintain core temperature at 40°F or less and ship well within shelf-life expiration	6	Maintain ref. temperature at 40°F or less, range: 32–40°F Do not ship if 10 days or less shelf-life	Examine strip chart on refer. temperature recorder. Visually inspect case code	Every hour Each intended shipment	Warehouse supervisor Warehouse dispatcher
Refrigerated truck distribution (Note: Sanitation of truck compartment covered by SSOPs)	Growth of microb. pathogens	7	Maintain core temperature at 40°F or less	7	Compressor must be operational and compartment air temperature must be reduced to 40°F or less before loading.	Examine temp. gauge with compressor on (doors closed; 10 minute cooling)	Before loading	Warehouse loader

Part 8.0
HACCP Plan Tabulation for Product or Process
Refrigerated Fresh Celery Sticks/Slices

CCP & CL #	Corrective Actions for Line if Limit Exceeded & Person(s) Responsible	Corrective Actions for Product Lot(s) if Limit Exceeded & Person(s) Responsible	HACCP Records, Where Located and Person(s) Responsible	Verification Procedure and Frequency	Persons Responsible for Verification
6	Immediately contact QA manager and the maintenance supervisor. Lower temp. ASAP. Repair if necessary. Develop plan. QA superv. Do not ship product that has 10 days or less shelf-life. Prepare deviation report.	Hold lot(s) up to previous in-spec. monitoring check. QA to determine if product safe and its disposition. Handle as above Prepare deviation report.	Daily records located in the designated areas* Person designated provides his/her initials on monitoring documents and on corrective action documents. Supervisor reviews records at end of each shift for completeness and accuracy and signs and dates records.	Compare records for compliance to HACCP plan. Use NACMCP92/97 company HACCP verification procedure. Audit every two weeks. Conduct external HACCP verification audit on quarterly basis.	HACCP team (Internal HACCP verification) Corporate QA: HACCP team from another food plant; consultant; etc.
6	Do not load truck. Determine if trailer compressor will cool ref. temp. to 40ºF. If not, use another truck/trailer that will cool and operate properly. Prepare deviation report. Warehouse loader & supervisor.	Should not load. If loading had taken place, test product core temperature which should be 40ºF or less. If above 40ºF, place on QA hold and immediately return it to plant QC. Immediately advise QA and prepare deviation report. Warehouse supervisor.			
NOTE: Prepare deviation report describing corrective action taken and product hold information. All deviations must be reviewed and handled by QA.					

CCP = Critical Control Point
CL = Critical Limit
* Daily records are maintained in the corresponding manufacturing area or department.

THE SCOPE OF HACCP

Obviously, the scope of HACCP programs based on the particular hazard involved can be expanded or limited at the discretion of food plant or quality systems management. Generally, HACCP programs are restricted to food safety, but include physical, chemical, and biological hazards and it is in this vein that the HACCP approach, historically, has proven to be most useful. Many aspects of food safety management, however, can be included. An example might be foreign and extraneous materials such as insect fragments or pieces of metal or glass. In other cases, some plans include economic factors, such as control of ingredient weights, as an effort of the manufacturer to closely control the addition of expensive ingredients, or to control the quality of the product.

Many experts believe that, despite the attempts of many to broaden the application of HACCP concepts, this type of predictive QA should be restricted to safety issues, which would include physical, chemical, and microbiological hazards. Many prefer to establish an HACCP program for microbiological safety issues and add a nonmicrobiological HACCP program at a later time, using the former as a guide. In reality, it would be valuable for such programs to be maintained as separate documents if more than one aspect is to be covered by the general plant program. This facilitates presentation to regulatory personnel who may request them, and makes these documents more useful throughout the plant. In any event, the plant sanitarian is likely to be exposed to all HACCP programs and should be familiar with their development, application, and significance.

HACCP programs should be reserved exclusively for safety issues. These need not necessarily be microbiological safety, but should encompass issues that may result in a hazard to the consumer. Manufacturing plants already have QC programs that deal with the other quality issues, and they were implemented years ago; however, it is important to understand that they are not, nor should they be, part of a true HACCP program.

REGULATORY ASPECTS OF HACCP

In some respects, it is surprising that U.S. regulatory agencies have not incorporated HACCP requirements to a greater extent in their inspection programs. Former practice has been to inspect a food product facility unannounced and at some frequency determined by the agency involved. The evaluation obtained was based on the assumption that the operational condition of the plant at the time of the inspection was typical of operations throughout the remainder of the year. Areas visited and examined often varied greatly, depending on which inspector was doing the inspecting

and the particular emphasis that this inspector might have on specific areas or conditions. With a system control approach such as HACCP, the regulatory inspector may never need to set foot inside the process area. If direct observations are necessary, they can be concentrated at specific CCPs in the process that must be operative in order to assure the ultimate safety of the product. Time is saved and a better, more realistic inspection results. The FDA has been using HACCP as an inspectional and regulatory tool for low-acid canned food plants since 1973. This alternative to observation-based inspections has proven to be a highly useful and efficient means of inspection control.[25]

SANITATION AND THE HACCP CONCEPT

Sanitation procedures may become integral elements of operating CCP programs throughout the food plant. To an important degree these procedures may be the tools that are used to establish CCPs, as well as the means by which critical points in the process are controlled. For example, a wet conveyor belt may be shown to be a source of food-borne pathogenic bacteria within a process. However, careful cleaning and sanitation will exert control over this potential source of hazard and thus can become a CCP.

CONCLUSIONS

- HACCP is a simple system to follow. It concentrates on critical hazards helping to prevent foodborne illness.
- Manufacturing plant management should conduct an in-depth audit of the entire HACCP system at least once a year and whenever there are new products, new manufacturing lines, or new processes. Each of these requires a new HACCP program.
- Customers may add potential safety problems, depending on how they handle and store the food they buy, particularly at ready-to-eat locations. This could be considered a last CCP to deal with.

In such circumstances, a control to minimize possible contamination is to provide the consumers with visible instructions and informative labels on how to handle and serve the food. This may lower the probability of safety problems.

REFERENCES

1. Food and Drug Administration (FDA), 1992. Thermally processed low-acid foods packaged in hermetically sealed containers. Title 21, Code of Federal Regulations, part 113. U.S. Government Printing Office, Washington, D.C. http://vm.cfsan.fda.gov/~lrd/cfr113.html. Accessed March 30, 2003.
2. Food and Drug Administration (FDA), 1992. Acidified foods. Title 21, Code of Federal Regulations, part 114. U.S. Government Printing Office, Washington, D.C. http://vm.cfsan.fda.gov/~lrd/cfr114.html. Accessed March 30, 2003.
3. Stevenson, K.E. and Bernard, D.T. (Eds.). 1999. *HACCP. A Systematic Approach to Food Safety*, 3rd. ed. National Food Processors Association, Washington, D.C.
4. Food and Drug Administration (FDA), 1973. Thermally processed low acid foods packaged in hermetically sealed containers. Part 128B. Federal Register 38(16):2398–2410.
5. FDA/CFSAN, 2002. Grade "A" Pasteurized Milk Ordinance. 2001 Revision. May 15, 2002. http://vm.cfsan.fda.gov/~ear/pmo01toc.html. Accessed March 30, 2003.
6. National Academy of Sciences, Institute of Medicine, 1985. An evaluation of the role of microbiological criteria for foods and food ingredients. Subcommittee on Microbiological Criteria, Committee on Food Protection, National Research Council. National Academy Press, Washington, D.C.
7. FAO/WHO, Codex Alimentarius Commission, 1993. Codex Committee on Food Hygiene. Guidelines for the application of Hazard Analysis Critical Control Point (HACCP) System. (Alinorm 93/13A, Appendix B), Food and Agriculture Organization/World Health Organization, Rome, 1993. http://www.who.int/fsf/Codex/HACCP.htm
8. Ohio State University Extension Bulletin 901, 2002. Ensuring Safe Food. A HACCP-Based Plan for Ensuring Food Safety in Retail Establishments. Appendix 5. HACCP Origins. Ohio State University Extension, Columbus, OH. http://ohioline.osu.edu/b901/appendix_5.html
9. Bauman, H.E., 1987. The hazard analyses critical control point concept, in *Food Protection Technology,* C.W. Felix, Ed., Lewis Publ., Chelsea, MI, pp. 175–179.
10. Pillsbury Company, 1973. Food Safety through the Hazard Analysis Critical Control Point System. Contract No. FDA 72-59. Research and Development Dept. The Pillsbury Co., Minneapolis, MN.
11. Department of Health, Education and Welfare (DHEW), 1971. Proceedings of the 1971 National Conference on Food Protection, U.S. Department of Health, Education and Welfare, Public Health Service, Washington, D.C.
12. ASQ Food, Drug and Cosmetic Division, 2002. *The Quality Auditor's HACCP Handbook*, ASQ Quality Press, Milwaukee, WI.
13. Corlett, D., 1998. *HACCP User's Manual*, Aspen Publishers, Inc., Gaithersburg, MD.
14. National Academy of Sciences, 1985. *An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients*, National Academy Press, Washington, D.C.
15. Pierson, M.D. and Corlett, D.A., Jr., 1992. *HACCP Principles and Applications*, Van Nostrand Reinhold, New York.
16. Mortimore, S. and Wallace, C., 1998. *HACCP A Practical Approach*, Aspen Publ., Gaithersburg, MD.

17. Riswadkar, A.V., 2000. An introduction to HACCP: the hazard analysis and critical control point system for food processors, *Prof. Safety*, June, 33–36.
18. National Advisory Committee on Microbiological Criteria for Foods (NACMCF), 1992. Hazard analysis and critical control point system, *Intern. J. Food Microbiol.*, 16, 1–23.
19. HHS/FDA, 1997. FDA/Seafood Industry Food Safety Initiative Goes into Full Effect. HHS News. http://www.fda.gov/bbs/topics/NEWS/NEW00608.html. Accessed March 26, 2003.
20. Food Safety and Inspection Service, United States Department of Agriculture (FSIS/USDA), 2002. Pathogen Reduction/HACCP & HACCP Implementation. December 30, 2002. http://www.fsis.usda.gov/OA/haccp/imphaccp.htm. Accessed March 3, 2003.
21. HHS/FDA, 1998. FDA Proposes New Rules to Increase Safety of Fruit and Vegetable Juices. April 21, 1998. http://www.cfsan.fda.gov/~lrd/hhsjuic2.html. Accessed March 15, 2003.
22. HHS/FDA, 2001. FDA Publishes Final Rule to Increase Safety of Fruit and Vegetable Juices. January 19, 2001. http://www.cfsan.fda.gov/~lrd/hhsjuic4.html. Accessed March 15, 2003.
23. FAO/WHO, 1998. Guidance on regulatory assessment of HACCP. Report of a Joint FAO/WHO Consultation on the Role of Government Agencies in Assessing HACCP (WHO/FSF/FOS/98.5). http://www.who.int/fsf/REP983A.html
24. Surak, J.G. and McAnelly, J.K., 1992. Educational programs in quality for the food processing industry, *Food Technol.*, 46(6):80–90.
25. Tisler, J.M., 1991. The Food and Drug Administration perspective on HACCP, *Food Technol.*, 46(6):125–126.
26. World Health Organization (WHO), 1989. Health surveillance and management procedures for food-handling personnel. Tech. Rept. Series 785. World Health Organization, Geneva, Switzerland.
27. Sperber, W.H., 1991. The modern HACCP system, *Food Technol.*, 45(6):116–118, 120.
28. U.S. National Advisory Committee on Microbiological Criteria for Foods (NACMCF), 1998. Hazard Analysis and Critical Control Point Principles and Application Guidelines. Adopted August 14, 1997.
29. Stevenson, K.E. and Bernard, D.T., 1995. *HACCP. Establishing Hazard Analysis Critical Control Programs. A Workshop Manual*, 2nd. ed., The Food Processors Institute (FPI), Washington, D.C.
30. FAO, 1998. Food Quality and Safety Systems. A Training Manual on Food Hygiene and the Hazard Analysis and Critical Control Point (HACCP) System. Food Quality and Standards Service. Food and Nutrition Division, Food and Agriculture Organization of the United Nations. Publishing Management Group, FAO Division, Rome, Italy.
31. FDA/CFSAN, 2003. *Foodborne Pathogenic Microorganisms and Natural Toxins Handbook* (The "Bad Bug Book"). http://vm.cfsan.fda.gov/~mow/intro.html. Accessed March 23, 2003.
32. Riswadkar, A.V, 2000. Risk assessment and HACCP: begin at the beginning, Quality Corner, *Food Quality*, January/February, 3.
33. International Commission on the Microbiological Specifications for Foods (ICMSF), 1988. *HACCP in Microbiological Safety and Quality*, Blackwell Scientific, London.

34. National Academy of Sciences (NAS), 1985. *An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients*, National Academy Press, Washington, D.C.
35. National Advisory Committee on Microbiological Criteria for Foods (NACMCF), 1994. The role of regulatory agencies and industry in HACCP, *Int. J. Food Microbiol.*, 21:187–195.
36. U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS), 1999. Guidebook for the Preparation of HACCP Plans and the Generic HACCP Models. Office of Policy, Program Development, and Evaluation (OPPDE) Inspection Systems Development Division, Washington, D.C.

GLOSSARY OF TERMS

Acceptable Quality Level (AQL) In a continuing series of lots, a quality level that for the purpose of sampling inspection is the limit of satisfactory process average.

Acceptance Number The maximum number of defects or defectives allowable in a sampling lot for the lot to be acceptable.

Acceptance Sampling Inspection of a sample from a lot to decide whether to accept that lot.

Acceptance Sampling Plan A specific plan that indicates the sampling sizes and associated acceptance or nonacceptance criteria to be used.

Accreditation Certification by a duly recognized organization of the capability, objectivity, competence, and integrity of an agency, service, operational group, or individual to provide the specific service or operation needed.

Accuracy The characteristic of a measurement that tells how close an observed value is to a true value. It has no numerical value.

Acid Food A food that has a natural pH of 4.6 or below.

Acidified Food A low-acid food to which acid(s) or acid food(s) are added and which has a finished equilibrium pH of 4.6 or below and a water activity (a_w) greater than 0.85.

Action Plan A specific method or process designed to achieve the desired results. May be a simpler version of a project plan.

Additives Materials added intentionally to foods during manufacturing to aid processing or to give specific properties to the finished food product.

Adulteration Condition in which a product is unfit to be sold as a result of contamination, mix-ups, or errors, or has been manufactured under conditions that were not under proper control.

Affinity Diagram A tool used to organize ideas, usually generated through brainstorming, into groups of related thoughts, with emphasis is on a gut-felt sort of grouping, often done by the members of the group with little or no talking.

American Society for Quality (ASQ) A professional, not-for-profit association that develops, promotes, and supplies quality-related information and technology for the private sector, government, and academia.

Analysis of Variance (ANOVA) A basic statistical technique for analyzing experimental data.

Analyte The substance to be measured.

Analytical Data from laboratory analysis of one or more food samples.

Analytical Error Difference between the estimated value of a quantity and its true value. This difference (positive or negative) may be expressed either in the units in which the quantity is measured or as a percentage of the true value.

Arrow Diagram A planning tool to diagram a sequence of events or activities (nodes) and the interconnectivity of such nodes.

Assessment A systematic process of collecting and analyzing data to determine the current, historical, or projected status of an organization.

Attributes Data Data counted in discrete units such as dollars, hours, items, and yes/no options. The alternative to attributes data is variables data, which are data measured on a continuous and infinite scale such as temperature or distance.

Audit A systematic and functionally independent periodic inspection of a process or quality system to ensure compliance to requirements.

Auditor A person who is qualified to carry out a quality audit.

Availability The ability of a product to be in a state to perform its intended function at a given time and under appropriate conditions.

Average Chart (X-Bar Chart) A control chart in which the average of the subgroup, represented by the X-bar, is used to determine the stability or lack thereof in the process. Average charts are usually paired with range charts or sample standard deviation charts for complete analysis.

Average Outgoing Quality (AOQ) The expected average quality level of outgoing product for a given value of incoming product quality.

Average Outgoing Quality Limit (AOQL) The maximum average outgoing quality over all possible levels of incoming quality for a given acceptance sampling plan and disposal specification.

Background Variable Blocking or noise variable; a variable that might affect a response variable in the experiment but is not of interest as a controllable variable.

Bar Chart A chart that compares different groups of data to each other through the use of bars that represent each group.

Benchmarking A technique that involves comparing one's own processes to excellent examples of similar processes in other organizations or departments. Through benchmarking, rapid learning can occur, and processes can undergo dramatic improvements.

Bias A systematic difference between an observed value and some measure of the truth. Generally used to describe the inaccuracy of a method relative to a comparative method.

Block Groups of experimental units treated similarly during a designed experiment.

Block Diagram A diagram that shows the operation, interrelationships, and interdependencies of components in a system. Boxes, or blocks (hence the name), represent the components; connecting lines between the blocks represent interfaces.

Brainstorming An idea-generating technique used to encourage creative thinking and new ideas. A group formulates and records as many ideas as possible concerning a certain subject, regardless of the content. The ideas are not discussed or reviewed until after the brainstorming session.

Brand Any name, sign, symbol, or design used to identify the products of one firm and set them apart from competitors' offerings.

Breakthrough Thinking A management technique that emphasizes the development of new, radical approaches to traditional constraints, as opposed to incremental or minor changes in thought that build on the original approach.

Calibration Adjusting a measuring instrument to make it accurate. The process of periodically checking and adjusting measuring devices and instruments to ensure specified accuracy and precision that are traceable to national or international standards.

Cause An identified reason for the presence of a defect or problem.

Cause-and-Effect Diagram A tool for analyzing process dispersion. It is also referred to as the "Ishikawa diagram" and the "fishbone diagram," because the complete diagram resembles a fish skeleton. The diagram illustrates the main causes and subcauses leading to an effect (symptom).

CCP Decision Tree A sequence of questions to assist in determining whether a control point is a CCP.

Center for Food Safety and Applied Nutrition (CFSAN) Branch of the FDA that makes policy decisions concerning food and cosmetics.

Centerline A line on a graph that represents the overall average (mean) operating level of the process.

Central Tendency The tendency of data gathered from a process to cluster toward a middle value somewhere between the high and low values of measurement.

Certificate of Analysis Documentation from a supplier guaranteeing the content and quality of raw materials or components.

Certification The procedure by which official certification bodies or officially recognized certification bodies provide written or equivalent assurance that foods or food control systems conform to requirements.

Certified Quality Auditor (CQA) An ASQ certification.

Characteristic The factors, elements, or measures that define and differentiate a process, function, product, service, or other entity.

Chart A tool for organizing, summarizing, and depicting data in graphic form.

Check Sheet A customized form used to record data. Usually, it is used to record how often some activity occurs.

Checklist A tool used to ensure all important steps or actions in an operation have been taken. Checklists contain items important or relevant to an issue or situation. Checklists are not to be confused with check sheets.

Clean Free from dirt or impurities, freshly washed.

Cleanliness The practice or principles of freedom from dirt or pollution.

Code of Federal Regulations (CFR) Government publication that contains all regulations. FDA regulations can all be found in 21 CFR.

Coefficient of Variation (CV) The relative standard deviation, i.e., the standard deviation expressed as a percentage of the mean [CV = 100(s/x)].

Common Causes Causes of variations that are inherent in a process over time. They are typical of the process, not unexpected. They affect every outcome of the process and everyone working in the process.

Company Culture A system of values, beliefs, and behaviors inherent in a company. To optimize business performance, top management must define and create the necessary culture.

Compliance The state of an organization that meets prescribed specifications, contract terms, regulations, or standards.

Concession Use of known bad materials or sale of known bad product, or a rebate given in return for accepting bad product.

Conformance An affirmative indication or judgment that a product or service has met the requirements of a relevant specification, contract, or regulation.

Consensus Acceptance and support of a team decision by everyone on that team.

Consultant An individual who has experience and expertise in applying tools and techniques to resolve process problems and who can advise and facilitate an organization's improvement efforts.

Consumer The external customer to whom a product or service is ultimately delivered; also called end user.

Contamination The presence of any substance in a food product that makes it impure, unclean, or unfit for use. This agent is capable of causing an adverse reaction in a person ingesting the food product.

Continuous Flow Production When items are produced and moved from one processing step to the next one piece at a time without any time lost due to waiting, as in a traditional batch-and-move production system. Continuous flow production results in better quality because defects are observed immediately.

Continuous Improvement Ongoing improvement of any and all aspects of an organization including products, services, communications, environment, functions, individual processes, etc.

Control (1) To manage the conditions of an operation to maintain compliance with established criteria. (2) The state where correct procedures are being followed and criteria are being met.

Control Chart A chart that indicates upper and lower statistical control limits, and an average line for samples or subgroups of a given process. If all points on the control chart are within the limits, variation may be ascribed to common causes and the process is deemed to be "in control." If points fall outside the limits, it is an indication that special causes of variation are occurring, and the process is said to be "out of control."

Control Limits The statistically determined boundaries of a process within specified confidence levels, expressed as the upper control limit (UCL) and the lower control limit (LCL). They are used to analyze variation within a process. If variation exceeds the control limits, then the process is being affected by special causes and is said to be "out of control."

Control Measure Any action or activity that can be used to prevent, eliminate, or reduce a significant hazard.

Control Point (CP) A point, step, or procedure that controls food safety hazards, including those of biological, physical, and chemical natures. Generally, a receiving or storage point.

Control Procedure, QC Procedure The protocol and materials that are necessary for an analyst to assess whether the method is working properly and test results can be reported.

Corrective Action The implementation of solutions resulting in the reduction or elimination forever of a specific cause of an identified nonconformance.

Correlation (Statistical) A measure of the relationship between two data sets of variables.

Cost of Quality (COQ) A term coined by Philip Crosby referring to the costs incurred by producing products or services of poor quality. Usually includes the cost of inspection, rework, duplicate work, scrapping rejects, replacements and refunds, complaints, and loss of customers and reputation.

Count Chart (c-Chart) An attributes data control chart that evaluates process stability by charting the counts of occurrences of a given event in successive samples.

Criterion A requirement on which a judgment or decision can be based.

Critical Control Point (CCP) A point, step, or procedure in the product-handling process where controls can be applied and a food safety hazard can be prevented, eliminated, or reduced to safe levels.

Critical Factor Any property, characteristic, condition, aspect, or other parameter, variation of which may affect the scheduled process delivered and thus the commercial sterility of the product.

Critical Limit A maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard.

Critical Processes Processes that present serious potential dangers to human life, health, and the environment, or that risk the loss of very large sums of money or customers.

Cross-Contamination The transfer of biological, physical, or chemical hazards to food products by dirty sanitation rags, contact with other raw food products, contact with previously cooked food, contact with dirty contact surfaces, or contact with a worker's dirty hands.

Cultural Resistance A form of resistance based on opposition to the possible social and organizational consequences associated with change.

Culture Change A major shift in the attitudes, norms, sentiments, beliefs, values, or operating principles and behavior of an organization.

Culture, Organizational A common set of values, beliefs, attitudes, perceptions, and accepted behaviors shared by individuals within an organization.

Cumulative Control Limits Control limits calculated from estimates of the mean and standard deviation that represent a time period longer than a month. Common practice is for laboratories to calculate monthly control statistics.

Cumulative Sum Chart Control chart that shows the cumulative sum of deviations from a set value in successive samples. Each plotted point indicates the algebraic sum of the last point and all deviations since.

Customer Any recipient of a product or service; anyone who is affected by what one produces. A customer can be external or internal to the organization.

Customer Relationship Management (CRM) A strategy used to learn more about customers' needs and behaviors to develop stronger relationships with them.

Customer Supplier Partnership A long-term relationship between a buyer and a supplier characterized by teamwork and mutual confidence. The supplier is considered an extension of the buyer's organization.

Data A set of collected facts. There are two basic kinds of numerical data: measured or variable data, such as 16 oz, 4 mi, and 0.75 in., and counted or attribute data, such as 162 defects.

Decision Matrix A planning model used by teams to evaluate problems or possible solutions.

Defect A product's or service's nonfulfillment of an intended requirement or reasonable expectation for use, including safety considerations.

Defect Free A personal performance standard that says specifications should be met every time. An attitude that displays personal commitment to doing the job right the first time, every time.

Defective A unit of product that contains one or more defects with respect to the quality characteristic(s) under consideration.

Detergent A cleansing substance, especially a synthetic liquid that dissolves dirt and oil.

Deviation In numerical datasets, the difference or distance of an individual observation or data value from the center point (often the mean) of the set distribution. Failure to meet a critical limit.

Diagnosis The process of investigating symptoms, collecting and analyzing data, and conducting experiments to determine the cause(s) of quality deficiencies.

Disinfect To clean something so as to destroy disease-carrying microorganisms and prevent infection.

Disinfectant A chemical that destroys or inhibits the growth of microorganisms that cause disease.

Distribution (statistical) The spread and shape of a frequency curve of some variable. A histogram is one way to graphically display the distribution of test results by showing the frequency of observations on the y-axis vs. the magnitude on the *x*-axis.

Drained Weight Weight of the solid portion of the product after it has been processed and after draining the covering liquid for a specified time with the appropriate sieve.

Driving Forces Forces that tend to change a situation in desirable ways.

Effect What results after an action has been taken; the expected or predicted impact when an action is to be taken or is proposed.

Efficiency A term describing a process that operates effectively while consuming the minimum amount of resources, such as labor and time. The ratio of the output to the total input in a process.

Eighty-twenty (80:20) A term referring to the Pareto principle, which was first defined by J.M. Juran in 1950. The principle suggests most effects come from relatively few causes; i.e., 80% of the effects come from 20% of the possible causes.

Employee Involvement Regular participation of employees in decision making and suggesting how their work areas operate, including making suggestions for improvement, planning, goal setting, and monitoring performance.

Empowerment Usually refers to giving employees decision-making and problem-solving authority within their jobs. A condition whereby

employees have the authority to make decisions and take action in their work areas without prior approval.

Equilibrium pH The pH of the product in its container.

Ethics The practice of applying a code of conduct based on moral principles to day-to-day actions to balance what is fair to individuals or organizations and what is right for society.

Expectations Customer perceptions about how an organization's products and services will meet their specific needs and requirements.

Experimental Design A formal plan that details the specifics for conducting an experiment, such as which responses, factors, levels, blocks, treatments, and tools are to be used.

External Customer A person or organization that receives a product, service, or information but is not part of the organization supplying it.

Facilitator A specifically trained person who functions as a teacher, coach, and moderator for a group, team, or organization.

Failure The inability of an item, product, or service to perform required functions on demand due to one or more defects.

Failure Cost The cost resulting from the occurrence of defects.

Failure Mode Analysis (FMA) A procedure to determine which malfunction symptoms appear immediately before or after a failure of a critical parameter in a system.

FDA An acronym for the Food and Drug Administration, U.S. Department of Health and Human Services, which regulates the safety, purity, and effectiveness of food, drugs, medical devices, biologics, and cosmetics.

FDA Form 482 FDA-written notice of inspection presented by the investigator at the beginning of an inspection.

FDA Form 483 A summary report of inspectional observations. It lists objectionable conditions or practices observed during the inspection. It is prepared by the FDA investigator and presented to the auditee at the conclusion of an inspection.

Federal Food, Drug and Cosmetic Act (FD&C Act) This law gives the FDA the authority to ensure that all products it regulates are safe, pure, and effective.

Fermented Food A food preserved by the growth of acid-producing microorganisms in the food which lowers the pH to 4.6 or less.

Fill Weight The weight of the product particulates before processing. It does not include the weight of the container or covering liquid.

Fishbone Diagram Also known as a Cause-and-Effect Analysis Diagram, used by a problem-solving team during brainstorming to logically list and display known and potential causes to a problem.

Fitness for Use A term used to indicate that a product or service fits the customer's defined purpose for that product or service.

Flowchart A graphical representation of the steps in a process.

Focus Group A group, usually of 8 to 10 persons, invited to discuss an existing or planned product, service, or process.

Foodborne Illness Illness carried to humans through consumption of food, food products, or water that carry biological, chemical, or physical hazards.

Foodborne Infection Infection caused by ingestion of large amounts of bacteria that have been allowed to multiply in a food product that has been mishandled or temperature abused.

Foodborne Intoxication Illness caused by ingestion of toxins produced by bacteria as a naturally occurring by-product of their metabolic processes. These toxins can be in the bacteria and are released into the human system through the digestion process or they can be excreted directly into the food.

Food Contamination Any foreign material that is absorbed by the food during production, processing, distribution, and food handling in the home.

Formulation The estimated proportion by weight of ingredients in a multi-ingredient commercial food item when other characteristics of the food item are known or can be set.

Frequency Distribution An organization of data, usually in a chart, which depicts how often a different event occurs. A histogram is one common type of frequency distribution.

FSIS Food Safety and Inspection Service, USDA.

Gantt Chart A bar chart that depicts planned work progress and finished work in relation to time. Each task in a list has a bar corresponding to it. The length of the bar is used to indicate the expected or actual duration of the task.

Gaussian Curve, Gaussian Distribution Normal curve, Normal distribution. Refers to a symmetrical bell-shaped distribution whose shape is given by a specific equation (called the normal equation) in which the mean and standard deviation are variables.

Generally Recognized As Safe (GRAS) When using food ingredients considered GRAS, manufacturers need not prove to the FDA that they are safe.

Goal A broad statement describing a desired future condition or achievement without being specific about how much and when.

Go/no-go State of a unit or product. Two parameters are possible: go (conforms to specifications) and no-go (does not conform to specifications).

Good Manufacturing Practice (GMP) Also know as cGMP, meaning "current" Good Manufacturing Practice, is a set of regulations requiring that quality, safety, and effectiveness be built into foods, drugs, medical devices, and biological products. Its goal is consumer protection, and

manufacturers must comply with them as they carry the force of the law.

Grading The sorting of unlike lots of the same product into uniform categories, according to quality standards.

Group Dynamics The interaction (behavior) of individuals within a team meeting.

HACCP A systematic approach to the identification, evaluation, and control of food safety hazards.

HACCP Program The written document which is based upon the principles of HACCP and which delineates the procedures to be followed.

HACCP System The result of the implementation of the HACCP program.

HACCP Team The group of people who are responsible for developing, implementing, and maintaining the HACCP system.

Hazard A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

Hazard Analysis The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP program.

Hazard Analysis Critical Point Control (HACCP) A quality management system based on assessment of food hazards and the use of written standards and monitoring procedures to effectively and efficiently eliminate, minimize, and control potential biological, chemical, and physical hazards from foods, ensuring farm to table food safety and quality in the U.S. HACCP regulations for various sectors are established by the USDA and the FDA.

Headspace, Gross The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (the top of the double seam of a can or the top edge of a glass jar).

Headspace, Net The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the inside surface of the lid.

Hermetically Sealed Container A container that is designed and intended to be secure against the entry of microorganisms and to maintain the commercial sterility of its contents after processing; for example, a tin, steel, or aluminum can; glass jar; bottle; or pouch.

HHS (Department of Health and Human Services) The head of this department is a member of the President's cabinet. The FDA is an agency of this department.

Histogram A graphic summary of variation in a set of data. The pictorial nature of the histogram lets people see patterns that are difficult to detect in a simple table of numbers.

Hygiene The science dealing with the preservation of health. Also called hygienics.

Inaccuracy Numerical difference between the mean of a set of replicate measurements and the true value. This difference (positive or negative) may be expressed in the units in which the quantity is measured, or as a percentage of the true value.

In-Control Process A process in which the statistical measure being evaluated is in a state of statistical control; in other words, the variations among the observed sampling results can be attributed to a constant system of chance causes.

Indicators Established measures used to determine how well an organization is meeting its customers' needs as well as other operational and financial performance expectations.

Indictment A formal accusation by a grand jury that sets forth charges against a defendant and states when the alleged crime occurred. An indictment is not a finding of guilt; guilt can only be determined by a judge or jury after a trial.

Injunction A civil action taken against an individual or company to stop production or distribution of a violative product.

Imputed Nutrient values developed when analytical values are unavailable. Nutrient values from another form of the same food or another species of the same genus are examples of imputed values.

Inputs Products or services others provide to a process.

Inspection Activities such as measuring, examining, testing, and gauging one or more characteristics of a product or service and comparing the results with specified requirements to determine whether conformity is achieved for each characteristic.

Inspection Cost The cost associated with inspecting a product to ensure it meets the internal or external customer's needs and requirements; an appraisal cost.

Inspection Lot A collection of similar units or a specific quantity of similar material offered for inspection and acceptance at one time.

Inspection, 100% Inspection of all the units in the lot or batch.

Inspection, Reduced Inspection in accordance with a sampling plan requiring smaller sample sizes than those used in normal inspection. Reduced inspection is used in some inspection systems as an economy measure when the level of submitted quality is sufficiently good and other stated conditions apply.

Inspection, Tightened Inspection in accordance with a sampling plan that has stricter acceptance criteria than those used in normal inspection. Tightened inspection is used in some inspection systems as a protective measure when the level of submitted quality is sufficiently poor.

Inspections Periodic audits of the workplace environment, including equipment, chemicals, building structure, documented procedures, records, and employee knowledge of job requirements and hazards.

Intermediate Customers Organizations or individuals who operate as distributors, brokers, or dealers between the supplier and the consumer/end user.

Internal Customer Someone within your organization, further downstream in a process, who receives the output of your work.

Internal Failure A product failure that occurs before the product is delivered to external customers.

Juran Trilogy Three managerial processes identified by J.M. Juran for use in managing for quality: quality planning, quality control, and quality improvement.

Label Data printed on a food label, as supplied by its manufacturer.

Leader An individual who is recognized by others as a person they will follow.

Leadership An essential part of a quality improvement effort.

Lot A defined quantity of product accumulated under conditions considered uniform for sampling purposes.

Lot Size (also referred to as N) The number of units in the lot.

Low-Acid Food Any food (other than alcoholic beverages) with a finished equilibrium pH greater than 4.6 and a water activity greater than 0.85, excluding tomatoes and tomato products having a finished equilibrium pH less than 4.7.

Lower Control Limit (LCL) Control limit for points below the central line in a control chart.

Manager An individual charged with the responsibility of overseeing resources and processes.

Manufacturing Audit An audit conducted for any activity that affects the final quality of goods or services. The audit is usually made of a specific activity against a specific document, such as manufacturing operating instructions, employee training manuals, certification of personnel for critical operations, and quality provisions in purchasing documents.

Matrix A planning tool for displaying the relationships among various data sets; or, the physical and chemical nature of the specimen, the substances present, and their concentrations.

Mean The arithmetic average of a set of values, determined by dividing the sum of the values by the number of values in the group. A measure of central tendency of the distribution of a set of replicate results. Often abbreviated by an x with a bar over it.

Median The middle of a group of measurement values when arranged in numerical order. If the group contains an even number of values, the median is the average of the two middle values.

Method Validation The process of testing a measurement procedure to assess its performance and to validate that performance as acceptable.

Mode The most frequently occurring value in a dataset.

Monitor To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.

Monitoring Tracking actual performance vs. planned performance.

n The number of units in a sample.

N The number of units in a population.

National Health and Nutrition Examination Survey (NHANES) Conducted by the National Center for Health Statistics, U.S. Department of Health and Human Services.

Nesting Containers that fit within one another when stacked.

Net Weight The weight of all the product in a container, including brine or sauce, but not including the weight of the container.

Noncompliance A deviation from the requirements of the standard.

Nonconformity The nonfulfillment of specified requirements.

Nondestructive Testing and Evaluation Testing and evaluation methods that do not damage or destroy the product being tested.

Normal Distribution (Statistical) The charting of a dataset in which most of the data points are concentrated around the average (mean), thus forming a bell-shaped curve.

np-Chart A control chart indicating the number of defective units in a given sample.

Nutritional Labeling Labels that provide consumers with information about products' nutritional content.

Nutritional Labeling and Education Act of 1990 (NLEA) Refers to food labeling regulations promulgated by the FDA.

Objective A specific statement of a desired short-term condition or achievement; includes measurable end results to be accomplished by specific teams or individuals within time limits.

Official Accreditation The procedure by which a government agency having jurisdiction formally recognizes the competence of an inspection or certification body to provide their services.

Open-Code Dating Food labels providing consumers with information on when food was processed and packaged, when it should be sold or withdrawn from the market, or when the product is no longer acceptable for sale.

Out-of-Control Process A process in which the statistical measure being evaluated is not in a state of statistical control.

Out of Spec A term that indicates a unit does not meet a given requirement.

Outputs Products, materials, services, or information provided to customers (internal or external) from a process.

Packing Medium The liquid or other medium in which the low-acid or acidified product is packed.

Pareto Chart A bar chart that orders data from the most frequent to the least frequent, allowing the analyst to determine the most important factor in a given situation or process.

Pareto Principle The idea that a few root problems are responsible for the large majority of consequences. It is defined as the idea that 80% of all effects are produced by only 20% of the possible causes.

Partnership/Alliance Both a strategy and a formal relationship between a supplier and a customer that engenders cooperation for the benefit of both parties.

Percent Chart (p-Chart) A control chart that determines the stability of a process by finding what percentage of total units in a sample are defective.

Performance Characteristics Those properties that describe how well a procedure performs.

Performance Standard The metric against which a complete action is compared.

Pest Management Practices aimed at controlling pests or vectors, e.g., insects or rodents, and ensuring the safe use of pesticides and herbicides.

Pie Chart A chart that compares groups of data to the whole dataset by showing each group as a slice of the entire pie. Particularly useful for investigating what percentage each group represents.

Population Total set of items from which a sample set is taken.

Precision The agreement between replicate measurements. It has no numerical value.

Prerequisite Programs Procedures, including Good Manufacturing Practices, that address operational conditions providing the foundation for the HACCP system.

Prevention Cost The cost incurred by actions taken to prevent a nonconformance from occurring.

Preventive Action Action taken to remove or improve a process to prevent potential future occurrences of a nonconformance.

Private Label A brand used exclusively by a wholesaler or retailer, and usually not widely advertised.

Probability, p The likelihood an event will occur, usually stated as a decimal fraction between 0 and 1, 0 meaning that the event will never occur and 1 meaning that the event will always occur.

Problem Solving The act of defining a problem; determining the cause of the problem; identifying, prioritizing, and selecting alternatives for a solution; and implementing a solution.

Procedural Manual A written description of what operations are to be performed to carry out a particular process.

Procedure The steps in a process and how these steps are to be performed for the process to fulfill customer's requirements.

Process A set of interrelated work activities characterized by a set of specific inputs and value-added tasks that make up a procedure for a set of specific outputs.

Process Authority The person or organization that scientifically establishes thermal processes for low-acid canned foods or processing requirements for acidified foods. The processes are based on scientifically obtained data relating to heat or acid resistance of public health and spoilage bacteria and/or upon data pertaining to heat penetration in canned foods, which allows the elimination or reduction of microorganisms of humn health significance to safe levels.

Process Capability A statistical measure of the inherent process variability for a given characteristic.

Process Control A system of measurements and actions within a process intended to ensure that the output of the process conforms with pertinent specifications.

Product Audit A detailed study of the products in a product mix to analyze their performance in quantitative and qualitative terms. The comparative study of the quality of a product brand against similar products from competitor brands.

Project Management The application of knowledge, skills, tools, and techniques to a broad range of activities to meet the requirements of the particular project.

Prosecution A criminal action taken against a company or individual charging violation of the law.

Quality A subjective term for which each person has his or her own definition. In technical usage, quality can have two meanings: (1) the characteristics of a product or service that bear on its ability to satisfy stated or implied needs; (2) a product or service free of deficiencies.

Quality Assurance All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.

Quality Audit An independent investigation and assessment of quality activities and results to determine whether or not the quality plan is effective and appropriate.

Quality Circles Quality improvement or self-improvement study groups composed of a small number of employees (10 or fewer) and their supervisor.

Quality Control The operational techniques and activities that are used to fulfill requirements for quality.

Quality Cost Analysis of costs involved in maintaining quality in the following areas: preventive costs, appraisal costs, and failure costs.

Quality Engineering The analysis of a manufacturing system at all stages to maximize the quality of the process itself and the products it produces.

Quality Improvement A systematic approach to the processes of work that looks to remove waste, loss, rework, frustration, etc. in order to make the processes more effective, efficient, and appropriate.

Quality Improvement Team A group of employees that take on a project to improve a given process or design a new process within an organization.

Quality Loss Function An algebraic function that illustrates the loss of quality that occurs when a characteristic deviates from its target value. It is expressed often in monetary terms.

Quality Management That aspect of the overall management function that determines and implements the quality policy.

Quality Management System (QMS) A formalized system that documents the structure, responsibilities, and procedures required to achieve effective quality management.

Quality Manual The top level document defining the quality system.

Quality Plan A document or set of documents that describes the standards, quality practices, resources, and processes relevant to a particular product, service, contract, or project.

Quality Policy An organization's general statement of its beliefs about quality, how quality will come about, and what is expected to result.

Quality Records Written records retained in accordance with the requirements.

Quality Score Chart A control chart for evaluating the stability of a process.

Quality System The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

Quality Trilogy A three-pronged approach to managing for quality. The three legs are quality planning (developing the products and processes required to meet customer needs), quality control (meeting product and process goals), and quality improvement (achieving unprecedented levels of performance).

Random Cause A cause of variation due to chance and not assignable to any factor.

Random Error (RE) An error that can be either positive or negative, the direction and exact magnitude of which cannot be predicted exactly. In contrast, systematic errors are always in one direction.

Random Sampling A commonly used sampling technique in which sample units are selected so that all combinations of n units under consideration have an equal chance of being selected as the sample.

Range (Statistical) The measure of dispersion in a dataset (the difference between the highest and lowest values).

Range Chart Control chart in which the range of the subgroup is used to track the instantaneous variation within a process. Range charts are usually paired with average charts for complete analysis.

Range Chart (R Chart) A control chart in which the subgroup range, R, is used to evaluate the stability of the variability within a process.

Recall Action taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or in some cases by FDA order under its legal authority.

Registration A certification made by an accredited registration agency declaring that the processes in an organization comply with the requirements.

Registration Agency An organization accredited by a registration board authorized to provide registration of client companies.

Registration Audit A comprehensive quality audit conducted by a registration agency for the purposes of establishing registration of an organization.

Regression Analysis A statistical technique for determining the best mathematical expression describing the functional relationship between one response and one or more independent variables.

Rejection Number The smallest number of defectives (or defects) in the sample or samples under consideration that will require the rejection of the lot.

Reliability The probability of a product or service successfully doing its job under given conditions.

Requirements The ability of an item to perform a required function under stated conditions for a stated period of time.

Responsibility Being obliged to answer, as for one's actions, to an authority that may impose a penalty for failure.

Rework Process undertaken when product does not conform to specifications but can be corrected so that the manufacturer will be able to sell it.

Right the First Time A term used to convey the concept that it is beneficial and more cost effective to take the necessary steps up front to ensure a product or service meets its requirements than to provide a product or service that will need rework or not meet customer needs.

Risk Analysis A process consisting of three components: risk assessment, risk management, and risk communication.

Risk Assessment A scientifically based process consisting of the following steps: (1) hazard identification; (2) hazard characterization; (3) exposure assessment; and (4) risk characterization. Risk assessment provides an evaluation of the likelihood and severity of adverse effects on public health arising, for example, from the presence in foodstuffs of additives, contaminants, residues, toxins, or disease-causing organisms.

Risk Management The process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.

Robust The ability of a product or service to function appropriately regardless of external conditions and other uncontrollable factors.

Robustness The condition of a product or process design that remains relatively stable with a minimum of variation even though factors that influence operations or usage, such as environment and wear, are constantly changing.

Root Cause A factor that caused a nonconformance and should be permanently eliminated through process improvement.

Run Chart A chart showing a line connecting numerous data points collected from a process running over a period of time.

Sample A subset of a population used to represent the population in statistical analysis. Samples are almost always random, which means that all individuals in the population are equally likely to be chosen for the sample.

Sample Size [n] The number of units in a sample.

Sampling, Double Sampling inspection in which the inspection of the first sample leads to a decision to accept a lot, reject it or take a second sample; the inspection of a second sample, when required, then leads to a decision to accept or to reject the lot.

Sampling, Multiple Sampling inspection in which, after each sample is inspected, the decision is made to accept a lot, reject it, or take another sample; but there is a prescribed maximum number of samples after which a decision to accept or reject the lot must be reached.

Sampling, Single Sampling inspection in which the decision to accept or to reject a lot is based on the inspection of a single sample.

Sampling, Unit Sequential sampling inspection in which, after each unit is inspected, the decision is made to accept a lot, reject it, or inspect another unit.

Sanitation A comprehensive term referring to the development and application of measures designed to protect public health.

Sanitize To clean something thoroughly by disinfecting or sterilizing it.

Scatter Diagram, Scatterplot A tool that studies the possible relationship between two variables expressed on the x-axis and y-axis of a graph. The direction and density of the points plotted will indicate various relationships or a lack of any relationship between the variables.

Scheduled Process The ordinarily used filed scheduled process for a given product under normal conditions.

Seizure An action to remove a violative product from the market by requesting a court to direct a U.S. Marshal to take possession of goods until a matter is resolved.

Seven Tools of Quality Tools that help organizations understand their processes to improve them. The tools are the cause-and-effect diagram, check sheet, control chart, flowchart, histogram, Pareto chart, and scatter diagram (see individual entries).

Severity The seriousness of the effect(s) of a hazard.

Special Causes Causes of variation in a process that are not inherent in the process itself but originate from circumstances that are out of the ordinary.

Specification Limit An engineering or design requirement that must be met in order to produce a satisfactory product.

Specifications The documents that prescribe the requirements with which the product or service has to conform.

Specimen Material available for analysis.

Standard The metric, specification, gauge, statement, category, segment, grouping, behavior, event, or physical product sample against which the outputs of a process are compared and declared acceptable or unacceptable.

Standard Deviation(s) Describes the dispersion or spread of a set of measurements about the mean value of a Gaussian or normal distribution. Calculated from the equation:

$$s = \sqrt{\left[n\Sigma x_i^2 - \left(\Sigma x_i\right)^2\right] \Big/ \left[n\left(n-1\right)\right]}$$

where n is the number of measurements, and x_i is an individual measurement.

Standard Operating Procedure (SOP) Documents required to exist and be followed under GMP regulations to ensure that all products are manufactured in a state of control.

Standardization The grouping of unlike items into uniform lots on the basis of qualitative criteria, such as a food grade.

Statistical Process Control (SPC) The application of statistical techniques to control a process.

Step A point, procedure, operation or stage in the food system from primary production to final consumption.

Sterilize To kill all living microorganisms in order to make something incapable of causing infection.

Supervisors Employees who have authority to direct the tasks of other employees and are, therefore, responsible for the job-related environments to which their workers are exposed.

Supplier Anyone whose output (materials, information, service, etc.) becomes an input to another person or group in a process of work. A supplier can be external or internal to the organization.

Supplier Quality Assurance Confidence a supplier's product or service will fulfill its customers' needs. This confidence is achieved by creating a relationship between the customer and supplier that ensures the product will be fit for use with minimal corrective action and inspection.

System A group of interdependent processes and people that together perform a common mission.

Systematic Error (SE) An error that is always in one direction and is predictable, in contrast to random errors that may be either positive or negative and whose direction cannot be predicted.

Tampering Action taken to compensate for variation within the control limits of a stable system. Tampering increases rather than decreases variation.

Task A specific, definable activity to perform an assigned piece of work, often finished within a certain time.

Team A group of individuals organized to work together to accomplish a specific objective.

Thermal Process The application of heat to food, either before or after sealing in a hermetically sealed container, for a period of time and at a temperature scientifically determined to achieve a condition of commercial sterility.

Tolerance The maximum and minimum limit values a product may have and still meet customer requirements.

Total Quality A strategic integrated system for achieving customer satisfaction that involves all managers and employees and uses quantitative methods to continuously improve an organization's processes.

Total Quality Control (TQC) A system that integrates quality development, maintenance, and improvement of the parts of an organization. It helps a company economically manufacture its product and deliver its services.

Total Quality Management (TQM) Managing for quality in all aspects of an organization focusing on employee participation and customer satisfaction. Often used as a catch-all phrase for implementing various quality control and improvement tools.

Traceability The ability to trace the history, application, or location of an item or activity and like items or activities by means of recorded identification.

Training Classroom instruction, job-site safety meetings, on-the-job training, and written materials provided to employees to make them aware of workplace hazards and how to prevent accidents and illnesses.

Tree Diagram A management tool that depicts the hierarchy of tasks and subtasks needed to complete an objective. The finished diagram bears a resemblance to a tree.

Trend The graphical representation of a variable's tendency, over time, to increase, decrease or remain unchanged.

***t*-Test** Assesses whether the means of two groups are statistically different from each other. This analysis is used to compare the means of two groups.

Type I Error Rejecting something that is acceptable. Also known as an alpha error.

Type II Error An incorrect decision to accept something when it is unacceptable. Also known as a beta error.

u-Chart A control chart showing the count of defects per unit in a series of random samples.

Unit An object on which a measurement or observation can be made.

Universal Product Code (UPC) A unique product identification number found on most product labels, represented by bar and number codes.

Upper Control Limit (UCL) Control limit for points above the central line in a control chart.

USDA U.S. Department of Agriculture

USDHHS U.S. Department of Health and Human Services

Validation That element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP program, when properly implemented, will effectively control the hazards.

Value Added The parts of a process that add worth from the perspective of the external customer.

Variable A quantity of interest whose value or magnitude fluctuates or changes.

Variable Data Data that is measured on a continuous and infinite scale such as temperature, distance, and pressure rather than in discreet units or yes/no options. Variables data are used to create histograms, some control charts, and sometimes run charts. Control charts based on variable data include average (X-bar) chart, range (R) chart, and sample standard deviation (s) chart.

Variance A measure of deviation from the mean in a sample or population.

Variation A change in data, characteristic, or function caused by one of four factors: special causes, common causes, tampering, or structural variation (see individual entries).

Verification Reviewing, inspecting, testing, checking, auditing, or otherwise establishing and documenting whether items, processes, or services, or documents conform to specified requirements.

Vision Often incorporated into an organizational mission (or vision) statement to clarify what the organization hopes to be doing at some point in the future.

Warning Letter An informal written advisory to a firm, communicating FDA's position on a matter but not committing the agency to take enforcement action.

Waste Any activity that consumes resources and produces no added value to the product or service a customer receives.

Water Activity (a_w) A measure of the free moisture in a product. It is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

Water Activity Controlled Products Low-acid canned foods that rely on control of water activity, in conjunction with a thermal process, to prevent the growth of microorganisms of public health significance as well as microorganisms of nonhealth significance.

Work Instructions A written description of how to carry out the operations of a particular process.

Work Team A team comprising members from one work unit.

Zero Defects A performance standard and methodology developed by Philip B. Crosby that states if people commit themselves to watching details and avoiding errors, they can move closer to the goal of zero.

z-Score, z-Value A calculated number that tells how many standard deviations a control result is from its mean value.

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