John E. Stauffer

QUALITY ASSURANCE OF FOOD

Ingredients, Processing and Distribution

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by

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DEDICATION

In Memory

of

HANS STAUFFER

whose genius, drive and vision

shall always be an inspiration

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PREFACE

No food processing organization can function successfully without quality assurance. It is the essential discipline needed to guarantee a safe, wholesome, and functional product. From the first conception of a new product, quality assurance must be made an integral part of ingredient testing, processing, and distribution. The customer must be satisfied that every precaution has been taken to assure product excellence.

From the outset, a distinction needs to be drawn between Quality Assurance and Quality Control. Unfortunately, because these two terms have been used interchangeably the difference between them has become blurred. Quality Assurance can be defined as a strategic management function which establishes policies related to quality, adopts programs to meet the established goals, and provides confidence that these measures are being effectively applied. Quality Control is a tactical function which carries out those programs identified by Quality Assurance to be necessary for the attainment of the quality goals.

The aim of this book is to describe the scope, applications, and benefits of quality assurance. For the sake of clarity, the subject is divided into four parts: Product Planning, Manufacturing, Customer Service, and Distribution. Within each section, selected topics of vital importance to quality assurance are discussed; these chapters include Good Manufacturing Practice, Hazard Analysis and Critical Control Points, Kosher Certification, Packaging, Labeling, and Product Recall. The practices outlined in this book have been tried and proven in industry, and they represent the best tools available for achieving the highest standards.

When properly conceived and executed, quality assurance is a strong asset to an enterprise. Rather than throwing up roadblocks in the way of progress, this discipline is designed to help a manufacturer expedite the production of quality products. By specifying those procedures which must be routinely followed, an effective quality assurance program helps to avoid much unnecessary, redundant, and tedious activity. Moreover, time and again such programs have been demonstrated to be financially sound. Doing the job right the first time is good business. Any program which helps to reduce losses and promotes efficiency can only have a positive effect on profits.

In advance, a few caveats are in order. The reader looking for an exhaustive discussion of a given topic may be disappointed. That person is referred to the many excellent monographs in print. Other readers may become impatient with

historical and anecdotal material included throughout the text. Entertaining as these accounts may or may not seem, their only purpose is to show the relevancy of basic concepts. And finally, those readers, who have an aversion to legal phraseology, are reminded that existing government regulations, which codify many of the principles of quality assurance, must be accepted as the final authority.

This book is written for and dedicated to all quality assurance personnel whose responsibility it is to maintain a safe food supply. It is directed at those persons charged with making the day-to-day decisions, whether working in industry or government. This volume also has special significance for those selfless instructors in academia whose role is to train the future managers and inspectors. The success of this book will ultimately be measured by how well it serves the requirements of these individuals for whom it was intended.

JOHN E. STAUFFER

FOREWORD

A country's food industry, at whatever level of complexity it has achieved, provides a basic product. Whether grown in one's backyard, obtained by barter from a neighbor's farm or purchased in a corner delicatessen or shopping mall supermarket, we cannot do without it. Even when we seek the convenience of another's final preparation in a fast food outlet or enjoy gastronomic delights in a *haute cuisine* restaurant, we are satisfying a most fundamental and indispensable need. This may, upon reflection, seem obvious, but in our modern technological society, fulfilling our requirement for sustenance is neither simple nor easy.

Few, if any, can live exclusively on the fruits of their own labor, for our farms and ranches today are too specialized to provide all the ingredients of a "balanced diet." Thus over the years we have become almost entirely dependent upon others to supply our food, giving birth to today's multibillion dollar food industry. We rely on its rapid and often highly complex means of production, processing, marketing and distribution to provide us with a daily array of products that are appealing, affordable and wholesome. Underlying these desirable and important attributes there is, we assume, quality.

There is no single definition which immediately flows from the concept of food quality. In various contexts it can mean purity, safety, value, nutrition, consistency, or honesty, e.g., in labeling. This list is certainly not exhaustive. But whatever the circumstance, we presume there are standards which, when met by a particular product, define its quality. There was a time when standards were obvious and immediately verifiable. We harvested our own wheat certain it was not contaminated or admixed with other grains. A neighbor's steer gave us what we knew was only fresh sirloin since we saw it dressed. Now the situation is more complicated, for food manufacturers rely on multi-source ingredients often from distant points. Processing utilizes sophisticated methodology and distribution is rapid through complicated marketing channels. Consumer needs and expectations have given rise to the use of added flavorings, colors, and preservatives. The economics of farming have led to expanded use of fertilizers and pesticides. Nutritional concerns raise questions about macroingredients like protein and fat, and microingredients like vitamins and sodium.

These and related aspects of food quality demand standards, some of which are determined within the food industry and others by the many government agencies which function with legislative mandates. These latter are, in fact, congressional interpretations of consumer needs and expectations. Thus from various sources there are hosts of prescriptive and proscriptive standards to which those in the many food companies, large and small, must adhere.

How they do it is quality assurance. It is to this monumental subject, its history, strategies, methodologies and pitfalls that this book is addressed. Although comprehensive in scope, this volume has a focus which is sharp and unwavering. Logically organized it begins with product planning and proceeds through manufacturing and customer service to distribution. Critical areas such as good manufacturing practices (GMP's), packaging and labeling, and product recall are explored with illustrative examples and, where appropriate with tables, diagrams and charts. Clearly written and well-documented, this is at once a textbook, manual, and reference work. Every reader will not agree with all the author's conclusions and suggestions, but were such not the case, a book on this topic would be banal and superficial. This volume, in short, is a guide which is both stimulating and challenging. Its publication is an important contribution to the literature of the quality assurance of our food supply.

ARTHUR HULL HAYES, JR., M.D.
Formerly Commissioner,
U.S. Food and Drug Administration

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PART I

Product Planning

CHAPTER ONE
ORGANIZATION AND MANAGEMENT

In the absence of clearly defined responsibilities within a corporation, quality assurance becomes everybody's business and nobody's business. Quality assurance is the concern of everyone, from the newly hired shift operator to the Chairman of the Board, but without an effective corporate organization these individuals, by default, all too often will fail to perform the tasks required of them. Recognizing the need to hold managers answerable, the Food and Drug Administration (FDA) stipulates in the *Code of Federal Regulations*, 110.10(d) that:

> Responsibility for assuring compliance by all personnel with all requirements of this Part 110 shall be clearly assigned to competent supervisory personnel.

Individual responsibilities must be delineated in formalized procedures that cover the different functions of quality assurance. Until decisive measures are taken to enforce specific objectives, any quality assurance program will remain a well-meaning but ineffective body of rhetoric and platitudes. Procedures should be concise, lucid statements that pinpoint job assignments and provide means for communication within the organization. In the preparation of such directives, a realistic appraisal should be made of the needs of the business and the resources and manpower available for meeting these demands. A quality assurance manual comprised of these procedures should be distributed to all supervisory personnel.

Organization requires careful thought and deliberation; this necessity will be made clear in the following sections of this chapter. Left to the whims of management or the vicissitudes of mergers, acquisitions, and divestitures, corporate structure soon becomes disordered. Haphazard planning can only result in people working at cross purposes. No other assignment in quality assurance 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. These civil servants are involved with the same food-related issues, albeit from a different point of reference. What the government regulators say and do has as great a bearing on product planning as any decisions made by industry personnel.

PARK DECISION

Two decisions by the United States Supreme Court have far-reaching consequences for food processors and the conduct of their affairs. These cases unequivocally hold the chief executive officer responsible for the actions of his subordinates. This tenet is unabridged by any consideration of company size, good intentions, lack of knowledge, or other mitigating circumstances.[1]

In the Dotterweich case that goes back to 1943, the doctrine of "strict" liability, sometimes referred to as "absolute" or "vicarious" liability, was enunciated. In this landmark case the court held that the president of a small drug repackaging establishment could be found guilty of a violation of the Federal Food, Drug and Cosmetic Act (FD&C Act) even though he personally may not have been involved with the given transgression. The decision took cognizance of an unusual feature of the FD&C Act, namely, its failure to specify any element of intent, knowledge, or willfulness as a prerequisite to criminal prosecution. Thus, a defendant is barred from relying on any assertion that he was ignorant of an offense.[2]

The strict liability doctrine was upheld and expanded in a subsequent Supreme Court action. In 1975, the Park decision not only reaffirmed that lack of knowledge is an invalid defense, but it went on to state that persons in high corporate positions of authority can be held accountable for failing to take preventive measures.[3] The court found that John R. Park, President of Acme Markets, Inc., which operated more than eight hundred food stores, was guilty when his supermarket chain was condemned for rodent infestation in one of its warehouses. Chief Justice Warren E. Burger in writing for the majority maintained that "the requirements of foresight and vigilance" demanded of chief executives must be upheld.[4]

Commenting on the strict liability doctrine, the Department of Health, Education and Welfare (HEW), testified in a Senate hearing in 1976 as follows:

> Since the civil remedies available to FDA . . . are essentially retrospective in effect, food processors can, and too many do, simply sit back and wait for FDA to act. It is far cheaper to risk the loss of a few hundred or thousand dollars as a result of an occasional seizure or injunction than to regularly allocate many thousands of dollars necessary to maintain facilities in sanitary condition. The primary impetus to self-regulation is the fear that criminal penalties may be imposed for failure to take every precaution to ensure that violations — and their potentially harmful consequences — will not occur.[5]

The debate goes on whether it is fair to hold senior officers in major food corporations responsible for the errors of their underlings, but so far the court decisions stand. Congress has held numerous hearings on new food legislation during which this issue has continued to be aired. Some people feel that constitutional rights are being encroached by adhering to such a strict standard. The prevailing opinion, however, asserts that in the sensitive area of food safety, the public's welfare takes precedence over consideration of individual claims.

ORGANIZATION CHART

The court finding in the Park case, specifically, that a CEO can be held accountable for the actions of his subordinates, is very significant when addressing the question of organization. A prudent chief executive is compelled to establish clear channels of communication between the persons making the decisions at the plant level and those executives responsible for setting policy. Senior management should have access to operational data, and line supervisors should be able to report developments as they occur. Impediments to the exchange of information, whether built into the organization or unknowingly present, can only lead to misfortune.[6] A simplified organization chart is shown in Figure 1.1. It includes the primary functions of marketing, manufacturing, and quality assurance, but it does not attempt to designate all supporting groups which may vary from one company to another. While some variations from the basic structure are possible, several key features should be noted. The senior person responsible for quality

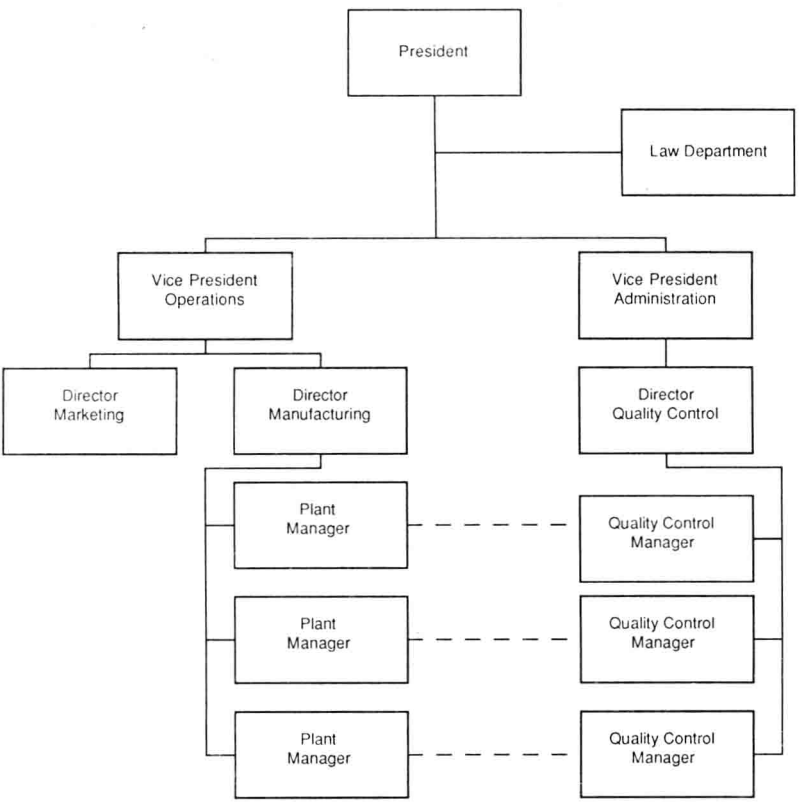

FIGURE 1.1. ORGANIZATION CHART

assurance reports directly to top management and has equal status with the heads of marketing and manufacturing.[7] The plant quality control managers each report to the Director of Quality Assurance although dotted lines on the organizational chart indicate close functional ties with the plant managers.[8]

In the quality assurance profession, strong feelings have been expressed about the need to have the plant laboratories report directly to Quality Assurance rather than to Production. If quality control is allowed to slip into the manufacturing organization, there may arise a tendency to overlook danger signals and to delay corrective actions.[9] For the quality control manager to discharge his duties effectively, he must be given wide latitude without fear of reprisals. When the quality control manager is exposed to subtle pressures or is subject to undue influence in hiring, firing, and salary administration, he loses an important sense of perspective.[10]

The cornerstones of any quality assurance program are the food scientists in the plant control laboratories. Upon their shoulders rest much of the burden to maintain 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 problems that beset quality, but unfailingly they are far more efficient than corporate staffs in handling the deluge of requests from customers.[11]

The Director of Quality Assurance is charged with exercising tight control over all aspects of quality. His accepted duties include the approval of all labels, packaging, product specifications, special releases of product, and data sheets. The organization depends more on the Director of Quality Assurance than any other person for implementing the necessary programs and procedures. The CEO can sleep better at night knowing that this critical job is in the hands of a competent professional.

RECALL ORGANIZATION

The events leading up to a product recall can engulf an organization with bewildering and traumatic swiftness. The company's response to such a challenge is crucial in order to avert confusion, indecision, and errors in judgement. How well management reacts in a recall situation depends in large measure on whether the company has taken certain preparatory steps in advance. Of foremost importance is the establishment of a standby recall organization. As soon as a crisis strikes, this organization is ready to respond immediately to the emergency and thereby head off potential disaster.[12,13]

While the mechanics of product recall are reviewed in detail in Chapter Thirteen, the organization used to implement a recall is described in this section. This discussion highlights the differences between a recall organization and the normal business structure which it supplants in times of such upsets. Whereas the

company's usual way of conducting its affairs is suitable for making everyday decisions, that structure is inadequate to cope with a crisis. Responses are too slow and deliberate to meet effectively the developments which unfold in a matter of hours instead of days or weeks.

Central to any recall organization is the Recall Coordinator as shown in Figure 1.2. This position is filled by one person, not by a committee. The person usually selected for this assignment is the Director of Quality Assurance because of his familiarity with all concerns relating to quality. For the duration of the recall he assumes the powers of a czar; he is entrusted to make the necessary snap decisions, however controversial they may seem at the time. He is given access to the President's Office, bypassing the normal lines of communication.[14]

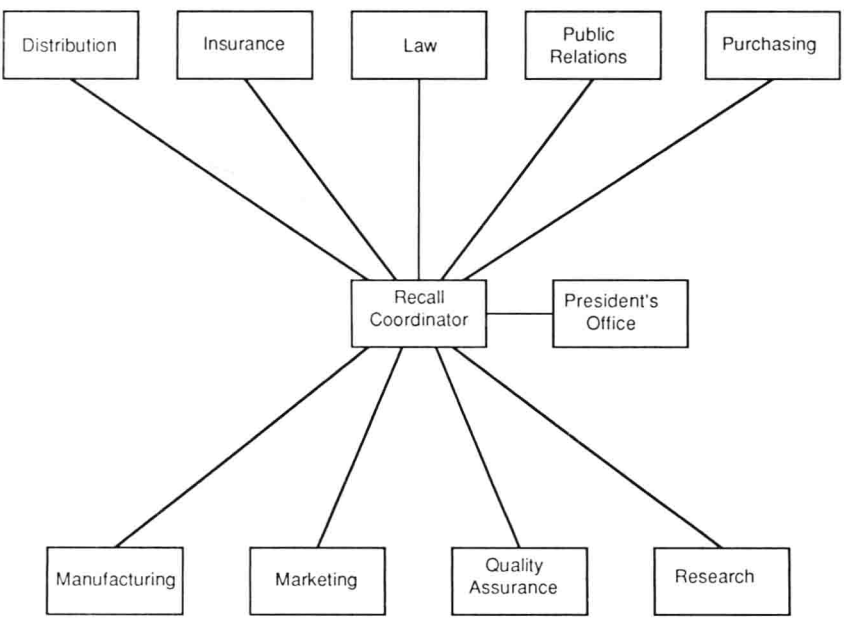

FIGURE 1.2. RECALL ORGANIZATION

Notwithstanding the authority vested in the Recall Coordinator, he does not act alone. Rather, he orchestrates a complex assembly of individuals consisting of line managers, administrative personnel, and representatives from staff departments. When called upon, all of these persons cooperate by providing information, giving assistance, and offering advice to the Recall Coordinator. Directly or through spokesmen, he coordinates all contacts with persons outside of the company whether they are customers, regulatory officials, or the press. To a significant degree the success or failure of a recall rests in the hands of the Recall Coordinator. The following account illustrates better than any exposition the lessons to be learned from an actual recall.

A Recall by Hygrade Food Products

When Hygrade Food Products Corporation of Southfield, Michigan, received a report on the last Wednesday in October, 1982, that customers in the Detroit area were finding razor blades in its Ball Park hot dogs, the meat packer desperately began recalling millions of frankfurters. In vain the company searched for some demented criminal either within its ranks or outside the organization. As the hours passed into days and the mystery remained unsolved, officers of the company began to fear for Hygrade's very existence. Alarmist reports about the incident were circulated in the newspapers and on TV. The Department of Agriculture (USDA), which was overseeing the massive recall, failed to uncover any clues. Finally, after days of frantic efforts, the case was resolved: the reports were all hoaxes planted by either pranksters, extortionists, or sociopaths.

From the beginning of the recall, Hygrade's Operations Vice President assumed responsibility for coordinating the investigation and acting as spokesman for the company. Key strategy decisions were made on the spot by him in consultation with the President. One important decision was regrettable, namely, to issue a press release supporting what later turned out to be a false lead. But the other actions which were taken effectively dispelled the rumors and helped to calm the hysteria. By its decisive and forthright stance, the company, in the end, more than regained its lost business and restored customer confidence in its products. This frightening occurrence vividly dramatizes the unexpected twists of events during a product recall, and it illustrates how a company like Hygrade, when properly prepared, can successfully confront the challenge.[15]

COMMITTEES AND TASK FORCES

Committees are a way of corporate life. Even if an agreement could be reached to banish them, there is some doubt whether this could be achieved. Instead of debating their merits, the more rewarding approach is to examine the special situations where committees are useful in quality assurance.

Because many disciplines are involved in the management of quality assurance, individuals who are expert on all subjects are difficult to find. Therefore a manager must rely on the input from many sources in order to assess his options adequately. The formation of standing committees whose members represent different backgrounds provides an effective means of bringing these skills to bear on particular problems. Committees, for example, can be established for reviewing government regulations, packaging, or labeling.[16]

While committees are well suited for communication, they have their shortcomings in decision making. Unless the chairman is given the necessary authority or by his station wields sufficient influence, he will be frustrated in attempting to reach a consensus on any particular issue. Because the forces within a committee are diffuse, they are not easily mobilized in support of a given course of action.