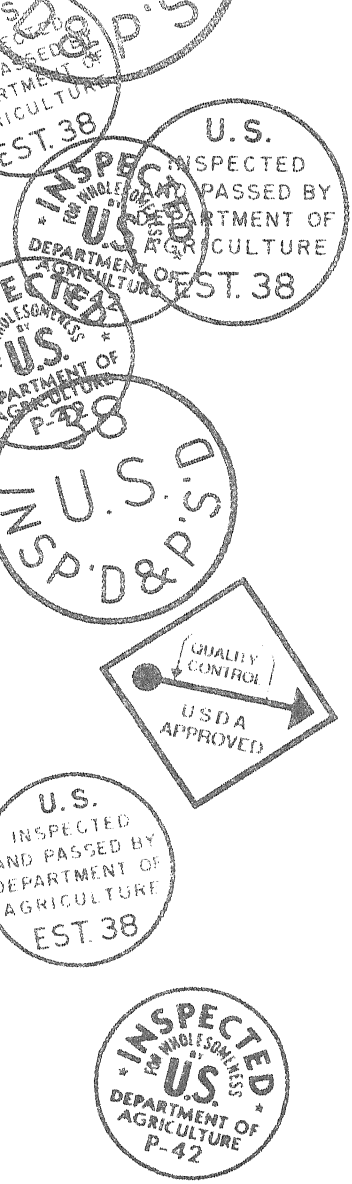

Meat and Poultry Inspection

The Scientific Basis of the Nation's Program

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Meat and Poultry Inspection

The Scientific Basis of the Nation's Program

Prepared by the Committee on the Scientific Basis of the Nation's Meat and Poultry Inspection Program

Food and Nutrition Board
Commission on Life Sciences
National Research Council

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This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

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Committee on the Scientific Basis of the Nation's Meat and Poultry Inspection Program

Robert H. Wasserman (*Chairman*), New York State College of Veterinary Medicine, Cornell University, Ithaca
John C. Bailar III, Harvard School of Public Health, Harvard University, Boston, Massachusetts, and Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services, Washington, D.C.
Frank Bryan, Centers for Disease Control, U.S. Public Health Service, Atlanta, Georgia
Billy M. Colvin, Veterinary Diagnostic and Investigational Laboratory, University of Georgia, Tifton
Bernard Easterday, School of Veterinary Medicine, University of Wisconsin, Madison
Thomas Grumbly, Health Effects Institute, Cambridge, Massachusetts
Harold Hafs, Merck, Sharpe, and Dohme Research Laboratory, Rahway, New Jersey
Norman D. Heidelbaugh, Department of Veterinary Public Health, Texas A & M University, College Station
John E. Kasik, Department of Internal Medicine, Veterans Administration Medical Center, Iowa City, Iowa
Herbert W. Ockerman, Department of Animal Science, Ohio State University, Columbus
Morris Potter, Centers for Disease Control, U.S. Public Health Service, Atlanta, Georgia
Michael Pullen, College of Veterinary Medicine, University of Minnesota, St. Paul
S. Benson Werner, California Department of Health Services, Berkeley

Zain Abedin, *Project Director*
Susan Berkow, *Staff Officer*
Marianne E. La Veille, *Research Associate*
Janie B. Marshall, *Secretary*
Linda Starke, *Editor*

Sushma Palmer, *Executive Director,* Food and Nutrition Board

Food and Nutrition Board

Preface

The U.S. Department of Agriculture (USDA) established the Food Safety and Inspection Service (FSIS) to carry out the department's legal responsibilities for assuring the safety and wholesomeness of meat and poultry products for human consumption. In late 1983, FSIS asked the Food and Nutrition Board (FNB) of the National Research Council to evaluate the scientific basis of the current system for inspecting meat, poultry, and meat and poultry products. This volume is the report of the committee appointed by the Research Council to do the evaluation.

Traditional inspection methods remained unchanged for nearly 70 years, and the public seems to have high confidence in the system. Some members of the public, however, have expressed concern about the potential effect on public health of some recently introduced changes and of others under consideration. There has been little attempt to date to evaluate these changes systematically. FSIS, recognizing the need to reevaluate the system under these changing conditions, asked the Research Council to undertake this task.

The Committee on the Scientific Basis of the Nation's Meat and Poultry Inspection Program formed in response to this request was asked to:

- assess the scientific foundation for USDA's meat and poultry inspection programs to determine its impact on the quality, quantity, and health of livestock and on the character and degree of various risks to human health;
- make a comprehensive analysis of different inspection strategies, including comparative risk assessment, to predict their impact on public health; and
- make recommendations based on new developments in biological research and technology and in food science that might be used in the inspection program to further enhance its effectiveness and efficiency while maintaining or improving the current degree of public health protection.

The Research Council made special efforts to ensure that the collective knowledge of the committee encompassed all the types of expertise needed to conduct a study of this scope and complexity. The resulting

multidisciplinary group included experts in public health, food microbiology, food science, veterinary medicine, analytical chemistry, toxicology, biostatistics, and risk analysis.

The subject of this study is of interest to members of the general public, who are concerned about the safety of the meat and poultry products they consume; to the industry, which must provide safe and economical products in return for the opportunity to earn fair profits; and to the regulatory agencies, which are responsible for inspecting the slaughter, processing, and distribution of food-animals to ensure that only safe and wholesome products are delivered for human consumption.

The committee had to address such complex questions as: What is the scientific basis for our traditional inspection system? How did it evolve? How effective are current monitoring and surveillance procedures in minimizing public health risks? What is the degree of risk to public health from the recent changes in inspection procedures? How can the inspection system be made more effective and efficient in providing protection for the public? How well do the underlying mechanisms for policy development work, and can they be improved?

In attempting to answer these questions, the committee was primarily concerned with two kinds of human health hazards: (1) diseases transmitted from animals to humans by infected or diseased animal tissues (zoonoses) or by pathogenic microorganisms (or their toxins) that can enter into the food chain during production, slaughter, processing, storage, transport, or preparation for consumption and (2) exposure to meat- and poultry-borne chemical residues such as antibiotics, hormones, growth promotion chemicals, pesticides, and industrial chemicals, whether the hazard arises from direct toxicity or from the release of antibiotic-resistant bacteria into the environment. (Nutritional-deficiency diseases and health hazards associated with the fat content of meat and poultry were not part of the charge to the committee and therefore are not considered in this report.)

The committee used data from FSIS sources and the general scientific and technical literature, supplemented by other sources, to produce a pragmatic report with recommendations that would be useful to FSIS, the public, and the industry. The additional sources included:

- *A public meeting* on April 26, 1984: Interested parties were invited to attend this widely advertised meeting, to speak, and to submit documents for the record. Consumer advocates and food scientists and technologists from research organizations, government agencies, the meat and poultry industry, and academic institutions presented their views and provided data on the safety of meat and poultry products.
- *Site visits* by committee members and staff: Firsthand information was obtained both through observation of slaughtering and processing plants and field laboratories and through discussions with personnel working there.
- *A questionnaire survey* of plant inspectors and supervisors: Approximately 200 plant workers, inspectors, and other FSIS employees, randomly

selected from the complete FSIS roster, were asked to respond to specific questions.

- *A workshop* on advances in science and technology: Experts in biotechnology, analytical chemistry, biological imaging techniques, and computer automation informed the committee on the state of the science in each area, including possible applications of advanced technology to meat and poultry inspection programs.

The committee met seven times to review and evaluate the data from these sources, to discuss past and current research publications, and to develop its conclusions and recommendations. Donald Houston of FSIS and his colleagues attended two committee meetings to discuss inspection strategies, risk profiles, and plans for the future. They also provided substantial documentation in response to inquiries about specific matters.

A summary of the committee's findings, conclusions, and recommendations appears in Chapter 1. Chapter 2 contains a historical perspective on the meat and poultry inspection system. Public health hazards caused by meat- and poultry-borne pathogenic microorganisms and by chemical residues are discussed in Chapters 3 and 4, respectively. Chapters 5, 6, and 7 are reviews of production and of inspection elements in slaughter and processing operations. Chapter 8 contains an evaluation of the concept of hazard analysis and critical control points and its applicability to meat and poultry inspection. Chapter 9 is a review of advances in analytical techniques and biotechnologies that might be adapted to meat and poultry inspection, and Chapter 10 is a discussion of broader issues concerning FSIS programs and the use of risk assessment in decision making, public policy, and management.

The committee is grateful for the invaluable assistance of the many individuals who provided testimony or submitted written information. Speakers at the public meeting were John Brown, University of Georgia; Garrison Koehler, Bactomatic; Rodney E. Leonard, Community Nutrition Institute; Janet Lowden, U.S. General Accounting Office; Kenneth N. May, Holly Farms Poultry Industry, Inc.; Carl L. Telleen, private veterinarian; and George D. Wilson, American Meat Institute. The workshop speakers were Harvey Brandwein, Genetic Diagnostics; Rita Colwell, University of Maryland; Dean L. Engelhardt, Enzo-Biochem; Rabia Hussain, National Institutes of Health; Larry Merricks, Dynamac Corp.; James Stouffer, Cornell University; and M. Ter-Pogossian, School of Medicine, Washington University.

The committee thanks the FSIS personnel who assisted in arranging for the various site visits: Francis Adams, Carl Blattenberg, E. K. Casey-Shaw, K. S. Daniels, Don A. Franco, R. L. Hardy, Joseph Lyons, Mark T. Mina, Ned Rice, Robert A. Stahnke, and C. Gil Varg. The study also benefited from the contributions of William L. Jenkins, Timothy D. Phillips, Barbara E. Richardson, Leon H. Russell, and Stephen H. Safe from the College of Veterinary Medicine, Texas A & M University. We especially thank Donald Houston and his staff for repeatedly providing requested

data and responding to detailed questions from the committee about FSIS programs.

Beyond these contributors, the committee thanks the many people it consulted who are not specifically acknowledged, and the following people who gave assistance either in person or in writing: Charles L. Cannon, National Live Stock and Meat Board; Charlie Cook, Oscar Mayer Company; H. Russell Cross, American Meat Science Association; Theodore Farber, Food and Drug Administration; Harold E. Ford, Southeastern Poultry & Egg Association; Scott Holmberg, Centers for Disease Control; Edward L. Menning, National Association of Federal Veterinarians; Alan Moghissi, Environmental Protection Agency; Harry C. Mussman and Lloyd R. Hontz, National Food Processors Association; Joseph Rodricks, Environ Corporation; Ann L. Shriver and Eileen V. Ravenswaay, Michigan State University; Kerri Wagner, National Broiler Council; Larry A. Ward, Tyson Foods, Inc.; and George Wilson and Jim Hodges, American Meat Institute.

On behalf of the committee, I would like to thank Zain Abedin, Project Director, for the considerable time and effort spent guiding our discussions of this important public health issue. The committee also wishes to acknowledge the extensive contributions of Sushma Palmer, Executive Director of the Food and Nutrition Board, to its deliberations and final product—this report. Additional thanks go to Susan Berkow, Staff Officer; Marianne E. La Veille, Research Associate; Linda Starke, Consultant Editor; Frances Peter, Research Council Editor; and Janie B. Marshall and Barbara Miller, Secretaries, without whom our report would not be before you now. Lastly, I would like to thank the other members of the committee for all the hard work they so willingly contributed.

Robert H. Wasserman
Chairman
Committee on the Scientific Basis of the
Nation's Meat and Poultry Inspection Program

Contents

1
Executive Summary

The American public expects that meat and poultry products in the marketplace are as safe and wholesome as technically feasible, and public opinion polls indicate that consumers generally have confidence that this is so. Indeed, meat and poultry products that pass through the inspection system are, for the most part, wholesome. The wholesomeness of the nation's meat and poultry supply depends on each link in a chain from the farm to the slaughterhouse to the table. This report addresses primarily the ways in which the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) can further strengthen its part of the chain not only to reduce the number of occurrences of bacterial infections but also to reduce chemical contamination and ensure the general safety and wholesomeness of meat and poultry.

The responsibility for ensuring the safety of meat and poultry products was conferred upon the USDA through a mandate in the Federal Meat Inspection Act of 1906 and subsequent acts and amendments. These documents directed the USDA to inspect meat and poultry products that enter commerce and are destined for human consumption. The wide-ranging obligations of the FSIS include the assurance of a sanitary environment in slaughter and processing plants and the monitoring of all relevant stages of animal slaughter as well as meat and poultry processing procedures. The overall goal of the inspection program has been to ensure that meat, poultry, and their products are wholesome, unadulterated, and properly labeled[1] and do not constitute a health hazard to the consumer. Toward this goal, FSIS personnel inspect meat and poultry products animal-by-animal and process-by-process in slaughterhouses and processing plants.

Slaughter inspectors rely almost completely on sight, smell, and touch to discern abnormalities in animals and carcasses. This procedure

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[1]The legal definition of these terms can be found in the Federal Meat

was designed primarily to protect consumers from grossly visible lesions or diseases. Although this labor-intensive system tends to ensure safe and wholesome products with respect to such lesions, its efficiency came under scrutiny by FSIS as science and technology advanced and the understanding of risks to human health became more defined.

In 1906, acute infections were the leading causes of human mortality and morbidity. Today, more than 60% of all human deaths in this country each year are due to cardiovascular disease and cancer--chronic diseases attributed primarily to life-style, products of industrialization, and the increasing average age of the U.S. population. Also, through improved controls and deliverance of health care to farm animals, certain animal diseases have been virtually eradicated. The importation of diseased animals into the United States has essentially been prevented, and diseases that can be transmitted from animals to humans have been curtailed or in some cases practically eliminated.

Simultaneously, the production of meat and poultry products has become increasingly complex. In contrast to the few basic cuts of fresh meat and poultry available early in this century, there is now a great variety of raw, canned, cured, dried, fermented, and frozen products. The technological growth that made these products possible has contributed to the greater need for sophistication in determining the origin and path of food-borne microbial infections. Finally, environmental contaminants and the increasing use of chemicals in animal feeds and to some extent in processed foods have led to the presence of chemical residues in meat and poultry, some of which may be sources of potentially deleterious effects.

These changes have led FSIS to institute new programs and procedures. In the past two decades, FSIS began programs for determining microbial and chemical hazards in meat and poultry; modified inspection procedures for chickens, swine, and turkeys to increase production efficiency and decrease inspection time; and, in processing plants, started to shift the burden for maintaining the quality and safety of processed products to plant management under FSIS supervision.

Is the inspection system in place today adequate to meet new challenges? Are the initiatives taken by FSIS consistent with current concerns about public health? Can technological developments in the detection and control of deleterious microbiological and chemical agents and advances in assessment of risks to human health be better applied to meat and poultry inspection? This was the essence of the charge given by FSIS to the National Research Council's Committee on the Scientific Basis of the Nation's Meat and Poultry Inspection Program, which was established to conduct this study within the Food and Nutrition Board of the Commission on Life Sciences in conjunction with the Board on Agriculture.

The committee organized its tasks by identifying and categorizing various risks that could be presented by different parts of the production and processing operations. It then based its analysis on an assessment of the literature, discussions with experts from FSIS and the scientific community, public testimony of scientists and others from the public and private sectors, an independent survey of FSIS inspectors in meat and poultry plants, and site visits to selected plants. The assessment was limited by incomplete data, including the lack of systematic data on various phases of inspection as they relate to public health, and by the inherent difficulty of relating findings during inspection to endpoints affecting public health, such as the incidence or prevalence of human diseases.

The committee did not limit its study to those activities directly under the jurisdiction of FSIS. Rather, it considered all potential sources of health hazards in meat and poultry products, including farms, feedlots, and the ultimate destinations--the food establishments and the homes where foods are handled, stored, and cooked.

The conclusions reached and recommendations made by the committee are aimed at developing programs to ensure that the inspection system keeps pace with advances in knowledge and is efficient with regard to public health protection. The committee has also identified characteristics that in its judgment constitute an optimal meat and poultry inspection program.

MAJOR CONCLUSIONS AND RECOMMENDATIONS

The meat and poultry inspection program of the FSIS has in general been effective in ensuring that apparently healthy animals are slaughtered in clean and sanitary environments. FSIS has made progress in reducing risks to public health from conditions that can be observed during antemortem and postmortem inspection and that can be evaluated during processing. However, substantial challenges continue to confront the agency. Some aspects of the inspection system are poorly defined in terms of objectives relevant to public health. A risk-based allocation of resources, supported by modern technology and a systematic evaluation of the program, would be valuable.

Public Health Risks Related to Biological Agents

It is well established that species of *Salmonella* and *Campylobacter* are major causes of diseases transmissible to humans through the consumption of meat and poultry products, and the committee concluded that current postmortem inspection methods are not adequate to detect these organisms. For example, meat and poultry were implicated in 1,420 of the 2,666 food-borne disease outbreaks from known sources reported to the Centers for Disease Control (CDC) between 1968 and 1977. *Salmonella* contamination accounted for approximately 26% of all food-borne outbreaks in 1981. Meat and poultry were also responsible

for 4 out of 23 outbreaks due to species of Campylobacter (a less easily detectable organism) reported to the CDC during 1981 and 1982. Of particular concern to the committee is the risk presented by food-borne microbial infections to susceptible subgroups such as young children and the elderly. Pathogenic microorganisms reside in the gastrointestinal tracts and on external surfaces of food-animals and cannot be detected by the usual organoleptic procedures (i.e., sight, smell, and touch) used during inspection. Therefore, human pathogens such as species of Salmonella, Campylobacter, Clostridium, and Staphylococcus are not ordinarily identified during slaughter.

Microbial contamination is common among fresh foods, including meat and poultry. Hazards from such contamination have been minimized, however, by FSIS inspection and by the USDA's educational efforts, which have resulted in improved handling of foods in slaughter and processing plants, food service facilities, and homes. Microorganisms in raw meat and poultry products can multiply, spread, and perhaps cross-contaminate other foods in food-service establishments and homes unless the products are handled properly in the plant, during transport, in retail outlets, and by the consumer after purchase. Proper handling and cooking are important to avoid contamination of meat and poultry by species of Salmonella and Campylobacter; for pork products that might contain the food-borne parasite Trichinella spiralis, proper cooking is essential.

Slaughterhouse employees are at especially high risk because of their exposure to infectious organisms that cause brucellosis and psittacosis--infections that humans can acquire by direct contact with diseased animals. Although an eradication program has effectively reduced the incidence of brucellosis in most of the U.S. population, the disease still occurs to some extent among slaughterhouse employees.

Recommendations. The committee recommends that FSIS intensify its current efforts to control and eliminate contamination with micro-organisms that cause disease in humans. Such efforts should include evaluation of rapid diagnostic procedures for detecting microorganisms, especially species of Salmonella and Campylobacter, and education of the general public, health care personnel, educators, and extension service workers in the safe handling of meat and poultry. The committee also recommends that meat handling practices in plants be monitored and evaluated in an attempt to prevent the occurrence of meat- and poultry-derived infections among plant employees. Although their prevalance is low, these infections present significant and avoidable occupational hazards. Better epidemiological surveillance and coordination of efforts to eradicate these diseases are also needed. (See Chapters 3, 6, and 7 for a detailed discussion of biological agents in meat and poultry that pose a risk to human health.)

Public Health Risks Related to Chemical Agents

The committee concluded that although significant strides have been made in protecting the public against exposure to hazardous chemicals

in meat and poultry, the fundamental design of FSIS's residue monitoring program needs to be improved to ensure maximum protection. In particular, the committee questions the adequacy of sampling size and procedures, the basis for and the utility of tolerance levels for chemicals, and the basis for setting priorities for testing chemicals.

Through its National Residue Program (NRP), which was instituted in 1967, FSIS applies new technologies and testing procedures in the monitoring of approximately 100 of the chemicals that may be found in meat and poultry. The chemicals analyzed are selected on the basis of toxicity, exposure level, persistence, and other criteria. During postmortem inspection, samples are taken from each animal species to test for compliance with tolerance levels for the chemical, as well as to determine the frequency, trends, and distribution patterns of the chemical in meat and poultry. In addition, samples suspected of containing unacceptably high residue levels are examined so that remedial action can be taken. The current residue testing strategy of FSIS to detect with 95% confidence whether or not a problem exists in 1% of the animal population is inadequate to eliminate consumer exposure to residues. Because millions of animals are slaughtered annually (e.g., between 36 million and 40 million cattle alone), the chance of any animal being sampled in the United States is minuscule. Furthermore, because of the increasing number and variety of contaminating residues that may constitute possible health hazards, especially to susceptible subgroups in the population, and because the overall contamination rate of less than 1% may be considerably higher for certain food sources or consumer groups, the committee questions whether the size of the sampling plan is adequate.

The committee identified some desirable characteristics of an optimal system for the NRP and compared them with the current program. It concluded that the NRP now meets its primary objectives and has made considerable progress in several categories, but that it is deficient in 3 of 10 desirable characteristics. Its sampling plan is not adequate to provide maximum protection to consumers, there is no free communication with experts outside the agency, and there is no formal risk assessment and risk management program. The committee believes that a program based on rational public health objectives and risk assessment would contain many of the characteristics identified and would ensure that no one person would consistently be exposed to levels of chemicals in excess of established tolerance levels.

Recommendations. The committee recognizes that the NRP is constrained in many ways by its legislative mandates. It recommends, however, that the NRP strive to make substantial progress in several categories to meet the requirements for an optimal program identified by the committee. In particular, the NRP should incorporate strategies that would prevent consumers from exposure to potential health hazards. One of the ways this could be accomplished is to introduce a system to identify and trace back animals to their farms. The sampling plan to test chemical residues should be revised to improve

the confidence level of detection by using appropriate statistical methods and new technological advances. Furthermore, the committee suggests that FSIS reexamine the priorities and the methods used by regulatory agencies for establishing tolerance levels of chemicals to ensure that they appropriately reflect the degree of risks to public health. Formal risk assessment and frequent communication with other regulatory agencies and with scientific peer-review groups would be particularly beneficial to FSIS in this endeavor (see Chapter 4).

Production of Food-Animals

The committee concluded that the most effective way to prevent or minimize hazards presented by certain infectious agents and chemical residues in meat and poultry is to control these agents at their point of entry into the food chain, i.e., during the production phase on the farm and in feedlots. However, FSIS cannot exercise such control because it has no jurisdiction in those areas. Environmental contamination and improper use of feed additives fall within the purview of other government agencies such as the Food and Drug Administration and the Environmental Protection Agency. The problem is compounded by the absence of an effective national surveillance system for monitoring the disease status of food-animals and by an inadequate mechanism for tracing infected or contaminated animals back to their source.

Currently, the probability of successfully tracing a diseased or contaminated animal to the producer is very low (approximately 10% for cattle and 30% for swine). Furthermore, although samples at the postmortem stage are tested for chemical residues and certain microorganisms, there is no mechanism for reliably tracing an unacceptably high level to its origin. The inability to institute action at the first critical point of production (on the farm) places a heavy responsibility on antemortem and postmortem inspections to identify potential health hazards, although, as explained above, such inspections by themselves cannot solve the problem.

Cattle are produced in many parts of the United States, and ownership usually changes several times before the animals reach the slaughterhouse. Transport from farms to feedlots and subsequently to slaughterhouses increases the chance of exposure to infectious agents and subjects animals to considerable stress, thereby increasing their susceptibility to pathogenic agents.

Veterinary medical care and federal and state animal disease regulatory programs have considerably improved the health of food-animals in the United States and reduced the prevalence of diseases such as brucellosis and bovine tuberculosis. However, potential new risks are presented by chemical residues derived from the widespread practice of adding antimicrobial compounds and other chemicals to animal feed to promote growth or prevent infection.

The committee examined some recent case histories concerning residues and infectious agents. These included the polychlorinated biphenyl contamination through fatty animal by-products added to feed in the western United States in the summer of 1979, contamination of turkey products with chemical residues in the state of Washington during 1979, and polybrominated biphenyl contaminations in Michigan. The committee also investigated Salmonella contamination. In each of these cases, contamination at the farm creates a significant problem that is difficult for the inspection system to control by traditional inspection methods. Once animals reach the slaughterhouse, the line speeds and economic concerns necessitate sampling for residues on a very limited basis, and mostly with technology that is still quite imperfect and is not yet adequate to alleviate the problem.

The committee noted that voluntary identification (trace-back) programs have had some success in the swine and poultry industries due to the changing structure (through vertical integration) of those industries. Recent evidence also suggests that cooperative programs between farmers, slaughterers, and the government can be effective in minimizing problems before they reach the slaughterhouse.

Recommendations. The committee recommends that means be found for FSIS to coordinate the control and monitoring of hazardous agents during production, where those agents enter the food supply. Furthermore, it recommends that a system be developed for keeping track of food-animals during their lifetime, that procedures be instituted to trace residues in samples back to their sources, and that a national center be established to monitor and store information on animal diseases. To assist in these efforts, the committee recommends that all USDA animal disease surveillance programs be designed and implemented to use fully the animal disease prevalence data obtained from meat and poultry inspection programs.

Meat and Poultry Processing and Inspection

For many years, FSIS used what is commonly referred to as traditional inspection procedures. Not until the last decade were some new procedures instituted. Between 1979 and 1983, for example, FSIS introduced several new postmortem inspection procedures designed to ensure wholesomeness, improve efficiency, and increase production: Modified Traditional Inspection and New Line Speed for chickens, New Swine Postmortem Inspection, and New Turkey Inspection procedures.

In the judgment of the committee, these new procedures are not likely to diminish protection of the public health. However, the committee could find no clear evidence that the traditional inspection system and modifications to it over the years are based on objectives and criteria that relate to public health. Furthermore, the committee could make no overall assessment of risks and benefits because it could find no comprehensive statement of criteria, no systematic accumulation of data, and no complete technical analysis of the hazards or benefits

to human health in the traditional inspection program or as a consequence of the adoption of new techniques. Similarly, it could find no scientific basis for several ante- and postmortem disposition guidelines--for example, the requirement that livestock bitten by a rabid animal must not be slaughtered for at least 8 months, or that livestock showing signs of the onset of parturition should be withheld from slaughter until after the birth and the passage of the placenta (see Chapter 6).

A major change also took place in processing plants in 1980 when voluntary Total Quality Control (TQC) was first permitted. In essence, TQC places the major responsibility for producing safe products and inspecting them on the industry, which is monitored by FSIS. Currently, approximately 7% (475) of all meat and poultry processing plants have USDA-approved TQC systems in place; these plants produce 9% of the processed meat and poultry in the country. In principle, TQC is more systematic and objective than the traditional FSIS inspection procedure. A recent evaluation of 15 establishments using TQC suggests that it benefits both USDA and the industry and possibly inspires greater confidence in compliance because it allows the FSIS inspector to review a broader scope of plant operations. Universal and mandatory application of TQC, however, would require that all plants have a long record of compliance with FSIS's inspection guidelines, a commitment on the part of plant management, and better training of both meat packers and federal inspectors in quality control procedures than currently exists. The TQC system is a relatively new FSIS inspection system, and there is little experience on which to judge its public health benefits. In the committee's judgment, the FSIS-instituted changes in processing procedures are not likely to reduce public health protection.

Another approach to inspection--Hazard Analysis Critical Control Points (HACCP)--is used or is being considered for use in some operations. It consists of determining hazards, identifying critical control points where hazards can be eliminated, and monitoring those points (see Chapter 8). With proper modifications, HACCP can be applied to each phase of the food chain and in each plant.

Recommendations. Overall, the committee recommends that the precepts of risk assessment (identification of the problem, exposure assessment, hazard assessment, and quantitative health risk assessment) be systematically embodied in the planning and evaluation of all phases of meat and poultry inspection, and that risk-assessment criteria be used regularly to assess consequences to public health of any modifications in the inspection process (see Chapter 10).

Despite its preliminary conclusion based on the limited information that TQC works satisfactorily, the committee recommends that newer technologies be incorporated into TQC and that personnel be recruited and trained to increase the efficiency of the system. As explained below, the committee favors the incorporation of the HACCP approach into meat and poultry slaughtering and processing operations, including the TQC program.

Whereas traditional inspection applies primarily to the ante- and postmortem phases and TQC is currently applied during the processing of meat and poultry, HACCP is a comprehensive approach applicable to the range of operations from production of animals to slaughter, processing, and handling in retail outlets, food-service establishments, and homes. Traditional inspection and TQC are structured to comply with federal inspection regulations, which are concerned to a large extent with plant sanitation and with aesthetics and economy in producing safe and wholesome products. In contrast, HACCP is concerned primarily with criteria relevant to public health.

The committee recognizes that FSIS has implemented the principles of HACCP in certain operations; however, it recommends that those principles be applied more rapidly and comprehensively in plant operations and that periodic evaluations be performed to ensure that critical control points related to public health are emphasized in the inspection process in addition to whatever control points are needed for reasons related to aesthetics and economy. This should apply to both traditional and TQC approaches. To achieve both operational efficiency and protection of public health, critical control points must be identified, inspectors trained in the HACCP approach, and procedures regularly monitored.

Advanced Technology

Although FSIS has adopted new technologies, the committee found that the efficiency of the current inspection and processing operations and the ability of those procedures to protect public health are impeded by the limited application of rapid, specific, and sensitive techniques to detect pathogenic microorganisms and deleterious chemicals in meat and poultry and by inadequate information acquisition and retrieval facilities. For example, the failure to apply sufficiently modern techniques to detect abnormalities in organs and tissues necessitates more extensive, yet less efficient, human resources during inspection.

The current FSIS computer capabilities for the acquisition, analysis, and transmission of data are relatively slow and are inadequate to meet the growing demands of the agency for rapid interpretation of, for example, data on the prevalence and public health implications of high levels of chemical and microbial residues in meat and poultry. Computer-assisted information systems with better capabilities are commercially available.

Recent advances in science and technology have made possible rapid, sensitive, and inexpensive techniques based on immunological and recombinant DNA principles (biotechnology), some of which can be applied at the farm level for screening microbial and chemical contaminants. The Swab Test on Premises (STOP) and the Calf Antibiotic Sulfonamide Test (CAST) are two such techniques used by FSIS for antimicrobial residues. STOP is a new fast screening test for antibiotics that is used at slaughter. CAST is a similar technique for antibiotics and

sulfonamide residues. The results of these tests can be obtained within 24 hours, compared with 1 to 2 weeks using conventional methods.

Recommendations. In the judgment of the committee, the techniques that have the greatest potential applicability to FSIS procedures are imaging techniques, computer-assisted information transfer, and automated laboratory methods for analysis and measurement. To achieve the goal of installing a modern, technology-based system, the committee recommends that FSIS develop a capability for conducting or contracting for scientific and technical research tailored to its needs, rather than depending on other USDA agencies. However, interaction with other USDA agencies, other government agencies, and private groups is essential. Thus, the committee also recommends the establishment of a scientific advisory body composed of representatives from government, industry, universities, and research organizations to facilitate such interaction (see Chapter 9).

CHARACTERISTICS OF AN OPTIMAL MEAT AND POULTRY INSPECTION PROGRAM

In view of the above conclusions and recommendations, the committee identified the following components (not in any order of priority) of an optimal meat and poultry inspection system. It recognizes that many of these components are part of the current FSIS system (see Chapter 10).

- A trace-back and recall system from final sale to producer for all animals and products destined to enter the human food supply. This is essential for the generation of data that are important to the prevention of disease in humans and that will enable processors and the government to solve problems in the food chain.

- Maximum use of plant personnel in process-by-process and day-to-day monitoring of critical control points, and FSIS oversight to ensure compliance.

- Use in all phases of inspection of a technically qualified team with up-to-date knowledge of veterinary medicine, food science, public health, food engineering, food technology, epidemiology, pathology, toxicology, microbiology, animal science, risk analysis, systems analysis, statistics, computer science, and economics. Similarly, managers should have expertise in several relevant disciplines, including veterinary medicine, food science and technology, nutrition, public health, and public management. No one discipline should dominate management.

- An inspection system with different levels of intensity, reflecting the degree of public health risk at various stages in the process, the reliability of the monitoring system, the compliance history of the slaughterhouse or processing plant, and the special needs of the intended consumer (e.g., military personnel and schoolchildren).

- Development of a list of the diseases that can be identified by each step in the inspection procedure. This list should be used to determine whether the steps are useful for protecting human or animal health, useful for detecting aesthetically objectionable conditions, necessary to protect consumers against fraud, or able to provide other identifiable benefits.

- Random sampling of retained or condemned carcasses and parts of carcasses in order to develop definitive diagnoses. These diagnoses can be used to establish baseline data on etiologies associated with each condemnation category and to provide material for pathology correlation sessions as continuing education for in-plant veterinary medical officers.

- Rapid, inexpensive screening tests to detect a broad array of chemical compounds and biological products that may be hazardous to the consumer.

- An adequate sampling plan, designed to protect the consumer from exposure to chemicals that are not randomly distributed across the country.

- Emphasis on hazard analysis and critical control points (HACCP), limiting inspection where the historic yield of violations is low and where public health risks are negligible.

- Documented assurance, backed by substantial compliance enforcement, of the sanitary wholesomeness of all meat and poultry products.

- Enhanced enforcement capability to impose a broad range of penalties upon violators, including refusal to inspect and approve their products.

- Adequate resources to ensure continued improvement of the technological base of FSIS, including the development of new inspection technologies to reduce cross-contamination of carcasses and more comprehensive assessment of toxicological hazards.

- A mandatory system of initial and continuing education for inspection personnel that emphasizes food science, food technology, pathology, and public health, combined with a recertification program.

- A substantial scientific and technical FSIS staff of respected scientists who play a substantial consultative role in the development of policy.

- The presence of standing advisory panels composed primarily of outside experts to provide consultation on both policy and practice regarding meat and poultry safety. Disciplines represented on these panels should include food science and technology, computer applications, microbiology, biostatistics, epidemiology, veterinary

icine, toxicology, systems analysis, animal health, economics, keting, nutrition, and risk analysis. Again, no one discipline uld dominate any panel. All major regulatory proposals should be iewed by standing advisory panels prior to finalization.

- Strong liaison between FSIS, CDC, the Food and Drug Administra- n, and relevant animal health agencies at the federal, state, and al levels to ensure that no hazards are overlooked.

- Substantial use of a rapid, timely, and flexible system (probably puter-based) to acquire, transfer, analyze, and make more widely ilable data related to inspection and to meat-borne hazards.

The committee encourages FSIS to compare its program with these teria and to establish a schedule for incorporating missing ponents as soon as feasible.

2
The History of Inspection Programs and the Debate on Current Procedures

The meat and poultry inspection system of the U.S. Department of Agriculture (USDA) was created just after the turn of the century, as the nation was evolving from an agrarian to an industrial society. Although the earliest laws were passed to assure European importers of the safety of the American meat supply, meat and poultry inspection practices today focus on providing safe and wholesome products for Americans. This chapter looks at the evolution of the current USDA inspection system to show how several technological and social changes have affected inspection concepts and procedures.

From earliest times humans have eaten meat from animals. Various ancient cults and religious groups prohibited the consumption of certain types of meat. The food edicts of ancient Egypt, for example, proclaimed the pig unclean and the cow sacred, and the eating of their flesh as food was banned. Prohibitions such as these were probably based on considerations of sacrament or perhaps economics rather than public health. The real reasons behind the ceremonial food prohibition have long been lost, and anthropologists speculate that the origins were probably many and illogical (Collins, 1966).

The first civilizations in the Mediterranean area regulated and supervised the slaughter and handling of meat-animals (Forrest et al., 1975). Both the slaughter and the marketing of meat were inspected in ancient Athens and Rome, and the general marketing of food was supervised by food inspectors in Athens. Jewish sacrificial animals had to be perfect enough to be eaten by a priest, so priests naturally became good judges of livestock. With time, the rabbis' authority stretched to include all meat in Jewish communities (Collins, 1966).

In the eighth century, Pope St. Zachary forbade the consumption of meat of animals ill with diseases that were considered dangerous to humans. Beginning in 1162, laws passed in England, France, and Germany banned the sale of meat from diseased animals. Some type of inspection system has been in existence ever since (Collins, 1966).

Although the sale of contaminated and unwholesome meat has been an offense in England since Anglo-Saxon times, the first relevant modern acts of Parliament were not passed until 1835. In 1938, regulations

Food and Drugs Act, consolidating previously existing legislation (Collins, 1966).

During the colonial period in the United States meat inspection was rudimentary and of little interest *per se* because the raising of livestock and the marketing of food-animals were entirely local enterprises. Animals slaughtered by local butchers were sold to customers who could identify the product closely with the butcher--and probably even with the farmer who produced the animal (Forrest *et al.*, 1975). As the nation grew, and as transportation systems developed, the physical distance between the producer and the purchaser increased. Interstate commerce in meat developed, and the country began to export meat to Europe.

In the early 1880s, the local press focused public attention on the problems of quality and purity of food products sold for public consumption, and some European countries, which regarded American meat as inedible, began to restrict imports (Libby, 1975).

The federal government enacted the first meat inspection statute, the Meat Inspection Act of 1890 (26 Stat. 414), to restore European confidence in the quality of American beef (Libby, 1975) and to expand the market for American meat by ensuring that exports met European requirements (Olsson and Johnson, 1984). The act provided for limited inspection of meat intended for export and did not concern itself with the state of health of the source-animal. It did not attain its goals, however, since many foreign governments still refused to recognize U.S. inspection certificates (Olsson and Johnson, 1984).

In 1891 and again in 1895, Congress strengthened meat inspection. The Federal Meat Inspection Act (P.L. 59-242) of 1906 called for mandatory inspection of all meat and meat products moving in interstate commerce. The act provided for antemortem and postmortem inspection of cattle, hogs, sheep, and goats, and it established sanitary standards within slaughter and processing facilities. It applied to meat and meat products in all stages of processing and to the surroundings in which livestock were slaughtered as well as the areas in which the meat was processed in the 163 plants under federal inspection at that time.

The New York Live Poultry Commission Association began inspection of live poultry after an outbreak of fowl plague (avian influenza) in 1924 (Libby, 1975), and by 1926 this was taken over by the U.S. Department of Agriculture (Olsson and Johnson, 1984). In 1928, USDA added to its responsibilities the voluntary inspection, for wholesomeness, of poultry and poultry products.

The events that led to the passage of the Federal Meat Inspection Act, its amendments, and its extensions to poultry and quality assurance are summarized in Table 2-1. Although meat inspection in the United States was introduced to protect the nation's interests in exporting meat and meat products to European markets, the act increased pressures within the country to keep contaminated meat out of food

channels and to make sure that slaughter and processing facilities were sanitary. A meat inspection system based on continuous inspection at slaughterhouses eventually developed as a tax-supported federal program.

As the nation became industrialized, the meat and poultry industry, including the pastoral setting of farm animals, changed markedly (Oltjen, 1984). Food-producing animals formerly grazed openly on farmlands, often large, where they were affected by marginal diets, predators, and exposure to the elements. With advances in animal and veterinary science, many infectious diseases were controlled (Schell, 1984), and more healthful and nutritious animal feeds became available. Improvements in animal health led to a severalfold increase in animal production. As food-animals grew faster and as consumers' tastes changed, the age at slaughter was reduced, so that age-related diseases declined even further.

In general, production units have grown larger over time. Modern technology provides vaccines against many infectious diseases as well as growth promoters, hormones, and antibiotics in the feed. While the human health hazards due to most zoonotic diseases have decreased, hazards associated with the crowding of animals and exposure to chemical residues have risen. Public health concerns therefore now include chemical toxicity as well as infectious diseases, including those caused by antibiotic-resistant bacteria (Schell, 1984).

With the increase in some of the food-animal populations, especially after the implementation of the Wholesome Meat Act (P.L. 90-201) of 1967 and the Wholesome Poultry Products Act (P.L. 90-492) of 1968, the number of slaughter and processing plants increased tremendously--from 163 in 1907 to almost 22,000 federal and state plants in 1980. Furthermore, traditional organoleptic inspection procedures (based on sight, touch, or smell) are inadequate to detect chemical and microbial hazards. These factors have necessitated a larger inspection force and more sophisticated inspection procedures, but financial and technical limitations have impeded responses to demands (Booz-Allen, 1977).

New information, new technology, and new health concerns have severely tested the efficiency and adequacy of the present labor-intensive inspection system, which was largely designed at the turn of the century to protect consumers from meat with grossly visible evidence of infectious hazards that were perceived at that time to be problems. Today, eight broad classes of public health risk are of concern in meat and poultry inspection: bacterial infections, bacterial toxins, parasitic infections, fungal toxins, viral infections, chemical residue toxicants, intentional additives, and process-induced toxicants. In response, USDA has had to shift regulatory strategies to improve various phases of the inspection system and take advantage of newer technologies. (For a summary of the implemented or proposed changes in the traditional inspection procedures in slaughter and processing, see Tables 6-1 and 7-1.)

TABLE 2-1 History of Meat and Poultry Inspection in the United States[a]

Time Period	Event or Status of Inspection	Consequence or Situation Regarding Product
Colonial	Rudimentary inspection existed	Farmers and butchers known by consumers
Westward development	Rudimentary inspection continued	Large packing plants built
1880	Press drew attention to poor sanitation and inadequate inspection in the meat industry	Inspection procedures instituted by some packers
1890	Congress passed a law for inspection of meat "in the piece"	Inspection required of meat for exports
1891	Secretary of Agriculture established antemortem inspection	Antemortem inspection required for meat products in interstate commerce
1895	Secretary of Agriculture extended laws to cover interstate transport of meat	Export or transport of condemned carcasses across state lines could be stopped by Secretary of Agriculture
1906	The Jungle published (Sinclair, 1906)	Attention focused on problems in packing-house operations
1906/1907	Federal Meat Inspection Act (P.L. 59-242) passed	Inspection required of all meat intended for interstate and foreign commerce, to include antemortem inspection, postmortem inspection, and inspection at all stages of processing, livestock holding, and meat packing equipment and facilities

1926	Voluntary poultry inspection initiated	Inspection required of all poultry intended for interstate or foreign commerc
1938	On-the-farm slaughter of animals from other premises prohibited (P.L. 75-776)	Commercial slaughter operations restricted to packing plants
1942	P.L. 77-602	Meat and poultry inspection extended to intrastate commerce until 1945
1957	Poultry Products Inspection Act (P.L. 85-172) passed	Antemortem and postmortem inspection required of poultry in interstate commerce and of slaughter and processing facilities
1958	Humane Slaughter Act passed	Humane slaughter required of animals providing products sold to federal agencie
1967	Wholesome Meat Act (P.L. 90-201) passed	Meat inspection extended to products in intrastate commerce by a state-federal cooperative program
1968	Wholesome Poultry Products Act (P.L. 90-492) passed	Inspection of poultry and poultry products required by USDA; poultry inspection extended to intrastate products
1978	Humane Methods of Slaughter Act (P.L. 95-445) passed	Meat Inspection Act of 1906, Humane Slaughter Act of 1958, and Wholesome Meat Act of 1967 amended to require that meat inspected and approved be produced only from from livestock slaughtered in accordance with humane methods
1980	Total Quality Control introduced by USDA	Control initiated in some plants on a voluntary basis

aAdapted from CAST, 1980.

When the Federal Meat Inspection Act was enacted in 1906, the leading cause of human morbidity and mortality in this country was infectious agents; the control of such diseases was, in general, amenable to centralized regulatory programs. Today, the two leading causes of death in humans are circulatory disease and cancer (DHHS, 1984). These changes may have substantial implications for all public health programs.

To date, no criteria have been established to measure scientifically the effects of recent changes in the inspection system on the health of consumers. The Centers for Disease Control has issued reports addressing food-borne outbreaks in general, some traced to meat and poultry sources (Bryan, 1980; see also Table 7-1). Polls taken by the Roper Organization (1983) and the Good Housekeeping Institute (1983) indicate that about 75% of the public believe that the USDA's Food Safety and Inspection Service (FSIS) is doing a "good" to "very good" job, versus 15% who label it fair, 4% poor, and 6% who had no opinion. The General Accounting Office (GAO, 1982; U.S. Comptroller General, 1979, 1981, 1983a,b) has assessed the management, regulation, and compliance aspects of USDA/FSIS and has addressed the issues of state-level inspection inadequacies, sanitation problems within plants, meat import regulations, standards for mechanically separated meat and poultry, and the effectiveness of Food and Drug Administration guidelines in reducing the violative residues monitored by FSIS.

In a recent report, Booz, Allen & Hamilton (1977) evaluated the inspection programs to improve cost-effectiveness and suggested ways to streamline them. Inasmuch as those investigators found little evidence that many of the procedures had measurable public health impact, they believed that some changes could be made without adversely affecting the public health aspects of the meat and poultry inspection system.

Justifiably or not, some of the recent changes in the meat and poultry inspection programs in the United States have been perceived by the public, consumer advocates, and inspection staff in the field as compromising human health and safety (CNI, 1977; Hughes, 1983; Smith, 1983). Their concerns have centered on several issues, including the rate at which slaughtered animals move through inspection, the necessity and efficiency of 100% antemortem and postmortem inspection of groups of animals that seem to be nearly uniformly healthy, the actual health hazard presented by microbial contamination of the meat and poultry supply, and the health effects of low-level contamination of meat and poultry by pesticides, drugs, and environmental contaminants. Some observers are further concerned that USDA has not adopted newer technologies to provide information and feedback that could improve the health of livestock and poultry or to address current health hazards, both microbiological and toxic (NRC, 1984).

It was in the context of these concerns and the debate about public health that the committee was asked by USDA/FSIS to review and evaluate the scientific basis of meat and poultry inspection programs and the

extent of protection from human health risks it provides. The committee's deliberations and conclusions on this key public policy issue are reflected in the remainder of this report.

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3
Public Health Hazards from Biological Agents

Meat-borne and poultry-borne pathogens that can be transmitted to humans pose health hazards to consumers and occupationally exposed persons that the current inspection strategies are not primarily designed to detect (Bryan, 1980; Horwitz and Gangarosa, 1976). Table 3-1 summarizes data on reported food-borne disease outbreaks in the United States for 1968-1980. Table 3-2 classifies the pathogenic microorganisms associated with various meat- and poultry-borne diseases, along with their modes of transmission.

Meat and poultry were implicated in 1,420 of the 2,666 food-borne disease outbreaks reported to the Centers for Disease Control (CDC) from 1968 to 1977 for which a food source was determined (Bryan, 1980). (An outbreak is defined as an incident in which two or more persons experience a similar illness, usually gastrointestinal, after ingesting a common food, which through epidemiological analysis is implicated as the source of illness; for botulism, the illness of one person is considered an outbreak [DHHS, 1983b].) The reported data are likely to represent only a small fraction of the true incidence of food-borne disease in the United States, and short-term trend analysis is therefore uncertain (Hauschild and Bryan, 1980; NRC, 1969).

When a contaminated food product is widely distributed and eaten at different times and places, outbreaks may be difficult to detect. This is particularly true of diseases for which there is no epidemiological marker (e.g., serotyping), so that strains recovered from ill persons and from foods cannot be compared. Outbreaks of Clostridium perfringens enteritis, for example, probably go undetected. And pasteurized foods may still harbor spores that can germinate and multiply if they are subjected to time-temperature abuse. Certain pathogens (e.g., Salmonella, Campylobacter jejuni, and Clostridium perfringens) are spread to carcasses and cuts of meat or to parts of poultry from infected tissues or contaminated surfaces of animals during slaughtering and processing, and they are then conveyed through further-processed raw meat and raw poultry into food-service establishments and homes. Cross-contamination may continue and other foods may become contaminated

TABLE 3-1 Meat- or Poultry-Borne Outbreaks of Known Etiology, United States, 1968-1980[a]

Disease	Beef	Pork	Lamb	Poultry	Other Meat Products	TOTAL	Distribution (%)
Bacillus cereus gastroenteritis or enteritis	2	1		2	1	6	0.7
Botulism	6	1		3	10	20	2.4
Campylobacter jejuni enteritis or enterocolitis				1	1	2	0.2
Clostridium perfringens enteritis	100	9	2	40	17	168	20.2
Escherichia coli diarrhea	2					2	0.2
Hepatitis A diarrhea		1			2	3	0.4
Salmonellosis	63	34		85	16	198	23.8
Shigellosis				3	2	5	0.6
Staphylococcal intoxication	37	163	2	67	24	293	35.2
Toxoplasmosis	1					1	0.1
Trichinosis	10	102			11	123	14.8
TOTAL	221	311	4	201	84	821	100.0
% of TOTAL	27	38	1	24	10	100	

[a]Data from Bryan, 1980; DHHS, 1981a,b, 1983a.

TABLE 3-2 Classification of Worldwide Meat-borne and Poultry-borne Microbial Pathogens According to Modes of Transmission

Pathogenic microorganisms transmissible to humans by ingestion of raw or undercooked meat and poultry:

Bacillus anthracis
Balantidium coli
Campylobacter coli
Campylobacter fetus subsp. fetus
Campylobacter jejuni
Escherichia coli
Francisella tularensis
Salmonella
Sarcocystis spp.
Taenia saginata
Taenia solium
Toxoplasma gondii
Trichinella spiralis
Yersinia enterocolitica
Yersinia pseudotuberculosis

Pathogenic microorganisms transmissible to humans by ingestion of cooked or otherwise heat-processed meat or poultry that became contaminated after the heat processing or that was improperly stored after initial heat processing:

Any of the above
Bacillus cereus
Clostridium botulinum
Clostridium perfringens
Shigella spp.
Staphylococcus aureus
Streptococcus pyogenes

Pathogenic microorganisms transmissible by contact with animal tissue or by inhalation of aerosols or dust from animals:

Bacillus anthracis
Brucella
Chlamydia psittaci
Cowpox virus
Coxiella burnetii
Erysipelothrix rhusiopathiae
Francisella tularensis
Leptospira
Listeria monocytogenes
Newcastle virus
Pseudomonas mallei
Streptococcus pyogenes
Toxoplasma gondii

Other bacteria sometimes on meat and poultry that have been reported to be pathogens but for which proof is lacking that meat and poultry are vehicles:

Aeromonas
Bacillus licheniformis
Citrobacter
Klebsiella
Plesiomonas shigelloides
Proteus
Providencia
Streptococcus faecalis
Streptococcus faecium

perfringens and Bacillus cereus, are spore-formers; they can survive cooking and can then germinate and multiply if the foods they commonly contaminate are subsequently mishandled.

Although the final abuse that leads to outbreaks mostly occurs after the food has been processed, many outbreaks would not have ensued if the pathogen were not already on the meat or poultry after slaughtering or processing. Outbreaks rarely result from direct inoculation of contaminants by food handlers at the point of preparation or serving. Thus, slaughtering plants and meat and poultry processors must share some of the responsibility for outbreaks that occur both in homes and food processing establishments. Yet the contaminating microorganisms enter the slaughtering plants in or on the live animals, and no inspection procedures are specifically directed toward these organisms.

INFECTIOUS AGENTS AND MODES OF TRANSMISSION

Illnesses due to infectious agents from food-animals can be divided into three major groups: enteric diseases from agents that reside in the digestive tract of food-animals; extraintestinal illnesses from food-borne infectious agents; and diseases transmitted to workers by handling food-animals and animal products (occupational diseases).

Enteric Agents

Enteric bacterial infectious agents are primarily health hazards for the consuming public; less commonly, they are occupational hazards in the meat packing industry. The major agents are Salmonella, Campylobacter spp., and Clostridium perfringens (Bryan, 1980).

Salmonella remains a major health problem and economic burden. Trends in reported cases of salmonellosis among the general public are shown in Figure 3-1. As indicated, the number of reported isolates of Salmonella from human beings in the United States has increased in the past 20 years, reaching 44,250 reported isolates in 1983 (DHHS, 1983c). Of the 568 outbreaks of food-borne diseases reported to CDC in 1981, 250 had a confirmed etiology; Salmonella was the single most frequent cause, accounting for 66 (26.4%) of the outbreaks (DHHS, 1983b). These 66 outbreaks were reported to have affected 2,456 persons, 11 of whom died. (Preliminary data for 1982 indicate a similar pattern of etiology.) A previous study of 500 outbreaks of salmonellosis that occurred from 1966 to 1975 showed that meat and poultry sources accounted for 30% (DHEW, 1977).

Studies of the ecology of Salmonella clearly establish the animals (genetic stock), feed and feed ingredients, and environmental sources as critical points at which to control for the hazard of Salmonella during livestock and poultry production (Barnum, 1977; Bryan et al., 1976; NRC, 1969). As with all the other enteric bacteria, monitoring

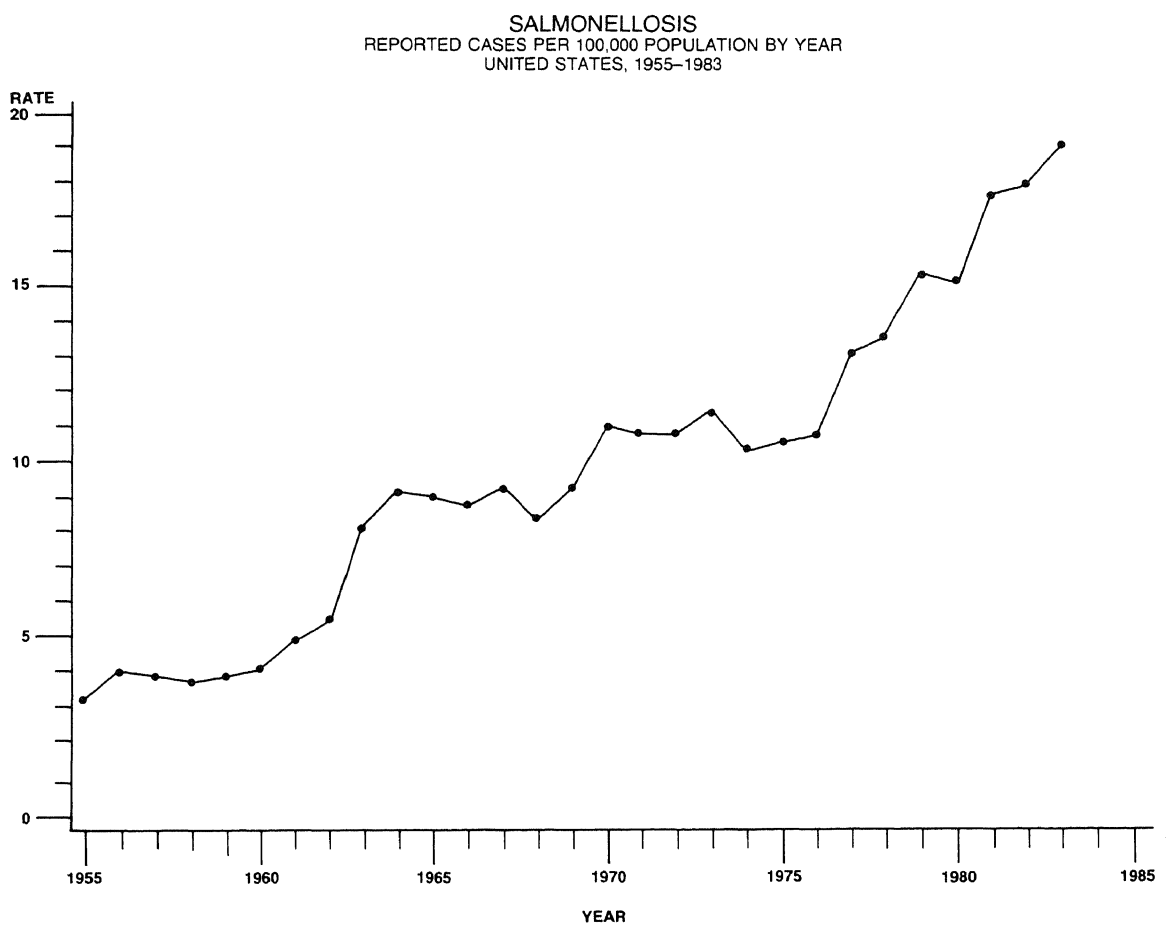

FIGURE 3-1 Salmonellosis (excluding typhoid fever)--reported cases per 100,000 population, by year, United States, 1955-1983. From CDC, 1984.

the public-health-related critical control points during the slaughter process involves careful cleaning and removal of external surfaces (skin, feathers) and especially the digestive tract to prevent contamination of edible tissues. Even salmonellae not adapted to hosts can cause clinically apparent disease in livestock and poultry, including septicemia and acute or chronic enteritis, but most infections of slaughter-age animals are subclinical (Blood et al., 1983). Thus antemortem inspection is of little value in identifying and removing infected animals from the human food supply. Prevention of fecal contamination of edible tissues is a critical control point in the programs of the Food Safety and Inspection Service (FSIS) for preventing enteric disease.

Because antimicrobial-resistant salmonellae account for a steadily increasing proportion of salmonellosis in the United States, and

because most outbreaks of resistant salmonellosis are traced to food-animal sources (Holmberg et al., 1984), the importance of reducing the Salmonella burden in the U.S. meat supply has become increasingly obvious. Clearly, current antemortem and postmortem inspection practices to identify salmonellae are less than adequate.

From 1980 to 1982, meat and poultry accounted for 4 out of 23 outbreaks of food-borne campylobacteriosis reported to CDC, second only to unpasteurized milk as a source of Campylobacter jejuni in the United States (Finch and Blake, 1984). A recent study in the Seattle/King County area of Washington identified consumption of poultry as a significant risk factor for acquiring infection by C. jejuni (Seattle-King County Department of Public Health, 1984). In hospital-based studies of diarrheal disease in humans, C. jejuni has surpassed Salmonella as the most commonly isolated bacterial enteric pathogen (Blaser et al., 1979, 1983). Because surveillance of campylobacteriosis is in its infancy and routine reporting of this disease is not yet required, data on disease prevalence among the public cannot be used to study trends or to assess the impact of meat inspection on public health.

C. jejuni appears to be a cause of hepatitis in poultry and may be a cause of diarrhea in many domestic species and of mastitis in cows (Campbell and Cookingham, 1978; Firehammer and Myers, 1981; Garcia et al., 1983; Lander and Gill, 1979; Logan et al., 1982). Many reports identify large numbers of healthy carriers among food-animals (Butzler and Skirrow, 1979; Garcia et al., 1983; Grant et al., 1980; Munroe et al., 1983). For example, up to 40% of healthy cattle have enteric cultures positive for Campylobacter spp. (Martin et al., 1983). C. jejuni has been isolated from between 2% and 85% of consumer-ready poultry (Christopher et al., 1982; Doyle, 1981; Kinde et al., 1983; Leuchtefeld and Wang, 1981; Simmons and Gibbs, 1979; Smith and Muldoon, 1974). C. jejuni is less of a public health hazard than it might be because the microorganisms tend not to multiply in food at room temperatures (Skirrow, 1982), although it can survive on chilled carcasses for months (Oosterom et al., 1983). Since antemortem and postmortem inspection can rarely identify Campylobacter spp.-infected food-animals, prevention of carcass contamination by fecal matter is a critical control point, as it is for salmonellosis.

From 1968 to 1977, Clostridium perfringens caused 139 of the 250 outbreaks reported to CDC (Bryan, 1980). Food-borne surveillance data for 1981 indicate that there were 185 outbreaks with confirmed bacterial etiology (DHHS, 1983b); C. perfringens caused 11% of the reported outbreaks and 1,162 illnesses. Clinical signs of illness in domestic animals and grossly visible lesions are not features of intestinal carriage of these organisms, so a major function of meat inspection regarding this enteric disease, as for Salmonella and Campylobacter spp., is to prevent fecal contamination of edible tissues.

Outbreaks involving Escherichia coli are less likely to be confirmed than are those involving Salmonella, Campylobacter spp., or Clostridium perfringens, because E. coli is often not considered in clinical, epidemiological, and laboratory investigations (DHHS, 1983b). In 1982, however, two outbreaks of food-borne disease due to infection by E. coli were identified, due to the unusual nature of the clinical disease and serotype of E. coli (Riley et al., 1983). In these outbreaks, E. coli was isolated from patient stools and from the epidemiologically associated ground beef, and the outbreaks were attributed to undercooked hamburger. Although it was previously known that E. coli could be transmitted by food (Merson et al., 1980), serotypes of E. coli not known to be enterotoxigenic or invasive were not investigated until these outbreaks occurred, because E. coli commonly present in food are nonpathogenic.

The possible development of antibiotic-resistant strains of bacteria resulting from these feed additives and the subsequent transfer of such resistant bacteria to humans are matters of public health concern (Levy, 1984; Meister and Greenberg, 1983). It has been shown that feeding subtherapeutic levels of antibiotics to food-producing animals can promote development of bacteria resistant to antimicrobials. Bacterial resistance to tetracycline was increased in feedlot heifers given subtherapeutic quantities of chlortetracycline in their diet (Stabler et al., 1982), and prolonged excretion of resistant coliforms has been documented in swine fed a number of antimicrobials in subtherapeutic amounts (Langlois et al., 1978a,b). In a study of Salmonella isolates from food-producing animals in 1973, for example, 70% of the isolates were found to be resistant to at least 1 of 11 antimicrobials tested, and resistance patterns of Salmonella isolates from animals were noted to be similar to those demonstrated for isolates from humans (Neu et al., 1975). A more recent study documented multiple drug resistance in 80% of 3,500 isolates of Salmonella from food-producing animals (Blackburn et al., 1984).

If resistant bacteria do occur in the intestinal tract of food-producing animals, and if the antimicrobial resistance of the intestinal flora is increased by feeding subtherapeutic amounts of antibiotics to these animals, can the resistant bacteria isolated from humans have a food-animal source? Experimental data demonstrate that direct contact with chickens infected by antibiotic-resistant Escherichia coli (Levy et al., 1976) and contact with contaminated poultry carcasses, as in food preparation (Linton et al., 1977), resulted in the spread of resistant bacteria to humans. There are also epidemiological observations suggesting that meat and poultry can be sources of antimicrobial-resistant Salmonella infections in humans (Holmberg et al., 1984a). An investigation of a four-state outbreak of multiply resistant Salmonella newport provided strong circumstantial evidence of resistant bacteria carried to consumers from food-producing animals fed subtherapeutic antibiotics (Holmberg et al., 1984b).

The investigation of the S. newport outbreak also demonstrated the inherent difficulty in documenting retrospectively the animal source of bacteria when investigating an outbreak of illness in humans. Although each step in the transmission of enteric flora from animals to the digestive tract of humans has been studied, documenting all the links in the chain in a single investigation is usually difficult, and often impossible. The presence of Salmonella in ground beef cannot be documented after all the beef has been consumed, nor can the levels of antibiotics fed be defined precisely when no records are kept. The difficulties of conducting an ethically acceptable experimental prospective study have been noted (Stallones, 1982) by the chairman of the National Research Council committee that studied the effects on human health of the subtherapeutic use of antimicrobials in animal feeds (NRC, 1980).

Extraintestinal Agents

Extraintestinal agents include Trichinella spiralis, Cysticercus spp., Clostridium botulinum, Staphylococcus aureus, and Toxoplasma gondii. Diseases such as shigellosis and hepatitis A have human reservoirs; they are transmitted through contamination of foods by human feces. Epidemiological, clinical, and laboratory studies suggest that viruses and rickettsia that might cause significant outbreaks of human disease can be transmitted through food. In the United States, however, there is no evidence that meat and poultry production are vehicles for these agents (Blackwell, 1980, 1984; Blackwell et al., in press; DHEW, 1965).

There have been several reports of food-borne transmission of toxoplasmosis (CDC, 1975; Desmonts, 1965; Kean, 1969; Masur, 1978), a disease commonly caused by the protozoan parasite Toxoplasma gondii. The population samples were quite small, however, and information on the source of the infectious agent was frequently lacking. Studies have shown that there is a greater prevalence of antibodies against Toxoplasma gondii in meat handlers than in controls (Beverley et al., 1954; Price, 1969), and these persons may therefore be at a greater risk of infection than the general population. Because of the life cycle and pathogenesis of T. gondii, the risk to public health can be mimimized by protecting livestock from cat feces during production.

Trichinosis has long been recognized as a meat-borne hazard. It now infects an estimated 0.1% of hogs in the United States, although it was previously more prevalent (Leighty, 1974). In humans, it has been associated with ingestion of undercooked pork, including hamburger and ground lamb contaminated with pork (CDC, 1980, 1982a; Potter et al., 1976). One hundred of the 689 meat-borne and poultry-borne outbreaks with known etiology reported to CDC from 1968 to 1977 were due to Trichinella spiralis (Bryan, 1980). The incidence of trichinosis in the United States is likely to remain stable or to decline if consumers continue to be educated about hazards associated with undercooked pork and pork products.

Cysticercosis--somatic infection by Taenia solium (pork tapeworm)--is uncommon in people born in the United States but it is found in immigrants from Latin America and parts of Southeast Asia and Africa (Hird and Pullen, 1979). After encysted raw or inadequately cooked pork is eaten, eggs hatch in the small intestine of a human and larvae can migrate to distant sites, causing a potentially fatal illness. Tapeworm eggs can further be spread to other people or to swine by exposure to the feces of a person harboring an adult worm. By preventing swine access to human feces, T. solium transmission has been essentially eliminated in the United States in this century (Hird and Pullen, 1979). In fiscal year 1984, of 80 million swine slaughtered only 4 were condemned for Cysticercus cellulosae infection.

Cysticercosis due to Taenia saginata in beef (beef measles) continues to be a problem in industrial countries such as the United States. This infection is seen primarily in feedlot cattle in the Southwest. It should not be viewed as a strictly regional problem, however, due to the movement of animals and meat within the country. Incisions into muscles followed by visual observation of cysticerci in slaughtered animals by meat inspectors is the most practical and widely used method of detection presently available. Muscles of mastication and the heart are probably prime targets for T. saginata cysticercosis. Postmortem inspection for detection of T. saginata cysticercosis lacks sensitivity. For example, cattle frequently harbor only a few cysticerci, and current inspection procedures may miss many light infections (Hird and Pullen, 1979). In fiscal year 1983, out of 36 million cattle inspected, 86 were condemned for Cysticercus bovis infection and 6,226 less severely affected carcasses were passed for freezing.

From 1977 to 1981, there were 131 outbreaks of staphylococcal food poisoning reported to CDC, involving 7,126 persons (Holmberg and Blake, 1984). Most often, outbreaks are attributed to a cooked, high-protein food that is contaminated during handling and then left at room temperature for too long (Bergdall, 1979; Bryan, 1978; Merson et al., 1980). Prevention of much staphylococcal food poisoning can best be achieved through good consumer and food-handler education.

Occupational Infectious Diseases

Slaughterhouse employees and inspectors represent a small proportion of the general population in the United States. The diseases that can be associated with these occupations may occur as outbreaks (e.g., of brucellosis and psittacosis) or as sporadic cases (e.g., of erysipeloid, streptococcosis, or leptospirosis) in persons exposed to meat and poultry production, slaughter, and processing environments. Contagious pustular dermatitis (e.g., ecthyma contagiosum or orf) and superficial mycoses occur among packing plant workers; outbreaks of Q-fever have been reported in rendering plant employees and the disease can occur in meat packers (Topping et al., 1947). Toxoplasmosis, salmonellosis, campylobacteriosis, and dermal

infections by streptococci (Clifton-Hadley, 1983) and other bacteria (CDC, 1977; Public Health Laboratory Service, 1983) can also be occupationally acquired. Some low-prevalence diseases, such as anthrax, listeriosis, and rabies, are of less concern in this country, but their diagnostic clinical presentation and the lack of grossly visible lesions are useful to demonstrate the value of proper antemortem inspection.

Brucellosis is a zoonotic infection transmitted by direct contact with diseased animals, aerosol exposure, conjunctival exposure, or ingestion of contaminated material (Buchanan et al., 1974; Kaufmann et al., 1980). The brucellosis eradication program, with its dependence on slaughtering infected livestock, has transformed brucellosis from a community-based disease to an occupational illness of slaughterhouse employees, a situation that is likely to persist until brucellosis is eradicated from cattle and hogs. Of the 2,302 cases of brucellosis reported in the United States from 1965 to 1974, 1,073 (52%) occurred in employees of the meat processing industry (Fox and Kaufmann, 1977).

Chlamydia psittaci can be transmitted to humans by direct contact with infected poultry or by inhalation of dust from their droppings (Schachter and Dawson, 1978). In 1983, there were 142 cases of psittacosis reported to CDC (CDC, 1984). From 1975 to 1977, 26 (12%) of the 219 reported patients in the United States for whom occupation was known were employees of turkey slaughtering plants. Cases tend to occur in widely separated outbreaks, and control of psittacosis in turkeys and turkey processors has been difficult to achieve (Anderson et al., 1978; CDC, 1982b; Durfee et al., 1975). Since gross lesions of psittacosis in turkeys resemble those of many other septicemias, they are difficult to identify with certainty.

MINIMIZING RISKS AFTER MEAT AND POULTRY ARE PROCESSED

Additional risks to public health can exist after meat and poultry products are shipped from processing plants. Carcasses and bulk items may be subjected to contamination in transit or in storage facilities, although this is rarely a problem for packaged products because their integrity is protected. Temperature abuse, however, is a more serious problem. Chilled and processed meat and poultry products that are not shelf-stable will eventually spoil. In retail outlets (e.g., butcher shops, grocery stores, or meat departments of supermarkets), raw meat and raw poultry are important sources of Salmonella, Campylobacter jejuni, Yersinia enterocolitica, Clostridium perfringens, and Staphylococcus aureus. Cross-contamination is likely to occur among raw items and perhaps between raw and cooked foods if rotisseries or deli operations are nearby.

Further cross-contamination occurs as raw foods bring pathogens into food-service establishments and homes (DeWit et al., 1979). These pathogens are spread by workers who handle raw and then cooked foods,

or by equipment used or cleaning cloths that go from raw to cooked products.

The major contributing factors to outbreaks of food-borne diseases in food-service establishments and homes are leaving cooked foods at room temperature, storing cooked foods in large containers during refrigerated storage, and preparing food a day or more before serving it (Bryan, 1978, 1980). Other frequently identified contributory factors are inadequate cooking, inadequate reheating, improper hot holding, contamination by colonized (infected) persons, and cross-contamination and inadequate cleaning of equipment (e.g., cutting boards, knives, slicers, grinders, table tops, and storage pans). A summary of the epidemiological data on factors that contribute to outbreaks of meat- and poultry-borne diseases is given in Table 3-3.

The precautions that can be taken to avoid these hazards include:

- washing hands after handling raw meat and raw poultry or when returning to work stations;
- being aware of cross-contamination from raw meat and raw poultry via hands, utensils, equipment, table tops, sponges, and cleaning cloths;
- cooking poultry and meat thoroughly;
- not keeping cooked meat and poultry at room temperature for long periods;
- cooling rapidly in shallow containers any leftovers and any food prepared for consumption on subsequent days; and
- reheating any leftovers thoroughly.

This information may be conveyed through the mass media, consumer groups, extension services, and schools. The committee recognizes that the U.S. Department of Agriculture (USDA) already has programs for educating the public, and it encourages the agency to continue and intensify its efforts in this area.

In addition to inspection and to identifying and monitoring critical control points, several measures can be taken to minimize public health hazards and spoilage risks. Although the details of these measures are beyond the charge of this committee, they are briefly mentioned because, along with inspection, they are essential to food safety.

Surveillance is an indispensable part of every successful disease control program. Food-borne disease surveillance consists of seeking

notification of illness, identifying and investigating outbreaks, interpreting investigative data, and disseminating findings (Bryan et al., 1976). The primary purpose of surveillance is to provide a basis for recommending actions to identify and control existing outbreaks and establish procedures to prevent future ones. In time, surveillance data become the basis for implicating principal vehicles of transmission and identifying the primary factors that contribute to the occurrence of outbreaks. These epidemiological data can be used to design control measures, identify critical control points, and set program priorities.

Microbiological and chemical analyses of samples of ingredients and materials, final products, and swabs of equipment surfaces can assist in assessing hazards, establishing and monitoring critical control points, and determining adherance to good manufacturing, handling, cleaning, and distribution practices. Rapid diagnostic procedures have been developed to identify various microbial agents (Firstenberg-Eden,

TABLE 3-3 Factors that Contributed to Outbreaks of Meat-Borne and Poultry-Borne Diseases, 1968-1977[a]

Contributing Factor	Confirmed	Suspected	Total	Outbreaks with Deficiency[b] (%)
Improper cooling of cooked foods	30	12	42	48
Prepared a day or more before serving	30	0	30	34
Inadequate cooking or thermal processing	14	10	24	27
Infected person touching cooked food	16	4	20	23
Inadequate reheating of cooked and chilled foods	18	0	18	20
Improper hot storage of cooked foods	16	1	17	19
Cross-contamination of cooked foods by raw foods	9	4	13	15
Inadequate cleaning of equipment	9	1	10	11
Ingesting raw products	4	3	7	8
Use of leftovers	3	0	3	3
Improper fermentation	1	0	1	1
Improper thawing of cooked foods	1	0	1	1
Inadequate processing/preparation space	1	0	1	1
Abscess on meat	1	0	1	1
Feeding animals mercury-treated grain	1	0	1	1
Eating animals that were sick or dying at slaughter	1	0	1	1

[a]From Bryan, 1980.
[b]Total exceeds 100 because more than one deficiency was frequently found.

1983; Olgaard, 1977; Seawright et al., 1981; van Schothorst and Oosterom, 1984) and criteria for certain microorganisms in some foods have been established or recommended (ICMSF, 1974). The value and use of microbiological criteria for foods are the subjects of another National Research Council report (NRC, 1984).

Microbiological hazards in foods that have passed inspection have been well documented. In terms of acute disease, food-borne infections and intoxication appear to pose greater health hazards than foods contaminated by pesticide residues, food additives, chemical toxicants, and natural toxic substances (WHO/ICMSF, 1982). In part, this relates to the fact that some microbiological contaminants have the ability to multiply in foods. However, just as the lag time (incubation period) of a few days between ingestion of food and the onset of an infectious food-borne disease makes it difficult to implicate a food as the vehicle in a specific event, the much greater lag time (latency period) before the expression of chronic disease after ingestion of a toxicant makes documentation of this association very complex.

SUMMARY AND RECOMMENDATIONS

Salmonella infections remain a major health problem and an economic burden. A considerable number of food-borne outbreaks of salmonellosis stem from the consumption of contaminated meat and poultry products, and these accounted for 30% of the Salmonella-related outbreaks from 1966 to 1975.

Salmonella and other enteric bacterial pathogens, such as Campylobacter jejuni, Clostridium perfringens, and Escherichia coli, originate in the digestive tract and fecal material of the slaughtered animal; inappropriate or ineffective slaughter procedures result in the contamination of the surfaces of meat and poultry products with these infectious agents. Infectious agents of nonenteric origin that have been implicated in food-borne diseases of meat and poultry origin include Toxoplasma gondii, Trichinella spiralis, Cysticercus spp., and Clostridium botulinum. Toxins from molds and other microorganisms, such as aflatoxin B_1, also have potential health implications for the consumer of meat and poultry products. Minimizing or eliminating potentially infectious enteric bacteria can be achieved by careful cleaning and removal of the external surfaces (skin, hair, feathers) of the slaughtered animal, and removal of digestive tracts in such a manner as to prevent contamination of edible tissues. Another important consideration is the cross-contamination of infectious agents from raw meat and poultry products to other foods in the home or in commercial kitchens.

Procedures on safely handling and processing meat and poultry products in the kitchen are well established and should be reemphasized to the public through appropriate educational vehicles. Among these procedures is the proper cooking of pork and pork products at the appropriate time and temperature to destroy the Trichinella organism, a

procedure that needs to be reinforced. Unless techniques are used in the United States to determine the presence of Trichinella spiralis in pork, pork products should be cooked thoroughly in order to prevent trichinosis.

Other points of consideration with regard to food-borne infectious agents of biological origin include the fact that the presence of pathogens in an animal cannot be detected by the usual organoleptic inspection procedures. Some diseased animals might be identified during antemortem inspection, but the detection becomes more unlikely after an animal has been slaughtered. The presence of infectious agents might be detected in the carcass, however, by rapid, immunologically based tests. Another concern is that microbial organisms contaminating meat and poultry products, unlike chemical residues, can multiply to increase the probability of disease. Thus proper handling, processing, and storage are required to inhibit bacterial growth or to destroy infective organisms. Surveillance of outbreaks is of utmost importance in order to determine, if possible, the causative agent responsible for an outbreak, the principal vehicle of transmission, and the factors that contributed to the outbreak.

In addition to worrying about the health of the consumer, there is also concern about diseases that can be acquired by employees and inspectors of slaughter and processing plants. These occupational diseases occur in low incidence but are obviously of importance. Outbreaks and sporadic cases in exposed individuals have occurred.

The committee recognizes that Salmonella and Campylobacter spp. are major causative agents of diseases transmissible through the consumption of meat and poultry products, but it concludes that it is virtually impossible to detect these organisms with current inspection methods. Moreover, it realizes that the USDA is both aware of and concerned about this problem and recommends that the agency intensify its efforts to implement procedures (see Chapters 5, 6, and 7) that reduce contamination by these microorganisms and destroy them during processing. Other organisms that constitute food-borne pathogens should be similarly reduced. Since some of the biological hazards that have been discussed do not constitute a major risk to public health because of low exposure or infrequent occurrence, the committee has not made specific recommendations for them. Furthermore, reliable information regarding the public health hazard from exposure to biological hazards such as mycotoxins is not available.

- The public and food-industry workers should be provided with information about hazards associated with improper handling of meat and poultry and practical measures to prevent these hazards. The committee encourages USDA to expand its public education efforts and to continue preparing packets of information (e.g., literature, films, and slides) for teachers and educational institutions, health care providers, extension services, and the general public.

- The committee recommends that FSIS expand its use of epidemiology as a tool for internal review and for evaluating the public health impact of changes in meat and poultry inspection programs. Observations made during antemortem and postmortem inspections should be tabulated, collated, and computerized to make them available to local veterinarians, health authorities, extension services, farm groups, and USDA epidemiologists. Information confirming diagnoses based on specimens submitted from slaughter establishments should be provided to the epidemiologist from the pathology, microbiology, and toxicology units so the data will be presented in an epidemiologically relevant manner. Epidemiologists are in a unique position to coordinate the activities of other disciplines within the science staff of USDA and to improve the usefulness of their activities.

- FSIS should review the available rapid diagnostic procedures that identify various microbial agents and evaluate their applicability to meat and poultry inspection programs.

Further recommendations that relate to control of biological agents are cited at the end of Chapter 7.

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4
Management of Chemical Hazards in Meat and Poultry

Since the end of World War II, there have been revolutionary developments in synthetic organic chemistry. As of spring 1985, the U.S. Environmental Protection Agency (EPA) had a list of 60,000 marketed chemicals, and new compounds can be expected to be added at the current rate of 1,200 each year (McCormick, 1985). Many of these enter our environment through use and disposal (Druley and Ordway, 1977).

This chemical revolution has produced fundamental changes in major sections of the U.S. economy, including agriculture and food processing, and has brought significant benefits to the American consumer in terms of low-cost, high-quality food--but not without its own costs. Although the nation's problems with chemical waste disposal and handling are not new, they have become more severe each year. Since the publication of Silent Spring (Carson, 1962), Americans have been greatly concerned about the presence of chemicals in their environment and food supply. To the extent that the raw material for U.S. meat and poultry is exposed both intentionally and accidentally to chemicals during processing and through contact with the air, water, and soil, the food supply provides a complex pathway for many different compounds.

In 1976, the National Institute of Environmental Health Sciences (NIEHS) noted that "the chemical entities comprising those constituents of foods that are pertinent to food safety encompass a wide spectrum of substances that are introduced into foods through a number of routes. Such substances can be categorized into two groups: (1) those present as naturally occurring components or contaminants; and (2) those added by man in the course of food manufacture or preparation" (DHEW, 1976). The second category is most important for the purposes of this report, because it includes substances that are intentionally added or that accidentally enter foods during production or processing. Among these are residues from seed, soil, or crop treatment as well as residues from the treatment of animals or from feed additives. The NIEHS report went on to note that "the breadth of this field makes it difficult to single out individual substances or even groups of related substances

CHEMICAL HAZARDS: SOME EXAMPLES

This section illustrates how chemicals can affect the nation's supply of meat and poultry, but it does not present a comprehensive review. The examples show the wide variety of chemicals (agricultural, environmental, pharmaceutical, and processing-related) that are potential public health hazards. They are arranged by major source or pathway by which the chemical may enter meat or poultry, but many chemicals (or groups) are not limited to one primary source or pathway. Pesticides, for example, might have been classified as agricultural or environmental. The committee chose this system of arranging these examples in order to provide some overview of the complex relationships between agricultural production, industrial processing, and other sources of chemicals that find their way into meat and poultry. These examples also show that the presence of chemicals in meat and poultry may be intentional (as in feed additives, growth promotants, or preservatives) or accidental (such as halogenated biphenyls, pesticides, or metals and metalloids) (DHHS, 1984; NRC, 1973; Preussmann, 1978).

Production-Related Chemicals

Agricultural Chemicals. Livestock can be exposed to many chemicals, which are used to promote or permit growth, improve feed utilization, promote rumen efficiency, control reproductive cycles, control pests, enhance feed acceptability, extend feed quantity, extend feed shelf life, prevent or treat disease, or enhance end-product acceptability. Many of these chemicals have received considerable public attention because of reported residues in meat and poultry. The public health implications of all such compounds warrant continuing evaluation and monitoring (Booth, 1982; Doull et al., 1980; Doyle and Spaulding, 1978; ILSI, 1984; NRC, 1974, 1981; OTA, 1979).

Two decades ago, the agricultural chemical of greatest concern to the public was diethylstilbestrol (DES), a synthetic estrogen used to promote weight gain in cattle. This became the focus of attention when residues of DES were occasionally detected in beef livers. DES is now known to be both carcinogenic and associated with reproductive disorders in humans when administered in high doses (CAST, 1977), and its use to promote weight gains in livestock has been banned in the United States.

Livestock feed can be a source of pesticide residue in meat and poultry. Some chlorinated hydrocarbons (CHCs), which are no longer permitted for unrestricted use on crops in the United States, may be environmentally persistent and a source of concern for public health. The National Residue Program (NRP) currently maintains surveillance of both domestic and imported meat and poultry for CHCs such as aldrin, benzene hexachloride, chlordane, dichlorodiphenyltrichloroethane (DDT), dieldrin, endrin, heptachlor, methoxychlor, and toxaphene. For a vast array of organophosphates, carbamates, and other synthetic pesticides

widely used in crop production (which are, in turn, used during meat and poultry production), residue tolerance levels in food have been established under Section 408 of the Federal Food, Drug, and Cosmetic Act (Ackerman, 1980; Barstad, 1978; Davison and Sell, 1972; Frank et al., 1978; Joint FAO/WHO Committee, 1976; USDA, 1984, 1985).

Environmental Chemicals. Health effects from the accidental contamination of the environment by chemicals are of increasing interest (Booth, 1982; Burrows, 1981; Cousins et al., 1973; Doyle, 1979; Jelliffe and Jelliffe, 1982; Oehme, 1979; Roberts, 1981; Russell, 1978; U.S. Congress, 1979). Polychlorinated biphenyls (PCBs), for example, were used in the manufacture of a variety of products before their long-term environmental impact was recognized. PCBs now appear to be part of the global ecosystem. By 1979, they were no longer manufactured or used in the United States (Drotman et al., 1983; Jones et al., 1975; Khan and Stanton, 1981; Kimbrough, 1980; Osheim et al., 1982; Safe, 1982). Because they are persistent and highly lipophilic, however, PCB residues are still routinely detected in the fatty tissues of humans, livestock, wildlife, and fish as well as in human milk.

The committee examined some case histories of environmental chemicals in meat and poultry, including PCB contamination through fatty animal by-products added to feed in the western United States in the summmer of 1979 (USDA, 1980), the contamination of turkey products with chemical residues in the state of Washington during 1979 (USDA, 1980), and polybrominated biphenyl contaminations in Michigan (Sleight, 1979). In each of these cases, contamination occurred on the farm and therefore out of the jurisdiction of FSIS. Thus, it was impossible for the inspection system to control through traditional procedures. The experience with PCB has taught us that before the use of industrial compounds is permitted, the compounds should be rigorously evaluated for public health and environmental effects, even if major human exposure is not expected or intended (Fazio and Howard, 1983; Hansen, 1979).

Mycotoxins, a class of toxic products of molds, are natural contaminants of food or feed. The most studied, and possibly most significant, of the food- and feed-borne mycotoxins is aflatoxin B_1. It is unlikely that significant amounts of aflatoxin B_1 are transferred into the human food chain from residues in animal tissues, because mature, nonlactating animals are effective mycotoxin modifiers and eliminators and because the aflatoxin content of feed grains is monitored in the United States.

In addition to aflatoxin, mycotoxins of public health concern include ochratoxin A, zearalenone, patulin, penicillic acid, and trichothecenes. Swine and poultry are susceptible to the nephrotoxic action of ochratoxin A, and residues have been found in swine tissue in Denmark, Sweden, and Yugoslavia. Affected animals exhibit gross renal changes easily detectable at postmortem inspection. Danish health authorities have established a system for ochratoxin analysis of all

suspect pig kidneys at slaughter. They require condemnation of the entire carcass if ochratoxin is detected. The frequency and levels of mycotoxins in some imported meat and poultry products may be higher than those of products produced in the United States. Monitoring for potentially toxic derivatives of mycotoxins is not routinely conducted in the United States (Rodricks et al., 1977; NRC, 1979).

Lead is a cause of accidental poisoning of food-animals. Sources of lead include feed, fuels, discarded lead-acid batteries, and lead-based paints. Most known cases occur on small farms and ranches. Lead is accumulated and stored mainly in the bone, liver, kidney, and, to a lesser degree, muscle. If bone chips containing lead are accidentally incorporated into processed meats, they could be a source of contamination (Edwards and Wiedemann, 1980; Fick et al., 1976; Oehme, 1978).

Pharmaceuticals. Veterinary pharmaceuticals may be administered on a one-time basis, for several days, or for longer periods. During the production of meat and poultry, the shorter periods of administration are generally for therapeutic purposes (as medication), whereas longer use, often at subtherapeutic dosages, is intended to improve production or prevent disease. The producer or veterinarian is responsible for determining the proper dosage and for discontinuing the drugs an appropriate interval before the animal is slaughtered. This withdrawal period has been established by the Food and Drug Administration (FDA) for each pharmaceutical to ensure that residues or derivatives in food do not exceed specified levels.

It is difficult to obtain accurate data on the use of antibiotics for subtherapeutic feeding of livestock, but there seems to be considerable variation across the industry. Various sources have reported that between 9 million (Schell, 1984) and 15 million (Toufexis, 1984) pounds of antibiotics are added to the feed of farm animals in the United States each year in order to enhance productivity. To various degrees the practice affects dairy calves, dairy cows, nursery pigs, growing hogs, calves, stocker cattle, feedlot cattle, and poultry. The industry generally believes that subtherapeutic levels of antibiotics in the feed are essential to prevent economic losses under current husbandry practices. It is often difficult to determine the precise antibiotic history for a particular animal because of inaccuracy in the reporting of concentrations added to feed when the mixing procedure is performed by the feeder. The serious public health concern posed by the possible development and transfer of antibiotic-resistant strains of bacteria to humans is discussed in Chapter 3.

Processing-Related Chemical Contamination

Concern for public health is an important consideration in the design of new meat and poultry processing procedures and is often a motivating factor for the adoption of sound manufacturing practices by

reputable processors. Aesthetics is a second priority. The impression of some consumers that the food industry pays insufficient attention to safety may stem from the absence of sanctioned criteria against which safety can be objectively measured. Moreover, there has been concern that the public health implications of chemicals added during processing may be overlooked in the fierce marketplace competition generated by the avalanche of new products (Ayres and Kirschman, 1981; Graham, 1980; Greig, 1984; Harris and Karmas, 1975; Jul, 1984; Pearson and Tauber, 1984).

Additives. All food additives used in meat and poultry processing are covered by the tolerance-setting process provided by Section 409 of the Federal Food, Drug, and Cosmetic Act (Joint FAO/IAEA/WHO Expert Committee on Food Additives, 1984; Joint FAO/WHO Expert Committee on Food Additives, 1980, 1983; Kroger and Smith, 1984). Committees of the National Research Council's Food and Nutrition Board have surveyed the food industry to identify the chemicals and amounts intentionally added to various food products and to assess the benefits derived from them. There are approximately 1,800 food additives, most of which are flavors and antioxidants (Rehwoldt, 1984). Probably less than 1% of these are used in meat and poultry products specifically. Factors that affect the use of chemical additives are safety, cost, reliability of supply, impact on net sales of the product, available quality of specific additives, technological changes, and public perception of safety (Joint FAO/WHO Expert Committee on Food Additives, 1983; Rehwoldt, 1984).

Chlorine. Water used in processing is chlorinated to reduce microbiological contamination of meat and poultry, although the efficacy of this practice under certain conditions is not certain. Chlorine has been recovered from animal lipids, depending on the concentration of chlorine to which the carcass had been exposed. The public health implications of this need further evaluation (Cantor, 1982; Cunningham and Lawrence, 1979; Mead et al., 1975; Meyers, 1984; Zoeteman et al., 1982).

Heating. Foods are browned upon heating when reducing sugars interact with amino acids to form polymers that are brown and have various organoleptic properties. Pigments produced by the browning reaction are toxic at relatively high concentrations, but the concentrations formed during normal cooking are generally not considered hazardous. These and other products of cooking, storing, and smoking meats and poultry have been the subject of numerous toxicity studies, especially for mutagenicity and carcinogenicity. When compounds formed by heating are isolated, concentrated, and tested, they are often found to be toxic. For example, polycyclic aromatic hydrocarbons (PAHs) are commonly found in fresh, smoked, grilled, and, especially, cured meats. Of the more than 100 PAH compounds identified, 5 are known to be carcinogenic when administered orally, and 3 of the 5 are part of the average U.S. diet. The impact of these compounds on humans at ordinary dietary levels throughout a lifetime is unknown (Meyer, 1960).

Fragments. Metal fragments sometimes enter meat and poultry during processing. The modern techniques of metal detection and retrieval (some of which are discussed in Chapter 9) are considered adequate for the reasonable protection of the safety of these products. Bone fragments of extremely small particle size sometimes enter processed meats as the result of manual or mechanical deboning procedures. When good manufacturing practices are followed, the public health risk due to bone fragments are minor.

Packages. Packages for meat and poultry are manufactured from many different components that have various chemical compositions and can affect the food they protect. Such interactions have been the subject of extensive study. For example, polyvinyl chloride and acrylonitrile can leach out of packaging materials and thereby become indirect additives to food.

Evaluation of the potential risks posed by packaging material is complex and difficult. It must include the identification, measurement, and toxicological evaluation of compounds extracted from the materials under various storage conditions. At present, no information directly links the small amounts of such compounds in foods to adverse effects on human health. Nonetheless, FDA approval is required for all materials used to package meat and poultry in the United States (Karel and Heidelbaugh, 1975; Sacharow, 1979).

Irradiation. Meat and poultry products are currently not irradiated in the United States, although certain doses and energy levels have been approved for other foods (FDA, 1981; Joint FAO/IAEA/WHO Expert Committee, 1981; Ley, 1983). The approved levels would generally leave no residual radioactivity in the food, but the process of irradiation causes concern because of its ability to create new chemical species through free radical formation. Through new technology, however, free radical reactions are controlled either by irradiating foods in the frozen state to immobilize the radicals or by lowering the dose and energy level of irradiation to minimize free radical formation.

Storage. During processing and storage, chemical and physical changes can occur in the tissues that comprise meat and poultry. Such intrinsic changes, which can occur without the presence of chemical contamination, may involve oxidation, dehydration, free radical formation, or polymerization phenomena that can generate other chemical compounds. The diversity of such changes can contribute to variety in taste and texture of the processed meat and poultry. The nature of these changes may be altered either intentionally for aesthetic reasons or merely as a result of new technology and distribution practices.

Regulatory agencies have been concerned primarily with intentionally or accidentally "added" chemicals. Thus, these intrinsic chemical changes have usually been regarded as "natural" and generally assumed to be safe. Nevertheless, few objective data are available regarding the long-term public health implications of such changes (Ames, 1983; Lee, 1983; Roberts, 1981).

THE UNCERTAIN REGULATORY CONTEXT

In the early 1970s, a conflict over programs to control chemical hazards resulted in a division of responsibilities between the U.S. Department of Agriculture (USDA) and the then new EPA. Pesticide regulation, which had once been the responsibility of USDA, was turned over to EPA. Over time, the fluctuating relationship between these two agencies resulted in an uncertain tie between EPA, which determines pesticide tolerance, and USDA, which monitors tolerances. Other objectives are divided between USDA's Food Safety and Inspection Service (FSIS) and FDA, and still others between FSIS and state agencies. Thus, the National Residue Program of USDA must monitor compliance while FDA sets the rules. FSIS is often criticized for failure to take action in areas not within its purview. Thus, although the protection of public health is a primary concern of all these agencies, the division of responsibilities to attain that goal is quite complex.

As administrations have changed, different emphases have been given to NRP, varying from strong support for its operation and output to a greater degree of skepticism about the seriousness of its mission and the importance of residue programs. This has made it difficult to maintain consistency in program administration and to develop a long-term plan.

The high level of conflict and uncertainty is exemplified by the current controversy surrounding antibiotics in animal feeds. Because of congressional action, the FDA (the standard-setter for animal drugs) has not been able to finalize its proposals for regulation of these compounds. From a public policy perspective, such disagreements make an adequate scientific evaluation of the chemical residue problem and its relevance to meat and poultry even more difficult than its technical complexity would imply.

THE NATIONAL RESIDUE PROGRAM

The National Residue Program, begun in 1967, is the federal government's principal regulatory mechanism for determining the presence and level of those chemicals in meat and poultry that have been judged (primarily by FDA, EPA, and FSIS) to be of public health concern. Through this program FSIS applies new technologies and testing procedures in the monitoring of approximately 100 of the chemicals that may be found in meat and poultry. These chemicals are selected on the basis of toxicity, exposure level, persistence, and other relevant criteria (USDA, 1983a,b, 1984, 1985).

NRP Objectives

The NRP has four major objectives: monitoring, surveillance, exploratory testing, and prevention of chemical residues in meat and poultry.

Monitoring. Monitoring is achieved by taking random samples of tissue from apparently healthy domestic meat and poultry animals as they pass through routine inspection at slaughter (postmortem inspection) and random samples of imported meat products. Approximately 22,500 domestic samples and 10,800 samples of imported products were scheduled for testing in 1985. (The sample plan proposed by FSIS for calendar year 1985 is summarized in Tables 4-1 and 4-2.) These samples are used to test for compliance with tolerance levels for the chemicals as well as to identify patterns and trends in the distribution, frequency, and levels of chemical residues. They also identify tolerance- or action-level violations. In addition, samples suspected of containing unacceptably high residue levels are examined so that remedial action can be taken. Meat and poultry tested under the monitoring system are normally sold and consumed before test results are available. However, information gathered in the monitoring program is referred to FDA or EPA for review and for use in on-the-farm inspections to determine whether chemicals are misused. Monitoring test results can trigger surveillance testing.

Some monitoring is for "generic" components (e.g., testing for any member of the family of arsenicals by testing for the presence of arsenic). Other chemicals are periodically added to or deleted from the test list in order to increase the variety and scope of the program. In general, the number of samples tested is designed to ensure, at the 95% confidence level, that the chemical will be detected in at least one sample if it occurs in 1% or more of the population of animals being observed during a given year. The current residue testing strategy of FSIS is to detect with 95% confidence whether or not a problem exists in 1% of the animal population. This is inadequate to prevent consumer exposure to the residues. Because millions of animals are slaughtered annually (e.g., between 36 million and 40 million cattle alone), the chance of any animal being sampled in the United States is minuscule. Furthermore, because of the increasing number and variety of contaminating residues that may constitute possible health hazards, especially to susceptible subgroups in the population, and because the overall contamination rate of less than 1% may be considerably higher for certain foods sources or consumer groups, the committee questions whether this sampling plan is adequate.

Surveillance. Surveillance is based on targeted sampling of meat and poultry products to control or investigate suspected violations. Approximately 8,850 domestic samples and 120 samples of imported products were planned for surveillance in 1985. Surveillance testing may be initiated when a producer is suspected of marketing animals with residues above limits set by EPA or FDA. Carcasses are retained while

TABLE 4-1 Species Groups and Production Classes for Chemical Samp in the National Residue Program, 1985[a]

Domestic Species (Production Apportionment)	Minimum Sample Un Analyzed Per Year
Horses	100
Bulls/cows (10%/90%)	300
Heifers/steers (34%/66%)	300
Calves	300
Sheep/lamb (20%/80%)	100
Goats	100
Hogs, market	300
Cows/boars (75%/25%)	300
Chickens, young	300
Chickens mature	300
Turkeys, young[b]	300
Turkeys, mature[c]	300
Ducks	300
Geese	60
Rabbits	100

[a]From USDA, 1985.
[b]Normally 16 weeks old.
[c]Breeding stock.

TABLE 4-2 Samples Designated for Chemical Analysis in the National Residue Program Plan for 1985[a]

Residue Designation	Domestic[b]	Imported[b]	Total
Albendazole	720	375	1,095
Antibiotics	10,075	1,892	11,967
Arsenic	900	0	900
Chloramphenicol	1,800	2,893	4,693
Chlorinated hydrocarbons	4,225	3,100	7,325
Cyromazine (Larvadex)	600	313	913
Diethylstilbestrol	300	0	300
Estrogenic compounds	300	0	300
Fenbendazole	450	0	450
Ipronidazole	900	0	900
Ivermectin	700	313	1,013
Lasalocid	600	0	600
Levamisole	1,300	276	1,576
Organophosphates	600	375	975
Pentachlorophenol	1,200	0	1,200
Sulfonamides	8,150	1,432	9,582
Trace elements	1,200	273	1,473
TOTALS	34,020	11,242	45,262

[a]From USDA, 1985.
[b]Figures reflect multiple tests of a single tissue sample.

the tests are conducted. If violations are found, the carcass is condemned and the producer may not market other animals until additional tissue samples show no illegal residues.

Imported meat and poultry products are tested for residues at the port of entry. Meat and poultry imported into the United States must undergo country-of-origin residue monitoring efforts similar to those in this country.

FSIS is developing new residue-testing methods to speed analyses. Inspectors use a Swab Test on Premises (STOP) to detect antibiotic residues in animal tissues within 24 hours, while the carcass is still in the plant, as compared with 1 to 2 weeks for routine laboratory testing done at an off-plant laboratory. If the test is positive for antibiotics, the carcass is held at the plant while samples are sent to an FSIS laboratory to identify the drug and the amount present. If residues above action levels are confirmed, the carcass is condemned. Recently a Calf Antibiotic Sulfonamide Test (CAST) was developed for use in plants where young calves are slaughtered.

Exploratory Testing. In exploratory testing, random or nonrandom samples are taken to study chemicals in meat and poultry for which safe limits have not been established (e.g., mycotoxins, trace chemicals, or industrial chemicals). Plans for 1985 include exploratory analyses of approximately 2,700 domestic samples and 273 samples of imported products. The information gained from these tests is used to define the frequency, distribution, and levels of occurrence of chemicals. The exploratory program also involves studies to help develop new methods for evaluating existing programs.

Prevention. In 1981, FSIS in collaboration with the USDA's Extension Service initiated a chemical residue prevention program. This effort is designed to help domestic livestock and poultry producers prevent chemical contamination of their animals. This program is primarily educational, providing counseling by extension service personnel and specialists who have been awarded contracts on a competitive basis (USDA, 1983a).

Evaluation of the NRP

The committee's work was hampered by the absence of meaningful technical data on NRP operation and information on its management. The current program seems to generate considerable data but they are not organized into a form that can be analyzed. This lack of information substantially inhibits program evaluation and tends to cast doubt on the NRP's utility, even if the program operations are in fact adequate.

The committee examined data from the NRP's Monitoring Phase Biological Residue Reports for each year from 1979 through 1983. These data appear to refer to numbers of positive tests, rather than to numbers of samples with one or more positive test results. Thus the

proportion of products affected may be higher than the figures cited. These data indicate that the sampling and analysis called for by the monitoring phase of the NRP have been performed. The range in the ratio of samples classified as "violative" per total number of samples tested varied with each species and market type. For example, this range in 1983 was 0 of 1,123 (violative samples among number tested) for ducks to 97 of 4,920 for calves. Such data indicate the incidence of violations for those chemicals for which tests were conducted. They do not, however, indicate consumer exposure or health risks (if any). The NRP is not designed to produce the data necessary for health risk assessment.

The data may, however, be used for other purposes, and internal analysis may suggest ways that program processes (if not outcome) can be improved. For example, there were no violative residues of organophosphates found in 1,418 samples taken from 1979 through 1983, yet the NRP plans to test 975 more samples for such residues in 1985, including 375 taken from imported products. Similarly, no violative residues of hormones were found in 3,024 samples, but the NRP plan calls for 600 samples for DES and estrogenic compounds in 1985. This raises the question of whether these testing resources might be put to better use. FSIS is, of course, under external constraints in this matter.

Conversely, where past results show a major problem, there is no clear evidence of increased efforts to characterize it in preparation for effective action. Violation rates from 1979 to 1983 were very high indeed for antibiotics (515 of 34,848, for a rate of 1.48%), sulfas (1,020 of 28,374, a rate of 3.59%), and halocarbons (103 of 29,495, which is 0.35%). All three seem to be particularly common in cows, calves, and swine; sulfas are also common in turkeys. The 1985 sampling plan calls for tests on 270 cows, 300 calves, 600 turkeys, and 600 swine--barely enough to tell (at the 95% confidence level) whether the problems still exist and not clearly adequate to study such important features as geographic or seasonal variation in violation rates, the general nature and sources of affected animals (e.g., the age and condition of cows), or correlations among violative residues (e.g., whether the high-antibiotic swine are also the high-sulfa swine). The committee recognizes that tissue samples from 3,460 meat and poultry animals, which will be subjected to 34,020 tests in 1985, is a large program. It maintains, however, that in terms of preventing potential health effects, the resources allocated to the program may be substantially less than those devoted to the traditional inspection program. The committee found no program analysis by FSIS indicating what allocation of resources to NRP would optimally protect public health.

AN OPTIMAL PROGRAM TO ASSESS AND MANAGE CHEMICAL HAZARDS IN MEAT AND POULTRY

Although the NRP has many features desirable in a program for tracking chemical residues in meat and poultry, the committee believes

that it may be helpful to identify the optimal characteristics that should be incorporated if the NRP were being designed today. Although some aspects of these optimal features are found in the NRP, others are not.

- The primary focus of the program should be prevention. Detection of problems can have little deterrent effect alone, especially in the absence of trace-back and with the very low sampling fractions. An emphasis on prevention implies major efforts to detect as well as to characterize hazards with respect to environmental or other sources, including suppliers, types and locations of affected food-animals, levels of contamination, correlations among contaminants, and other features. The link between testing for hazards and preventing them should be strengthened. Each finding of a violation should be reviewed to determine preventive measures.

- There should be a clear, precisely stated quantitative limit (tolerance) for each chemical to be regulated under the program, and the tolerances as a whole should be consistent and adequately measurable in FSIS laboratories. The selection of chemicals for control and the tolerance level (or perhaps levels) for each should be based on a single, consistent set of principles for protecting the public health (Farber, 1983). The establishment of tolerances should include evaluation of their adequacy as a public health protective measure, the adequacy of the data base supporting tolerances, and the adequacy of dealing with multiple residues, metabolites of residues, and multiple exposures from sources other than meat and poultry.

- Priorities should be determined in an open process by using specific, stated guidelines determined largely by considerations of public health. Priorities should be reviewed continually and changed in accordance with new evidence.

- Sampling methods are critical to prevention. Samples must be true probability samples. Moreover, they must be adequate not only to detect but also to characterize the nature and distribution of contaminants. The sampling scheme should be designed to change rapidly in response to new evidence (including that from the program itself) that the hazards have changed. Random sampling schemes other than simple random sampling should be considered with substantial technical advice from experts in sample surveys. Sample sizes must be based on sound statistical design to serve the needs of prevention.

- Formal risk assessment should play an explicit, prominent role in each of the features mentioned above: setting of tolerances, focus on prevention and hazard characterization, priorities, and sample design (see Chapter 10).

- Technical aspects of the testing program should be adequate to support the functions discussed above. The analytical methods used must be appropriate to the task. Quality control, including blind "known" samples and blind retesting by the same and different laboratories,

should be a prominent feature. The testing program will require substantial support for research, including the development of more accurate, more sensitive, and less expensive tests as well as tests for new hazards. The program staff and its advisors should have a strong voice in determining and meeting these research needs.

- The inspection service, including those who select the samples and those who collect them, must be trained and educated for their roles. Industry, too, must train and educate their personnel to promote appropriate use of the testing program to protect the public.

- Although prevention should be emphasized, the testing program as a whole should have close links to regulatory enforcement; each should have a substantial impact on the other. However aware of contamination and its prevention industry and its management may become, there will remain a likelihood that health hazards will still be inadvertently created by chemical contamination.

- Information systems should be an integral part of the program. The system should provide prompt feedback to the inspection service; rapid, accurate, and detailed reports to managers; and automatic flagging of potential problems. Substantial expertise on information systems in other federal regulatory programs may be helpful and should be tapped as appropriate. An "information system" in this context should be construed quite broadly to include data procedures and forms, transmission systems, computers and programs, built-in management checks on such items as adequacy of sampling and quality controls, and, of course, managers and data analysts adequate to make optimum use of the information. Throughout, needs for data recall and manipulation should be given high priority.

- The program should be developed and operated in a fully open manner, with peer review, continuing and systematic use of advisory committees, public hearings encouraging public participation, and substantial efforts to improve public understanding.

- The program must be flexible enough to recognize and respond to changes in this rapidly changing field with minimum restrictions.

To be optimal within overall departmental resource constraints, a program with these characteristics will require substantial resources: money, staff, and physical tools and facilities.

As a result of the committee's preliminary comparison of this optimal program and the current NRP, it believes that the NRP's primary objective --the protection of the public health--is correct but that the program falls short in implementing that objective in a number of important ways (see Table 4-3).

The current program is not sufficiently directed toward the prevention of serious public health problems in addition to its focus on

TABLE 4-3 A Chemical Residue Program: Comparison of Optimal Characteristics and Current NRP

Optimal Characteristics[a]	Current NRP	Comment
Public protection as the major objective	Public protection is the major objective.	Meets the objective.
Focus on prevention	Focus is primarily on detection; some change since 1981.	Some progress made; still needs improvement.
Clear tolerance levels available on all important substances	All important substances do not have tolerance levels.	Progress made; still needs improvement.
A sampling scheme adequate for prevention	Sampling scheme is not adequate for prevention.	Deficient.
Formal risk assessment	Risk assessment is not currently done.	Deficient.
Adequate analytical tools and testing capacity	Testing capacity has improved but is still inadequate.	Some improvements made.
A trained inspection service	Current training is insufficient in some areas.	Needs improvement.
Close links to regulatory enforcement	Structure of FSIS tends to discourage communication.	The field operations and NRP need closer ties.
Useful information system	Systems are adequate for current needs but not for anticipated problems.	Still needs improvement.
Priorities set through an open process	Priorities are set by a closed process.	Deficient.

[a]For details of optimal characteristics, see pages 54-58.

detection. Furthermore, the number and pattern of monitoring tests from year to year bear only a minimal relationship to the changing nature of potential public health problems. Formal risk assessment does not appear to be conducted, and although FSIS clearly states its own purpose with respect to the seriousness of the substances for which it is sampling, there does not appear to be a public process for either setting or reviewing the priorities of the agency. FSIS deserves credit for improving analytical testing procedures, yet the laboratory capacity for operating in case of emergencies is limited. The committee's overall impression is that the sampling system is primarily determined by laboratory capacity rather than by judgments about the size and nature of an optimal program to protect the public health.

Because of the organization of FSIS and the placement of the NRP within its science component, it is difficult to know whether there is adequate communication at the operations level between the program staff and those in the enforcement part of the organization. Communications may have been improved by the establishment of an agency-wide emergency response system following the 1979 PCB contamination in the western United States (USDA, 1980). However, the fundamental data base needed to design an enforcement program that rationally builds on the data collected through the NRP appears to be lacking. Because of this lack of planning ability, the agency can only cope with emergencies as they arise.

The agency has nonetheless made some progress. For example, it has developed better analytical methods for many chemicals, and as indicated earlier, greater resources have been allocated to the effort over the past 10 years. Yet, the committee finds that the current program is seriously deficient in 3 of the 10 major characteristics of an optimal system. Although the NRP does meet the primary objective of such a program, and although progress has been made in the other 6 categories, improvements are still needed. The committee recognizes that critical decisions about NRP are beyond the control of FSIS, and even of USDA, but believes strongly that steps must be taken to rectify these deficiencies to protect the public health.

THE ROLE OF THE PUBLIC

Improvements in the promotion and maintenance of good health could result from actions that are virtually matters of individual discretion (e.g., altering dietary habits, drug and alcohol use, exercise, and smoking, and using seat belts in cars). Similarly, most infectious and parasitic hazards associated with meat and poultry can be managed by measures that can be controlled largely by consumers (e.g., in cooking, handling, and sanitation). In contrast, toxic chemical hazards in meat and poultry are not usually amenable to management by consumer actions. Health problems associated with chemical hazards in foods must therefore be managed by the public rather than by the individual consumer.

The need for a public approach to the management of chemical hazards in foods is further reinforced by the difficulty in finding the source of

the contamination. This problem can stem from the potentially long interval between exposure and the effects associated with some chemicals, compared with the relatively short period between exposure and disease associated with most infectious microbiological hazards. In the past, society has sometimes waited too long to take action to control hazardous chemicals. In contrast, little harm (other than short-term economic costs) would be encountered by reacting too soon to a suspected hazard.

TECHNOLOGICAL ADVANCES AFFECTING INSPECTION

Scientists' understanding of toxicology is rapidly changing and expanding, and each major advance raises questions about additional groups of chemicals that may not yet be recognized as hazards in meat and poultry. The elements that are used in regulatory controls (e.g., permissible exposure levels and tolerances, avoidance, monitoring, surveillance, enforcement protocols, and recordkeeping) are evolving and must continue to change with advances in toxicology (Kroger and Smith, 1984). Laboratory analytical methods are also constantly improving. For example, state-of-the-science laboratories equipped with chromatographic mass-spectrometric analytical instruments can routinely detect parts-per-trillion quantities of some chemicals. In time, it may be possible to detect parts-per-trillion (or lower) quantities of chemicals in foods derived from contaminated food-animals (Roberts, 1981; Vettorazzi, 1980). The need to develop strategies and techniques appropriate to new approaches in meat and poultry inspection has recently been recognized (Dubbert, 1984; Heidelbaugh, 1982; Houston, 1984a,b; USDA, 1983b).

CONCLUSIONS AND RECOMMENDATIONS

Hundreds of thousands of chemicals can be identified in the environment. Thus, it is impractical to measure the presence or public health risk of every one that may be a part of, gain entrance into, or be generated within meat or poultry. Instead, to ensure the public health safety of meat and poultry requires that procedures used must continually identify chemical hazards, measure consumer exposures, evaluate the health responses to those exposures, and provide risk characterizations. The results of these assessments must be the subject of constant open and objective discussions and critiques. The overall goal should be a regulatory system that manages public health risks associated with chemicals in meat and poultry by integrating the results of scientifically developed risk assessments with considerations of political, social, and economic realities (Food Safety Council, 1979; NRC, 1983).

Given the data underlying tolerances and the current objectives of FSIS, the committee maintains that the NRP is not demonstrably adequate to ensure maximum protection of the public health. A more rational public health objective, based on the concepts of risk assessment and

risk management, would be to design the optimal system to ensure that no one person consistently receives a total exposure to levels of chemicals in excess of an established tolerance level. Such a system would incorporate all the characteristics of an optimal program identified earlier in this chapter.

The committee recognizes that the NRP is constrained in many ways by its legislative mandates. It must attempt to test for hundreds of chemicals, many of which do not have formal tolerances established by either the FDA or the EPA--agencies FSIS depends upon to describe acceptable limits. The committee recommends, therefore, that mechanisms be created to bring the standard-setting and the enforcement arms of the government closer together. Furthermore, to the extent possible within the limits of the legislative mandates, the committee recommends that NRP, FSIS, and USDA work toward the goals described below.

Since chemical hazard testing is likely to increase relative to more traditional kinds of testing, FSIS should continue to revise its program to accommodate the changing needs. Efforts should include the recruitment and development of management personnel, the development of a capability for quantitative health risk assessment, especially for the most urgent needs, and the development of sampling plans and testing capabilities.

Substantial research needs include the development of economic tests for many categories of chemicals that can be read while meat and poultry are still in the slaughterhouse. The sensitivity of the tests must be appropriate for relevant tolerance levels. New tests will be needed for the chemicals continually added to the list of potentially significant hazards.

NRP should promptly begin to develop an action-oriented information system for program management to identify and track each violative residue for appropriate action; to characterize hazards to assist in prevention and to guide the development of sampling plans; and to monitor and improve quality control in the testing program.

The committee further recommends that NRP consider strategies to prevent consumer exposure to potentially hazardous chemicals. To achieve this objective, the NRP should:

- Control the entry of chemicals at the farm. Introduction of an animal identification and trace-back system, as recommended in Chapter 5, will be very useful.

- Revise the residue sampling plan (e.g., increase the sample size and confidence level) to minimize consumer exposure. To ensure that optimal procedures are devised, appropriate recent advances in science and technology must be drawn upon.

- Introduce formal risk assessment as a tool to provide maximum protection.

- Encourage open communication between FSIS scientists and outside experts.

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5
Meat and Poultry Production

The human health risks presented by meat and poultry may be substantially affected by animal production practices. The ingredients of the animals' feed, the environmental and hygienic conditions under which they are raised, and the modes of their transportation and marketing determine how and where various hazardous agents could enter the meat and poultry supply. Although inspection of the production phase is not under the jurisdiction of the Food Safety and Inspection Service (FSIS), the committee believes that a comprehensive account of meat and poultry production practices sets the stage for the discussion of various contaminants detected during inspection.

This chapter describes where and how food-animals are produced and the infrastructure that supports production. Cattle, swine, sheep, chickens, and turkeys are emphasized because they provide most of the animal protein in the U.S. diet.

PRODUCTION AND FEEDING ENVIRONMENTS

Animals are the sum of the inputs, both planned and accidental, that contribute to their growth at any stage in their life. Although this chapter provides a review of the production environment, it is important to understand that the feed constituents--the grains and forages--are often grown by someone other than the animal producer. Thus the feed may contain chemical substances unknown to the producer.

Cattle

Beef cattle are raised throughout the country, but 49% of beef cows (breeding-age females) are produced in Iowa, Missouri, and the six eastern Great Plains states (Boykin *et al.*, 1980). Twelve southeastern states account for another 26% of all U.S. beef cows. The regions where beef cows are produced differ from areas that produce finishing or fed cattle--those given grain or other concentrates (rather than being left to graze pasture or rangeland) to achieve a U.S. Department of Agriculture (USDA) slaughter grade of at least "Good." According to an estimate for 1978 (Boykin et al., 1980), there were 39 million beef cow

become finishing cattle or beef cows) in the nation's 48 contiguous states. From 1968 to 1982, total annual production of beef and veal ranged between 36 billion and 44 billion pounds (USDA, 1983). The number of cattle increased 21% between 1968 and 1975. In 1982, 94% of the cattle and 88% of the calves were slaughtered in federally inspected facilities, 5% of cattle and 9% of calves in state-inspected facilities, and 1% of cattle and 3% of calves on farms. The percentage of federally inspected cattle and calves increased from 81% in 1968 to 93% in 1982.

Cattle feeding is much more common in North America than in other parts of the world. The practice expanded rapidly from 1960 through the early 1970s because of low-cost grain and a strong demand for beef (Van Arsdall and Nelson, 1983). Typically 100-500 cattle are in each open lot, unprotected from the weather, often with a dirt mound in the center. Feedlots usually keep their pens full year-round to make optimal use of capital resources, though the mud caused by prolonged wet weather may result in reduced weight gains and force closure until the pens dry out.

Forty years ago, nearly all cattle were fed on small farms, mostly in the north central region of the United States. Now cattle feeding is practiced throughout the country, but feedlots are concentrated in the western Corn Belt, the eastern Great Plains, and the High Plains of Texas. On the average, from 1977 to 1980 nearly 22 million fed cattle were marketed annually from only 11 states (Van Arsdall and Nelson, 1983). This pattern developed largely because of climatic and feed-cost advantages (Schertz et al., 1979).

Grains make up the bulk of the rations for fed cattle; corn is the principal source, but milo, wheat, and barley are also used as prices and supplies allow. Protein supplements usually are cottonseed meal, soybean meal, or urea. Where they are available, by-product feeds such as beet pulp, molasses, and brewer's grain are fed. Corn silage and alfalfa hay are the principal roughages. Most feed is purchased--hay and silage are bought from neighboring farmers to minimize transportation costs, but grains may be shipped great distances. Some cattle are fed additives to increase food efficiency in the rumen. A low or subtherapeutic level of antibiotic is often added, and many cattle are given subcutaneous implants of anabolic steroids.

About 80% of feedlot cattle are purchased at auctions or through order buyers (Van Arsdall and Nelson, 1983). In 1976-1977, most fed beef cattle (89%) were purchased from feedlots directly by packers, 7% moved through markets, and 3% were sold through auctions (Gee et al., 1979). Auctions (sale barns) receive cattle, often from as far as 500 miles away. Order buyers, who do not take title to the cattle, act solely as agents for the feedlots and purchase cattle from markets, auctions, or dealers or directly from farmers. The period from a few days before animals move into the feedlot until a week afterward is risky, and death rates average 1.0% to 1.5% in feedlots (Jensen and Mackey, 1979). Stresses include shipping, often over great distances,

without normal supplies of feed and water; new sources of feed and water; strange surroundings; exposures to other cattle that harbor pathogens; and numerous injections and treatments when entering the feedlot.

Appendix Tables A1 to A8 provide details on the number and classes of cattle, regional distributions, herd sizes, the number and distribution of feedlots, beef-cattle raising systems, the number of fed cattle marketed annually, and the number and classes of cattle slaughtered under federal inspection.

Swine

The number of pigs at any one point in time is more variable than that of cattle. According to the USDA (1983), 87 million hogs were produced in the United States in 1982. Pigs range in weight from 25 to more than 100 pounds when they enter the feeding period, but most are between 40 and 60 pounds and the average weight in 1975 was 51 pounds (Van Arsdall, 1978). Some producers sell "feeder pigs" to other farmers at 8 to 9 weeks of age, which allows approximately 3 weeks for the pigs to grow after they are weaned at 3 to 5 weeks of age. The farmers who purchase feeder pigs average 132 days from purchase to sale for slaughter, so these pigs are about 6 months old at slaughter (Van Arsdall, 1978) and weigh on average 223 pounds (Mueller and Kesler, 1983). The most common type of hog farmer raises pigs from birth through slaughter (farrow-to-finish enterprises) and markets them at about the same age and weight.

In the United States, hogs and grain are usually produced on the same farms. Two-thirds of the total live weight of the nation's hogs is produced in the Corn Belt and Great Lake states. There has been a tendency toward fewer and larger farms in the major hog-producing states, and most (80%) of the marketed hogs come from farrow-to-finish farms. Homegrown grains provide 80% of hogs' needs in the north central region and 50-75% in the Southeast, but only about 10% in the Southwest. Although less than half the grain used by producers of feeder pigs is homegrown, for farrow-to-finish producers, the figure is about 60% (Van Arsdall, 1978). Grain for pigs must be supplemented with additional protein, minerals, salt, and vitamins. These must be purchased, and most producers with larger farms also add a growth-permittant antibiotic (at a subtherapeutic level) to the ration to improve feed efficiency and growth rates (Crom and Duewer, 1980; Van Arsdall, 1978). (A growth-permittant antibiotic surpresses unwanted intestinal bacteria and thereby permits animals to more fully reach their growth potential.) More than 75% of farrow-to-finish producers, 63% of feeder-to-finish producers, and only 34% of feeder-pig producers make their own mix of corn, supplements, and antibiotics (Mueller and Kesler, 1983; Van Arsdall, 1978).

Until the end of World War II, most American farmers farrowed sows in portable houses that they rotated among clean pastures to control

diseases and parasites. Recently developed methods for controlling infections have enabled farmers to use a central farrowing house and to farrow sows year-round. Since weaning is a stressful period for pigs, approximately 40% are moved from a central farrowing house into a nursery when they reach about 30 to 40 pounds body weight and remain there about 1 month (Mueller and Kesler, 1983; Van Arsdall, 1978). During this period they usually are given a starter ration specially formulated for weaned pigs, including added vitamins, minerals, and growth-permittant antibiotics.

Up to 20% of the largest farms now raise hogs in confinement, allowing them no access to outside areas from birth to sale for slaughter (Mueller and Kesler, 1983). However, about half the feeders and the majority of finishing pigs still have access to the outdoors. Nationally, 22% of farms (mostly in the Southeast) furnished no shelter to finishing pigs in 1980 (Mueller and Kesler, 1983). Open-front buildings house nearly one-third of finishing pigs; for hogs in fully enclosed buildings, slotted floors with a pit below have become increasingly frequent--especially among the larger farms.

Most slaughter hogs (70%) are sold directly to slaughterhouses (Van Arsdall and Nelson, 1984). About 12% were marketed through terminal markets, 8% through auctions, and 8% through order buyers (Mueller and Kesler, 1983). Improved refrigeration has permitted new efficient slaughter and processing plants to be located where pigs are finished, and many older plants near population and consumption centers have been closed.

For details of the number and distribution of hogs, production facilities, marketing conditions, and average numbers slaughtered, see Appendix Tables A9 to A15.

Sheep

The number of sheep and lambs in the United States has fallen from more than 55 million in 1942 to less than 12 million in 1983. As a result, meat from sheep now accounts for less than 1% of the red meat consumed in this country. The proportion of sheep raised in various regions has remained relatively constant for 30 years. In 1982, Texas had 2.2 million stocker sheep (young animals suitable for being fed or to enter the breeding flock), Wyoming had 1.0 million, and California had 1.0 million, in total constituting 37% of the nation's sheep. The top 10 states had more than 70% of all stocker sheep. Dryland farming typifies the major sheep states.

Federal ranges provide half the feed for sheep in the West (Parker and Pope, 1983). They are managed extensively, often in high rangeland. Many animals are moved to high mountain meadows for summer grazing. In the fall, before heavy snowfalls, they are returned to lower elevations, where they may be housed and maintained during the winter largely on stored feed, until well after lambing in late winter or early spring.

Grazing begins in the spring at the lower elevations and follows the receding snow toward higher elevations as spring and summer progress.

Mechanization, self-feeding of concentrates, low-cost nonconventional feedstuffs, and enterprise specialization have contributed to fewer and larger lamb feeding operations (Parker and Pope, 1983). These trends toward more intensive management allow more health maintenance programs than are possible under extensive range conditions.

Zeranol (benzoxacyclotetradecin derivative) is the only anabolic agent currently approved for sheep. Although others are effective, according to published data (Parker and Pope, 1983), they lack Food and Drug Administration approval. The small size of the sheep market--in contrast to the markets for cattle, pigs, and broilers--makes it unattractive for pharmaceutical companies. The lack of clearances of new compounds or pharmaceuticals for sheep has been described as a major deterrent to improvements in the efficiency with which animals assimilate food for growth (Parker and Pope, 1983). Thus, current production systems and economics present little risk of contamination of sheep meat with medications and feed additivies.

Appendix Tables A16 to A18 indicate the number of sheep and lambs, their regional distribution, and the average numbers slaughtered.

Chickens

Broilers account for the vast majority of poultry meat--nearly 95% of all chickens are broilers. The number and total weight of broilers have risen steadily over the last 15 years, reaching more than 4 billion chickens representing 16.8 billion pounds in 1982. Approximately 36% of the farms that raised broilers in 1978 produced more than 100,000, but they accounted for nearly 82% of all broiler production (Lasley, 1983). The total number of chickens raised for eggs has remained relatively stable since 1968 at 250 million per year.

Vertical integration (coordination of all phases of production and marketing) is virtually complete in the U.S. broiler industry, where 99% of broilers are owned or contracted for by one decision-making unit of the industry. During the last 30 years, the poultry industry has moved from the northeastern and north central states to those in the South, which produced 44% of the eggs and 88% of the broilers in the country in 1980.

Improved disease control and nutrition allow producers to raise broilers in total confinement in large floor-pens, each with 10,000 to 20,000 birds (Lasley, 1983). The environment is controlled by supplemental heat or by natural ventilation. Evaporative cooling is used when air movement alone is insufficient to keep the birds comfortable. These housing systems permit year-round use of floor-pens, with up to five grow-outs (flocks) yearly. This results in efficient use of capital resources and encourages use of new technology.

Broiler bedding (most often hardwood shavings) often is reused for five or six grow-outs, with some fresh bedding added each time. Litter may be changed completely only about once yearly. Broilers may thus be exposed to diseases and parasites in the litter, so control programs are mandatory. For example, virtually all broilers are given a coccidiostat. The vast majority are also given a growth-permittant antibiotic mixed in the feed (North, 1984). The consensus in the industry is that without these additives, production costs would increase because of mortality and morbidity, and feed efficiency among the chickens that did not die would be seriously reduced.

Broiler producers grow little or none of their own feed. Broiler rations include added vitamins, minerals, and an arsenical along with the coccidiostat and antibiotic (North, 1984). Most rations are based on corn and soybean-oil meal that may be delivered by the carload to large producers. They are generally fed as mash in automatic feeders, but increasing numbers of producers pellet the ration because birds consume pelleted feed faster and the ingredients in mash sometimes settle unevenly. Animal and fish protein supplements may harbor microbiological contaminants such as salmonellae, which may infect broilers and eventually pose a serious human health risk. Pelleting destroys some salmonellae, but pasteurization is needed to kill them all (North, 1984).

The number of chickens, their regional distribution, farm sizes, feeding conditions, and numbers slaughtered by class are detailed in Appendix Tables A19 to A23.

Turkeys

In 1982, 184 million light and heavy breed (more than 12 pounds) turkeys were hatched in the United States (USDA, 1983). Turkey production is highly specialized and localized: Hatcheries in California, Missouri, Minnesota, and North Carolina produce 56% of all turkey poults. Ten states accounted for 81% of all U.S. turkey production in 1982, and 97% of the turkeys were slaughtered under federal inspection (USDA, 1983).

The industry is also vertically integrated--90% of the market outlet is determined before the poults are produced (Lasley, 1983). This degree of specialization, similar to that for broiler chickens, is a result of technical advances in management. Improved nutrition and disease control, in particular, allow producers to raise turkeys in total confinement houses (Lasley, 1983) in floor-pens containing 5,000 to 10,000 birds each. The environment may be controlled by supplemental heat or by natural ventilation. Evaporative cooling is used when air movement alone cannot keep the turkeys comfortable. These systems allow year-round use of the houses, with up to three grow-outs each year. Feeding and waste disposal are similar to those described for broilers, including a coccidiostat, an arsenical, and growth-permittant antibiotics, as well as added vitamins and minerals.

Appendix Tables A24 and A25 give the number of turkeys hatched, bred, and sold.

TRANSPORTATION

Many young meat-animals, especially cattle and pigs, are produced at one location and transported elsewhere, often far away, for further growth (finishing) before slaughter. This practice creates unusual health risks for the animals--sometimes leading to threats to human health. As mentioned with regard to cattle, long-distance transport, often without adequate feed or water, is directly stressful and may reduce the animals' immunological responsiveness. During such moves, the animals almost always have new sources of feed and water, and they may be exposed to new cohorts of animals that harbor infections not previously encountered. Furthermore, information on the origin of the animals, and thus any history of medication or food additives, is often lost during movement to distant feeding locations.

Many of the calves moved from farms to auctions and then to feedlots must be treated for "shipping fever" soon after they reach their destination. The pharmaceuticals used at this time are no threat to humans because the cattle are slaughtered after reaching market weight several months later. These drugs may become a human health threat only in the unlikely event of emergency slaughter of recently treated animals.

In the poultry industry, in contrast, there is very little movement during the production process, except when day-old chicks and poults are moved from the hatcheries.

HEALTH MAINTENANCE AND DISEASE CONTROL SYSTEMS

Infectious and parasitic diseases and infestations are significant economic factors because they can cause death, inefficient utilization of feed, lower reproductive efficiency, or increases in time from production to slaughter. Many are also significant public health hazards during production, at slaughter, or when the meat or poultry is eaten. Thus measures that reduce the level of infection in the production environment will reduce the introduction of those agents into the human food chain.

Health maintenance and disease control systems during production range from professionally supervised, comprehensive herd-wide health preventive medicine programs to minimal disease control by producers without professional animal health care. The widest range exists in the poultry industry. Large integrated operations have veterinary medical units, with one or more veterinarians providing health maintenance and disease control programs, whereas small, backyard flocks may have no health system at all other than advice from a feed supplier regarding the medicated feeds used.

Regardless of the species, health maintenance and disease prevention programs rely on a combination of prophylactic and therapeutic measures using biologics and medications. Vaccines of various kinds are given to prevent diseases that are economically important and that may also have public health significance. In addition to these, most producers rely on a variety of prophylactic medications, particularly antimicrobials and anthelmintics, to prevent or at least reduce the prevalence of infectious agents and parasites (see Chapter 4).

Health plans designed, supervised, and performed by professionals are likely to include vaccinations, medications, and examinations on a strict age-related schedule from the time animals enter the production unit until they leave it. However, no meat or poultry animals of the species considered in this report are vaccinated primarily to protect the public health. Although vaccination against such diseases as brucellosis and leptospirosis are of public health significance, the protection is provided primarily because of the economic consequences of such diseases. Vaccinations against bovine viral diarrhea, pseudorabies in swine, and infectious bronchitis in chickens have no direct public health considerations. They result in a generally healthier population that is more resistant to infectious agents that may have public health consequences.

To avoid contamination of meat and meat products from residual feed additives (subtherapeutic doses) and medications, the FDA regulations establish withdrawal periods before the animals are marketed. This period ensures that the animals do not contain any residues above permitted levels at the time of slaughter.

State and federal regulatory programs are significant components of health maintenance and disease control programs. During more than a century of federal programs, established originally as the Bureau of Animal Industry, several major livestock diseases have been excluded, eradicated, or controlled. Most regulatory programs were not designed primarily for public health purposes. Nevertheless, some, such as those for tuberculosis and brucellosis, had public health advantages. Infectious organisms such as these have been largely eliminated from food-animals in the United States, whereas others such as salmonellae and coliforms in food-animals continue to present serious public health threats.

THE POTENTIAL IMPACT ON PUBLIC HEALTH

Better control of any infectious agent in a food-animal population would reduce the number of human infections associated with the consumption of meat. An animal infected with or carrying an infectious or parasitic organism to which humans are susceptible is a potential public health hazard. Although the exact mechanism by which these diseases are transmitted is not known, contact with animals and carcasses and consumption of infected animal products were for a long time implicated in

such transmission. The diseases that are of significant public health concern in the production environment include brucellosis, tuberculosis, salmonellosis, cysticercosis, and trichinosis. The agents of concern include Campylobacter spp. and hemorrhagic coliforms. (These and other hazards are described in Chapters 3 and 7.)

No health status assessment is required in the United States before or as animals leave the production unit. Unless microorganisms produce some clinical symptom, such as septicemia, they are undetected as they enter the food chain. A local buyer or trucker buys the animals in lots, and the animals may change hands several times before slaughter. A producer, therefore, may have little to lose by sending a sick animal to slaughter.

For many years the major means of control over the entry of infectious organisms into the food chain was inspection just before animals were slaughtered. Eventually, this antemortem inspection was supplemented by federal and state regulatory programs to eradicate or control the disease in the animal population. The statistical summary of causes of condemnation published annually by FSIS indicates few specific causes among the approximately 40 tabulated. For example, human pathogens such as salmonellae, coliforms, Campylobacter, and trichinae are not named as causes for condemnation.

In the present system, the chance of a diseased animal being traced to the producer is very small. Normally, approximately 10% of the cattle and 30% of the swine that are condemned are traced back to their origin. Providing a health status certificate for animals as they leave production units would be a way to trace disease. Such a system would depend on a positive animal identification system and would yield important information from the farm, such as the use of medication and knowledge about possible residues and contaminants, as well as enabling diseased animals to be traced (Jagger, 1984).

SUMMARY AND RECOMMENDATIONS

The production environment of food-animals has changed considerably since 1940. There are fewer farms and those that remain are larger. Production units for all classes of food-animals have grown and often the producers have no control over the ingredients of their feed.

Although beef cattle are produced throughout the United States, 75% come from the Great Plains states or from the Southeast. Most calves are moved to feedlots in the regions where feed grains are produced. Thus, two-thirds of the nation's hogs are produced in the high corn-production areas--the Corn Belt and the Great Lakes states. Most hogs are sold directly to packers, and the slaughterhouses are located primarily in the regions where hogs are finished. There has been a sharp trend toward fewer and larger hog farms; in the major hog states, 80% of market hogs come from feeder-to-finish farms.

The proportion of sheep produced in different parts of the country has been unchanged for about 30 years; most are managed extensively in the West and Southeast, in areas of low rainfall. Broiler production, on the other hand, is concentrated in the Southeast. As for turkeys, California, Minnesota, and North Carolina are the leading producers.

The poultry industry is relatively easier to manage because most of it is vertically integrated and all phases--production through marketing--are under the same management. The pork industry may be integrated along similar lines in a few years. The cattle industry, however, is very complicated, and the animals are raised, fed, transported, and marketed under different conditions. Animals often change hands several times, through being auctioned and trucked, before they reach the slaughterhouses. The red-meat industry, as of now, is far from being vertically integrated.

Federal and state animal health regulatory programs, along with the high level of veterinary medical care in the private sector, provide healthy livestock and poultry. Despite this, there remain many infectious and parasitic agents that can find their way into the human food chain through meat and poultry products. In the past, the major efforts to reduce such public health hazards have taken place during slaughtering and processing. There is a need to reduce or eliminate those hazards before the animals arrive at slaughter.

A number of permanent animal identification systems have been researched, proposed, and, in some cases, tested. However, the lack of a national animal disease surveillance system and of animal identification and trace-back systems is a significant deterrent to the further reduction of the human pathogens in food-animals. Preventive medicine and herd health programs already in place provide producers with an opportunity to have a systematic health care and disease prevention program throughout the production cycle.

More effort should be made to detect and control infectious and toxic agents in meat and poultry, the committee notes, as opposed to the current emphasis on gross lesions and other signs at slaughter. Such agents can and should be addressed on the farm and at other points in the production cycle, not just at slaughter or during processing. The human health threat from animal tuberculosis was eliminated by action programs on farms. Similar action could be equally effective in reducing human health threats from other zoonotic diseases and from chemical contaminants. The producers of food-animals might take more responsibility for these matters if slaughtered animals could be traced back to the farm.

The committee recommends four major steps to improve animal health and reduce the threat food-animals may pose to human health:

- An animal identification system should be created to allow diseased or contaminated animals to be traced to their source, to

increase the farmer's share of responsibility for contamination, and to facilitate epidemiological studies of specific disease outbreaks.

- All USDA animal disease surveillance programs should be designed and implemented to use fully the animal disease prevalence data available from meat and poultry inspection and to ensure that FSIS routinely trace disease and contamination back to their source.

- An interagency center should be established to monitor the status of animal diseases nationally, to serve as a central repository of animal disease statistics, and to develop and recommend ways to reduce the threat of epidemics and thereby improve both animal and human health.

- Because infectious agents and toxic chemicals are initially introduced during the production of food-animals, FSIS should consider ways to minimize or eliminate their entry at this point.

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6
Slaughter and Inspection of Meat and Poultry

The Federal Meat Inspection Act of 1906 (P.L. 59-242), as amended, requires that each food-animal slaughtered in a federal or state establishment be examined before, during, and after slaughter. These ante- and postmortem inspections are conducted by veterinarians, or by trained inspectors working under their supervision, who have the professional knowledge required to evaluate the signs and lesions that occur in food-animals and to determine the animals' acceptability as food for humans. Because such scientific disciplines as anatomy, pathology, physiology, parasitology, biochemistry, and bacteriology are needed to implement the meat inspection program, general oversight of all areas is assigned to veterinarians (Brandly et al., 1966; Libby, 1975). Veterinarians who enter the meat inspection program receive additional training to enhance the part of their education that is relevant to meat hygiene and to ensure that their work meets high standards of competence and uniformity (Brandly et al., 1966).

The veterinarians receive counsel and reports on their work from experienced supervisors, as well as continuing education in comparative medicine, zoonotic diseases, toxicology, and other aspects of meat hygiene. Four pathology laboratories, staffed by veterinary pathologists who are experts on relating gross and microscopic lesions of food-animals to their suitability for food, are available for advice and to provide laboratory assistance as required.

ANTEMORTEM INSPECTION

Antemortem inspection has long been part of the total examination of red-meat animals destined for slaughter and is critical to the overall public protection goals of meat inspection (Booz-Allen, 1977b). Federal regulations require that all meat-animals intended for slaughter in a federal establishment be subjected to such an inspection both in motion and at rest on the day of slaughter. Some diseases (e.g., rabies, listeriosis, and heavy metal toxicoses) have distinct clinical signs that cannot be detected by gross postmortem inspection (Libby, 1975).

Furthermore, some microbial diseases that can seriously contaminate the slaughter environment (abscesses, anthrax) may be detected by thorough antemortem inspection, thus preventing the animal from entering the slaughterhouse.

The general purpose of antemortem inspection of red-meat animals is to determine whether each animal presented for slaughter is normal or abnormal. Those designated as normal are sent directly to be killed; those found to be abnormal are categorized according to perceived risks as unfit for slaughter, affected with a localized condition, or having a condition that does not render the animal unfit but that might influence carcass disposition upon postmortem examination (Libby, 1975).

Each year since 1917 an average of 99.7% of inspected animals have passed antemortem inspection (Booz-Allen, 1977b). Because of the high proportion of healthy animals presented for slaughter, a variable intensity of antemortem inspection, based on some valid sampling plan, might be more desirable.

In 1982, the U.S. Department of Agriculture (USDA) approved a plan that allows plant management to elect an alternative procedure if (1) the facilities and volume of operations are suitable, as determined by the area supervisor; (2) all abnormal animals are segregated; and (3) all animals (abnormal and normal) are held until examined by the inspector. Under this plan, the inspector must examine all animals designated to be normal by the establishment while they are "at rest"; select 5% to 10% of such animals from several lots and observe them on both sides while in motion; and examine each segregated abnormal animal, both at rest and in motion, and tag any that are suspect (USDA, 1983b). These suspect animals are examined more closely to determine their disposition.

The Wholesome Poultry Products Act of 1968 (P.L. 90-492) left the extent of antemortem inspection of poultry to the discretion of the Secretary of Agriculture. The large number of chickens and turkeys slaughtered annually in the United States (more than 4.5 billion birds in fiscal year 1983) makes bird-by-bird antemortem inspection impossible under current handling procedures. Thus, the veterinary medical officer (VMO) or food inspector (for slaughter) from USDA's Food Safety and Inspection Service (FSIS) examines the birds before slaughter on a flock or lot basis. Poultry are observed while they are in coops or batteries before or after removal from trucks (USDA, 1983b). Those found with abnormal conditions are categorized by perceived risk (Libby, 1975).

The VMO and food inspector (slaughter) are also responsible for enforcing the Humane Methods of Slaughter Act of 1978 (P.L. 95-445). Since this has no public health implication, the committee did not discuss this responsibility.

POSTMORTEM INSPECTION

Postmortem inspection of meat animals encompasses a wide variety of activities (Booz-Allen, 1977a). The steps or factors with direct public health significance are head, carcass, and viscera inspection; plant sanitation; sanitary slaughter and dressing; carcass reinspection; poultry chilling; biological residue monitoring; animal disease surveillance; and condemnation and final disposition.

The main purpose of postmortem examinations is to detect and eliminate abnormalities, including contamination, in order to ensure that only meat and poultry fit for human consumption is passed for food. Important subsidiary aspects are checking the efficacy of slaughter and carcass-dressing techniques and diagnosing disease conditions for control programs (Gracey, 1981). These examinations are the focus of an active inspection program. They provide information indispensable for the scientific evaluation of clinical signs and pathological processes that affect the wholesomeness of meat and poultry. In cases where the signs and lesions leave the final disposition in question, the VMO submits specimens for laboratory evaluation before making a final determination (Libby, 1975).

Head, Carcass, and Viscera Inspection

Postmortem inspection of food animals includes routine examination of the head and cervical lymph nodes, the visceral and body lymph nodes, the internal organs, and the exposed portions of the carcass. For red-meat animals (cattle and swine), the procedure also includes cervical, visceral, and carcass inspection (Gracey, 1981; Libby, 1975; USDA, 1983b, 1984a).

New methods of inspection in slaughter plants have been instituted, and more are under development (Table 6-1). The new cattle and swine slaughtering procedures are both under evaluation (Menning, 1984b). The changes seem to have achieved their basic aim of improving efficiency of inspection (Dubbert, 1984), but data to measure the impact of these changes on public health have not yet been analyzed.

Postmortem inspection of poultry is designed to find different kinds of problems and involves different procedures (Booz-Allen, 1977a), although the responsibilities that may affect public health are similar to those described for red meat.

Modified traditional inspection procedures reduce hand motions of poultry inspectors by dividing the tasks among three persons, thereby increasing plant production (USDA, 1983a). These were implemented for broilers in 1979 and are being adapted for inspecting mature chickens as well. Initial assessment shows that the Modified Traditional Inspection Method is faster and has resulted in the same inspection error rate as the traditional approach (USDA, 1983a).

TABLE 6-1 Meat and Poultry Postmortem Inspection Procedures: Past, Present, and Proposed[a]

Traditional	Present	Proposed by USDA
CATTLE		
During each of three phases--head, viscera, and carcass inspection--an inspector performs a sequence of observing, palpating, and, for head and viscera inspection, incising tissues.	Head inspection includes: • observing head's surface and eyes; • incising and observing mandibular, parotid, atlantal, and suprapharyngeal nodes; • incising and observing lateral and medial nodes; • incising and observing masticatory muscles (cheeks); and • observing and palpating tongue. Viscera inspection includes: • observing mesenteric nodes, abdominal viscera, esophagus and spleen, and ventral surface of lungs; • observing and palpating ruminoreticular junction, costal surfaces of lungs; • observing surfaces of liver; and • incising and observing bronchial and mediastinal lymph nodes, heart, hepatic nodes, and bile duct. Carcass inspection includes: • palpating lymph nodes; • observing lumbar region; • observing and palpating kidneys; • observing diaphragmatic pillars and peritoneum; • observing and palpating diaphragm; and • observing pleura, cut surfaces of muscles and bones, neck, and carcass exterior.	The proposed procedure differs from current inspection in that it would: • combine carcass with viscera inspection, thus reducing inspection stations in many places from three to two; • eliminate the need for the inspector to observe, palpate, and incise certain tissues at both the head and viscera station; • require plants to provide an employee to palpate tongue and be responsible for notifying inspector of abnormalities; • remove kidneys from their capsules for presentation at viscera station; and • remove dressing defects and minor conditions (small bruises, minor adhesions) to be verified by a reinspection program rather than by an inspector at the carcass station. The "Beef Carcass Online Quality Control System" is under study. Head inspection would eliminate the incising of atlantal nodes (observation still required) and the palpation of the tongue. Viscera/carcass inspection would eliminate: • observation of ventral surfaces of lung (though still requires observation and palpation of dorsal (costal) surfaces); • incision and observation of right bronchial node; • incision of hepatic nodes (observation required); • palpation of ruminoreticular junction (observation required); • palpation of diaphragm and supramammary and internal iliac lymph nodes (observation of diaphragm and nodes required); • observation of spinal column

TABLE 6-1 continued

Traditional	Present	Proposed by USDA
SWINE		
During each phase--head, viscera, and carcass inspection--an inspector performs a sequence of observing, palpating, and, for head inspection, incising tissues. Head inspection includes: • observing back and leading side of head and neck; • incising mandibular lymph nodes left and right; and • turning carcass and observing and palpating the heart. Viscera inspection includes: • observing and palpating the spleen; • observing and palpating the dorsal surface of the liver; • palpating the mediastinal nodes; • observing and palpating the dorsal surfaces of the lungs; and • observing and palpating the heart. Carcass inspection includes: • observing outer part of leading half of carcass, cut surfaces, and body cavities (pelvic, abdominal, and thoracic); • observing and palpating the kidneys; • observing lumbar and neck regions and outer parts of trailing half of carcass; and • directing trim, removing "retain" tags, or retaining carcass when required.	In mid-1981, certain techniques of traditional swine inspection were eliminated or replaced with less intense measures. For example, all duplicative examinations were eliminated and palpation of certain lymph nodes was replaced by observation alone. Inspectors are no longer required to: • turn the carcass and observe outside surfaces (except those of head) at head inspection station; • palpate the spleen, liver, mediastinal lymph nodes, lungs, and heart; or • turn the carcass at carcass inspection station and palpate the kidneys. • Carcass turning has been replaced by use of a mirror, and kidney palpation by turning and observing the kidneys.	Two major changes are proposed: • Inspection of activities traditionally conducted at carcass inspection station will be combined with those at viscera inspection station. In some instances, inspection of head, viscera, and carcass can be performed at a single point. Completion of inspection for all carcass pathology at the viscera station will strengthen the inspection system. • A "Swine Carcass Online System" will be implemented for either scalded or skinned carcasses. Field trials have been performed, and the system is being refined.

TABLE 6-1 continued

Traditional	Present	Proposed by USDA
POULTRY		
Broilers		
Ratio of one inspector to one bird; carcass rotation required.	A modified traditional inspection (MTI) was introduced in 1979. Three inspectors work in sequence: One examines the outside of carcass with aid of mirror; the other two examine the insides and viscera of every other carcass. MTI has three components: • each carcass is examined by inspector; • plant trimmer is directed by inspector to trim abnormalities; and • inspector verifies trim. The Hands Off/Hands On inspection is designed for the furthering of sequence inspection. Of a team of four inspectors, the first examines the outside of carcass, and the second examines drawn out viscera; both inspectors use mirrors, not hands. Each of the other two inspectors examine insides of every other bird, using their hands.	Field trials began in 1982 on new line speed (NELS).[b] Speed of NELS depends on plant's ability to provide inspector with uniform lots of clean, healthy, properly presented birds. Plants would be responsible for performing necessary trim of designated outside defects on passed carcasses and for operating an online quality control program.
Fowl		
Same as above.	Same as above.	NELS not yet proposed.
Turkeys		
Carcass rotation required; direct supervision of trim by inspectors; visceral organs are observed and palpated.	Unchanged.	New Turkey Inspection (NTI) involves no carcass rotation, no direct supervision of trim, and visceral organs would be manipulated rather than palpated. Field trials for NTI began in 1981 and were completed in the spring of 1982. Proposal being prepared for publication in Federal Register.

[a]Based on information provided by the Food Safety and Inspection Service (USDA, 1984a).
[b]USDA, 1984b.

Additional changes in poultry inspection for broilers are being tested in the new line speed (NELS) procedure. NELS will allow most broiler slaughter plants to increase line speeds to approximately 90 birds per minute. In all cases, the maximum new line speed would depend on a plant's ability to present the birds in a prescribed manner for inspection (Dubbert, 1984a). Presently, four U.S. plants are using NELS on a test basis and a similar procedure for turkeys is being evaluated (Menning, 1984a). Other modifications of poultry inspection procedures are being proposed or tested (Dubbert, 1984; USDA, 1984a).

There are as yet no data or information that the committee could use to appropriately evaluate the public health impact of any line-speed changes or modifications in inspection procedures.

Plant Sanitation

Inspection for sanitation begins in the livestock and poultry holding areas and continues through the handling of live animals and poultry, their carcasses, and the products derived from them. Sanitation includes structural aspects of the premises, water supply, manure and sewage disposal, equipment, personnel, and other health-related features of the plant environment (Libby, 1975).

Slaughter or processing in an unclean environment or under unclean conditions is prohibited--a requirement that is enforced by the inspector's ability to attach a "reject tag" to an unacceptable department or piece of equipment. The tag warns that the department or equipment identified must not be placed in service until it has been made acceptable and released for use by the inspector (Libby, 1975). In addition, the inspector completes a daily sanitation report (MP Form 455, August 1979) that covers such items as plant cleanliness, rodent-insect control, ice facilities, and dry storage areas. A copy of the daily report is provided to the establishment.

Sanitary Slaughter and Dressing

The principal objective of sanitary dressing is to defeather, remove, or clean skin and to remove the gastrointestinal tract and other internal organs with minimal contamination of the product. The process is complicated in animals or birds with localized or generalized diseases, infections, or contaminations, as many of these are not detected until the dressing operation has been partially or entirely completed (Libby, 1975).

The prevention of fecal contamination of the carcass from spillage of gastrointestinal contents or smearing of external fecal matter on the outside of the animals is the single most important aspect of sanitary slaughter and dressing. Ideally, slaughter and dressing should be designed to reduce (or eliminate) fecal contamination. However, especially in the case of poultry and scalded swine, current practices do not prevent cross-contamination during these procedures. Indeed, the major portion of the microbial load on the skin surface of poultry is established during defeathering (ICMSF, 1980).

Carcass Reinspection

After dressing operations and routine postmortem inspection are completed, selected samples are reinspected according to a preestablished sampling plan. Defects are evaluated using accept-reject criteria and the result is extended to all carcasses represented by the sample. The Acceptable Quality Level also provides information on the origin, extent, and nature of carcass contamination so that corrective action directed at the source can be initiated. This program is now used for both cattle and poultry (USDA, 1983b).

Poultry Chilling

Temperatures and procedures that are necessary for chilling and freezing ready-to-cook poultry are designed to cool the carcass promptly so as to inhibit microbial growth. All poultry that are slaughtered and eviscerated in an official establishment are chilled to an internal temperature of 40°F (4°C) or less within 4 hours (for a 4 lb. carcass), 6 hours (4 to 8 lb. carcass), or 8 hours (more than 8 lb. carcass) unless they are to be frozen or cooked immediately at the establishment. FSIS has responsibility for enforcing the poultry chilling regulations. Packed poultry held at the plant for more than 24 hours must be kept at 36°F (2°C) or less. Giblets are chilled to 40°F (4°C) or lower within 2 hours from the time they are removed from the inedible viscera, except when they are cooled with the carcass (CFR, 1983b). Only ice produced from potable water may be used for ice and water chilling. The ice is handled and stored in a sanitary manner; if it is block ice, it is washed by spraying all surfaces with clean water before crushing.

Biological Residue Monitoring

As described in Chapter 4, the National Residue Program that began in 1967 has both monitoring and surveillance phases to detect, identify and record violative levels of chemical residues in meat and poultry and in their products.

Animal Disease Surveillance

Although slaughter inspection has rarely been used for animal disease surveillance, bovine tuberculosis (TB) has been monitored in slaughterhouses. Of the 35 million cattle and calves inspected in fiscal year 1983, only 27 isolates from 1,578 submissions were confirmed as *Mycobacterium bovis*. Ten isolations were from adult cattle, 17 were finished cattle, and none were calves. Only 8 of the 27 TB-infected animals identified at slaughter were traced back to the farm of origin (Essey *et al.*, 1983; Hosker, 1983).

The identification of these herds demonstrates the value of epidemiological tracing and the ever-increasing dependence of bovine TB surveillance on trace-back from regular slaughter animals (Hosker, 1983). It also indicates that certain categories of cattle should

receive greater priority in order to achieve the greatest identification efficiency. For example, feedlots are the predominant source of tuberculosis found through slaughter surveillance in the United States (Essey et al., 1983; Hosker, 1983).

A great deal of the inspection effort as it relates to both beef and dairy cattle requires the incision and inspection of head and cervical lymph nodes, of bronchial and mediastinal lymph nodes, and of hepatic lymph nodes in order to detect tubercular lesions. One of the major purposes of this extensive and time-consuming activity is the identification of TB or TB-like lesions for the Cooperative State-Federal Tuberculosis Eradication Program. Therefore it is imperative that all TB-positive animals be traced back to farm of origin. Otherwise, this labor-intensive incision and submission of lesions by FSIS could continue for years, at great expense.

FSIS is also active in the Bovine and Swine Brucellosis Eradication Program. A major screening program utilized in brucellosis eradication is market cattle identification, introduced in 1959. This program consists of blood testing of cows at market centers and slaughterhouses to determine whether they have been adequately screened by the brucellosis ring test of milk. Animals that react to the blood test are traced to herds of origin, and the complete herd is then tested.

The market cattle program has contributed materially to brucellosis eradication in most sections of the country. Its universal adoption is anticipated since it will provide the frequency of screening necessary to disclose most outbreaks of brucellosis in beef cattle and thereby help ensure eradication. In addition, continuation of the ring test of milk and the market cattle testing program in those areas already free of brucellosis will provide a relatively inexpensive surveillance program (USDA, 1981). In fiscal year 1983, some 5.8 million cattle were tested at slaughterhouses: The market cattle reactor rate was 0.38% (Johnson, 1983).

The market swine testing program, analogous to market cattle testing in the bovine brucellosis program, was initiated in the late 1960s. Sows and boars are tested for brucellosis at markets and slaughter plants; for those that react, the herd of origin is traced and tested. Those found to be infected are slaughtered (USDA, 1981). In fiscal year 1983, a total of 2.1 million swine were tested at slaughter: The market swine reactor rate was 0.039% (Johnson, 1983).

In addition, FSIS occasionally collects blood and tissue samples for surveys of various diseases such as trichinosis and pseudorabies in swine.

Condemnation and Final Disposition

The criteria for disposition of carcasses and carcass parts after examination (both ante- and postmortem) and diagnosis are generally the

same for meat-animals and poultry. An entire carcass or parts of it can be passed for food or condemned (USDA, 1977).

The veterinarian makes a disposition based on five types of considerations: diseased or abnormal tissue; localized versus generalized disease and acute versus chronic; derangement of body functions; injury to consumer's health; and offensive or repugnant appearance (USDA, n.d.).

Poultry condemnations are recorded in 1 of 11 categories. In fiscal year 1983, less than 1% of the poultry examined were condemned on postmortem inspection for all classes of poultry (USDA, 1984c).

Most of the causes of condemnation are attributed to as a lesion or condition of the carcass rather than to a specific cause (e.g., a specific infectious agent). Conditions such as peritonitis, septicemia, abscesses, and pneumonia may be caused by infectious agents of public health importance. However, there is no provision for determining the cause of the lesion. On the other hand, many animals carrying or infected by agents of public health importance do not have lesions that justify condemnation of the whole or part of the carcass. The inspection system is not designed to detect human pathogens unless they produce an observable lesion. This therefore raises a fundamental question as to what the current inspection procedures provide for the public. Some effort should be made to address this question, including listing the diseases identifiable by each step in the inspection procedures for each species.

A sampling plan for histopathological, microbiological, and toxicological evaluation of condemned tissues might provide a measure of the health status of the nation's herds and flocks. A system that could identify the specific cause of condemnation and trace back to the production unit would be invaluable in reducing carcass losses and the presence of human pathogens.

Condemned animals, poultry carcasses and parts, and meat products are promptly destroyed under inspector supervision to prevent their entrance into the human food chain. The equipment used for handling condemned-inedible products is used exclusively for that purpose. Separation from edible food is strict. For example, holding containers are watertight to avoid contamination of the premises or other products with diseased material. The condemned or inedible product is kept under constant inspection supervision from the time it is condemned until it is properly disposed of. This is accomplished by a combination of personal supervision by the inspector and the use of sealed containers, trucks, chutes, and compartments equipped with seals that cannot be tampered with or removed without detection by the inspector. The containers are tightly constructed in order to make diversion of the condemned product unlikely (Libby, 1975).

SUMMARY AND EVALUATION

The federal meat and poultry inspection laws are quite explicit in defining adulteration, and in most instances the definition goes well beyond public health concern. The laws further require that each food-animal in federal or state establishments receive antemortem and postmortem inspections. The objective of the former is to determine if each animal presented for slaughter is normal or abnormal. Under the Wholesome Poultry Products Act of 1968, the extent of antemortem inspection of poultry is left to the discretion of the Secretary of Agriculture, and bird-by-bird antemortem inspection is not required.

The main purpose of postmortem examination is to detect and eliminate abnormalities, including contamination, in an attempt to ensure that only meat and poultry fit for human consumption is passed for food.

In light of changes in the disease prevalence in both meat and poultry, improved animal health husbandry, and financial resource limitations, FSIS has made certain changes in inspection procedures and has proposed others (see Table 6-1). The agency contends that none of these changes has reduced the effectiveness of the meat and poultry inspection program. Although the new procedures may have economic and aesthetic implications, their public health implications have not been evaluated directly.

Salmonella, Campylobacter jejuni, Escherichia coli, Clostridium perfringens, and other enteric pathogens are not identified by antemortem and postmortem inspection and may be conveyed into kitchens on raw meat and poultry. The number of such organisms that leave slaughtering establishments can be reduced considerably by improved dressing procedures to prevent fecal soilage of carcasses and carcass-to-carcass cross-contamination.

As an example of procedures that lead to carcass contamination, the committee is concerned about the "hide-on" slaughtering of calves. In fiscal year 1983, more than 2.7 million calves were slaughtered under federal inspection. FSIS estimates that 85% to 95% were slaughtered with the hide-on method. The entire process of slaughter and dressing is aimed at ensuring, as far as practicable, that the meat remains free of fecal contamination. In the Federal Republic of Germany, the practice of leaving calves unskinned was at one time permissible on the ground that it preserved the natural color of the flesh. Then it was shown that this was a serious source of bacterial contamination and that meat color could be maintained with proper refrigeration. Since 1961 the practice has been forbidden in that country (Gracey, 1981). Hide-on dressing of calves also makes it difficult to observe injection sites (Booz-Allen, 1977b).

The committee is also concerned about the reason behind several ante- and postmortem disposition guidelines. For example, there is no

apparent scientific basis for the requirement that animals bitten by a rabid animal must not be slaughtered for food purposes for at least 8 months (USDA, 1983b). Better guidelines for the handling of "downer" animals (those immobilized by illness or injury) are required. Furthermore, it is not clear to the committee why any livestock showing signs of the onset of parturition should be withheld from slaughter until after parturition and passage of the placenta (CFR, 1983a).

FSIS has also had great difficulty persuading the general public (as well as its inspection staff) that some kind of sampling system, with substantially more intense inspection of a small number of products, could in fact lead to better identification of problem areas and hence improve the public health. This is in contrast to the widespread belief in the scientific community--and endorsed by this committee--that more targeted and more intense study of a sample of products would have many advantages. The committee specifically considered whether to recommend a move toward less-than-continuous postmortem inspection for some aspects of slaughter (especially of poultry) but concluded that no such change should be recommended until a detailed risk analysis, based on sound scientific data, compares the present and proposed approaches and documents that efforts of FSIS to attain its major public health objectives would not be harmed. If sampling is justified and implemented, it should be in the context of the hazard analysis critical control point approach (see Chapter 8). The committee does not look on sampling primarily as a way to reduce costs--indeed they may increase--and it strongly recommends against the use of sampling simply to reduce the total inspection effort with today's methods.

RECOMMENDATIONS

- The present reliance on postmortem inspection is insufficient to guarantee consumer safety from many animal diseases (although they are of low prevalence), as well as from new hazards associated with drug and pesticide residues and antibiotic-resistant bacterial species. The committee notes that the mechanism recommended in Chapter 5 to trace carcasses from slaughter back to the animals' original production unit would not only result in improved quality meat and poultry but would also make available for epidemiological analysis valuable data obtained post mortem.

- In light of the continuing transmission of enteric pathogens to consumers via raw meat and poultry, the committee recommends that newer technologies (for example, hot water wash and irradiation) and modified slaughtering and dressing techniques be developed and implemented to reduce infectious and other hazardous agents in the meat and poultry products leaving slaughtering facilities. As part of a review and update of procedures used during slaughter, the committee recommends that FSIS reassess the "hide-on" slaughter of calves.

- The committee recommends that a sample of condemned tissues be submitted to appropriate pathology, microbiology, and/or toxicology laboratories to establish baseline data of etiologies associated with each condemnation category and to provide material for regularly scheduled gross/histopathology correlation sessions as an integrated part of their continuing education of in-plant VMOs.

- The committee recommends that FSIS periodically review and update antemortem and postmortem disposition guidelines and regulations and that the rationale for such policies be more fully developed and made public.

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7
Meat and Poultry Processing and Inspection

Meat and poultry products are highly perishable. Technological developments in food processing, preservation, and handling over the last few decades have provided a much greater variety of meat and poultry products than were available at the time of the 1906 Federal Meat Inspection Act (P.L. 59-242). This chapter contains a description of the broad categories of processed meat and poultry, followed by a profile and evaluation of the traditional, current, and evolving inspection strategies of processing operations.

Meat and poultry products are defined as processed if the carcass identity is lost (e.g., cut or ground meat) or if the product is subjected to some treatment other than refrigeration (above freezing) that changes its state, texture, color, or flavor, that prolongs its shelf life, or that kills pathogens. Products can be classified according to the processes that they have undergone to influence their safety, quality, or shelf life (ICMSF, 1980).

Distribution and storage usually require some degree of preservation. The most important means of preservation are chilling or freezing, heating, curing, and drying. Chilled meat and poultry can be held for several days and frozen meat and poultry for several months without appreciable change in their properties. When subjected to the other processes--cooking, retorting, smoking, drying, curing, fermenting--their characteristic properties change and these products are clearly different from fresh meat. Unique health hazards and spoilage concerns are thus associated with the product of each type of process.

The microorganisms that cause foods to spoil are generally not the same as those that cause disease. Spoiled foods when eaten seldom cause serious illness, and many food-borne pathogens (e.g., Salmonella and Staphylococcus aureus) even when present in large numbers do not adversely affect food taste or appearance. The committee opted to include spoilage in its discussion of the effects of processing, however, because many of today's inspection activities are intended to ensure that consumers have wholesome products that are unadulterated

The review of microbial hazards and spoilage of processed meat and poultry products in this chapter is based primarily on publications of the International Commission on Microbiological Specifications for Foods (ICMSF, 1980) and the Subcommittee on Microbiological Criteria of the National Research Council's Committee on Food Protection (NRC, 1985). For a discussion of hazards linked to chemical residues, see Chapter 4.

PROCESSING'S EFFECTS ON HEALTH RISKS AND SPOILAGE

Effective processing and storage can prevent health risks and prolong the shelf life of meat and poultry products. Despite the improvements in these procedures over the past 80 years, meat and poultry products are sometimes the vehicles of food-borne diseases, as described in Chapter 3. Outbreaks of food-borne disease or spoilage may result from raw material contamination, process failure, contamination after processing, or improper storage.

Despite currently used inspection procedures, processing-related outbreaks do occur occasionally, as shown in Table 7-1. Salmonellosis has usually stemmed from inadequate cooking and, most likely, cross-contamination in plants and further time-temperature abuse by food-service personnel, caterers, or the public. Improper fermentation of salami led to outbreaks of staphylococcal food poisoning. Trichinosis occurred because raw pork products were eaten or because they were just smoked and not heated to temperatures sufficient to kill Trichinella spiralis.

The final abuses of meat and poultry products that allowed them to become vehicles for transmission of pathogens usually occur in food-service establishments (65%) and homes (31%), but sometimes the abuse occurs during processing (Bryan, 1980). For example, from 1968 to 1977, at least 20 outbreaks of bacterial food-borne illness were traced to mishandling or improper processing in meat or poultry processing plants (Bryan, 1980).

One major factor that might contribute to minimizing such incidents would be to apply state-of-the-science technology for measuring time-temperature exposure of foods during processing. This technology has progressed beyond bayonet-type thermometers and wrist watches. Temperature could be measured with thermocouples (or other appropriate temperature-detecting devices) so as to pinpoint the temperature in the region of the food of concern (e.g., geometric center). Inspectors could be equipped with hand-held thermocouple digital read-out indicators or thermocouple data-loggers. Temperature sensors can be attached to strip-chart recorders or to data-loggers (if computers are available) so that time-temperature curves for each production lot are permanently recorded for review by quality control personnel and the Food Safety and Inspection Service (FSIS) inspector. Strip-chart

recorders and data-loggers can be equipped with alarm systems that can indicate when a specified temperature or duration has not been achieved.

The steps within the different categories of processing that are associated with health hazards are specific to those operations. Inspection strategies should match these categories for monitoring to be effective.

Raw Meat and Poultry: Chilled or Frozen

Raw chilled meat and poultry are commonly kept in chilled rooms, refrigerators, or refrigerated transit vans or containers at temperatures below 50°F (10°C), preferably near 32°F (0°C). These products may be contaminated by Salmonella, Campylobacter jejuni, Yersinia enterocolitica, Clostridium perfringens, and Staphylococcus aureus. These organisms can enter kitchens on raw meat and poultry and can be a source of contamination for cooked products or other foods. C. perfringens spores survive cooking, readily germinate after being heat-activated, and multiply rapidly as the temperature of cooked meat falls below 122°F (50°C). In rare occurrences, cases of salmonellosis have been associated in epidemiological studies with ingestion of raw ground beef (Bryan, 1980; CDC, 1982; Fontaine et al., 1978). Hamburgers sold by a large fast-food chain were the vehicle of transmission of hemorrhagic Escherichia coli that caused several cases of severe bloody diarrhea (CDC, 1982; Riley et al., 1983). Trichinella spiralis may be present in pork, particularly if the hogs have been illegally fed uncooked garbage.

Processing carcasses into primal, subprimal, and retail cuts of meat and cutting up poultry carcasses both increases the surface area and spreads and introduces bacterial contaminants. Additional handling tends to add new contaminants and spread those already present.

Spoilage of retail cuts is similar to that of carcass meat, but it may be hastened by extra handling, increased surface-to-volume ratio, and more diverse temperatures at retail or later. Pseudomonas, Acinetobacter, and Moraxella dominate the flora of moist meat that has been exposed to air and cold temperatures. Their multiplication causes meat and poultry surfaces to become discolored and malodorous, then slimy. In time, depending largely on both storage temperature and relative humidity, spoilage results in spite of good sanitation in plants and storage of the products at low temperatures.

Microbial contamination is likely to be 10 to 100 times greater in comminuted (ground) meat than in whole cuts of meat. The situation is similar for mechanically deboned meat and poultry parts that are ground or crushed and centrifuged or extruded. Subsequent development of microbial flora depends on whether meat is in oxygen-impermeable or oxygen-permeable packages and whether the organisms are on surfaces or in the interior of the product. Surfaces of aerobically stored comminuted meat are bright red when fresh. When Pseudomonas, Acinetobacter, and Moraxella multiply, they eventually produce

ABLE 7-1. Outbreaks Associated with Commercially Processed Meat and Poultry Products Reported in the nited States, 1974-1983

isease nd Causative rganisms	Commercially Processed Product	Year	Number Ill	Contributory Factors[a]	USDA Action	Reference
otulism Clostridium otulinum)	Canned beef stew	1974	1		Product recall	CDC 1974; Blake et al., 1977
	Chicken pot pie	1975	1			CDHS, 1975
	Pot pie	1976	1			CDHS, 1976
	Meat pot pie	1977	1	Left in oven 1 day after reheating		CDC, 1977f
	Pot pie	1983	1	Left at room temperature 2.5 days after reheating		CDC, 1983a
morrhagic litis scherichia li)	Hamburgers	1982	29	(Inadequate cooking; cross-contamination?)		CDC, 1982; Riley et al., 1983
monellosis lmonella rport)	Ground meat	1975	18	(Ingestion of raw beef)	Inspection; laboratory testing	CDC, 1975b; Fontaine et al., 1978
saint paul)	Precooked roast beef	1975	81[b]	Inadequate cooking (cross contamination; improper refrigeration; holding food at room temperature at food service establishments)	Laboratory examination of product; nationwide sampling program	CDC, 1976a

. bovis-rbificans)	Precooked roast beef	1976	46	Inadequate cooking (cross-contamination; improper refrigeration; holding at room temperature at food-service establishments)	Inspection; laboratory finding of inadequate cooking; sponsored research	CDC, 1976b CDC, 1977b
. newport)	Precooked roast beef	1977	243	Inadequate cooking (cross-contamination; improper refrigeration; holding food at room temperature at food-service establishments)	Laboratory isolation of Salmonella; recall	CDC, 1977a,c,d,e
Groups C1,C2)	Precooked roast beef	1978	41[c]	Inadequate cooking (cross-contamination; improper refrigeration, holding food at room temperature at food-service establishments)	Recall (state seized product)	CDC, 1978

ABLE 7-1 (cont.)

sease d Causative ganisms	Commercially Processed Product	Year	Number Ill	Contributory Factors[a]	USDA Action	Reference
. chester, S. phimurium)	Precooked roast beef	1981	13[b] 47[b]	Inadequate cooking (cross-contamination; improper refrigeration, holding food at room temperature at food-service establishments, by caterer, or in hospital)	Distribution halted	CDC, 1981b
newport, typhimurium)			42[b]			
roups B, C2)						
saint paul)	Precooked roast beef	1981	25[b] 4	Inadequate cooking (cross-contamination; improper refrigeration, holding food at room temperature at food-service establishments)	Laboratory isolation; recall	CDC, 1981a
chester, tennessee)			46			
chester, avana, S. imurium						
hylococcal poisoning phylococcus us)	Italian dry salami	1975	8	No starter culture used, no acidification	Laboratory detection of toxin and S. aureus	CDC, 1975a
aureus)	Genoa and hard salami	1979	19 (8 incidents)	Growth possible because of salt content and temperature during fermentation	Recall	CDC, 1979

aureus)	Ham[d] (ham and cheese sandwiches)	1983	14	Cold smoked for 6 hours; temperature abuse after process	Laboratory detection; recall	CDC, 1983b
aureus)	Ham[d] (stuffed chicken breast)	1983	48			
aureus)	Ham[d]	1983	51			
chinosis richinella iralis)	Ready-to-eat pork products	1975	8	Inadequate heat processing	Inspection; laboratory examinations (no isolations)	CDC, 1976c
spiralis)	Pork[e] and venison sausage	1976	73	Inadequate heat processing (smoking)		CDC, 1976d
spiralis)	Raw smoked sausage	1980	15	Inadequate heat processing (smoking)		CDC, 1983a,b

Parentheses indicate likely contributory factors.
Source of implicated beef traced to same processing plant.
Three outbreaks having the same source of meat.
Same phage pattern isolated from patents and foods and from ham processed at the same plant.
Custom locker plant, sampling done at Iowa State Department of Agriculture; T. spiralis identified at Iowa State University.

sliminess. In the interior, which is anaerobic unless loosely packed, lactic acid bacteria develop and cause souring. In oxygen-impermeable packaged meat, bacterial counts (mostly lactic acid bacteria) can become very high without obvious spoilage.

The pathogens of frozen raw meat are the same as those of the meat and poultry before freezing, but their numbers may be changed. Freezing kills parasites and some bacteria, but frozen meat is not likely to be free of pathogenic bacteria. Salmonella, for example, is frequently isolated from frozen meat and poultry. Bacterial spores and Staphylococcus aureus vegetative cells survive freezing and frozen storage quite well. Time-temperature abuse after thawing can encourage microbial multiplication. Cross-contamination from thawed products and from thaw water cause the same concerns as do raw chilled meat and poultry.

Bacterial spoilage does not occur in properly frozen and stored meat. Storage temperatures as low as 14°F (-10°C), however, permit slow development of molds that form spots on surfaces. Spoilage that usually occurs after thawing is the same as that in raw chilled meat. Surfaces become slimy under aerobic conditions and souring occurs under anaerobic conditions. Oxidation continues during frozen storage and results in deterioration of quality.

Cured Meat and Poultry

Meat and poultry are cured by the addition and penetration of solutions containing sodium chloride, nitrites, or nitrates. This treatment imparts color, flavor, antioxidant properties, and microbial stability. Depending on salt concentrations, the length of the cure, and subsequent drying, the moisture level of the product as measured by its water activity (a_w) varies. (Water activity is the ratio of the water pressure of a food to that of pure water at the same temperature. It is a measure of the water in a food available for use by microorganisms that have specific cardinal requirements for a_w; hence their growth in a food and the spoilage of that food is a condition of the a_w.)

Products are classified as having a_w values either above or below 0.92. The pathogens of most concern in high-a_w cured meats (e.g., bacon, raw ham, or unfermented sausage) are Salmonella, Staphylococcus aureus, and Clostridium botulinum either if insufficient concentrations of salt, nitrite, or nitrate are added or if cold storage is inadequate. Hams, after packages are opened, are commonly contaminated with S. aureus during slicing or other handling. If such ham is not properly chilled, S. aureus multiply and produce enterotoxin. Improperly home-cured hams have been implicated in outbreaks of botulism in France (Sebald and Jouglard, 1977). Rapidly cured, brine-injected bacon and ham, which are often sliced and vacuum-packed, require refrigerated storage. Gradually, surfaces become slimy, and flowery or acidic odors develop. Spoilage of vacuum-packed bacon is ultimately

caused by lactobacilli, but yeast may develop if acidity is low (i.e., if pH is higher). During drying, surface molds develop naturally. These are removed by washing and soaking prior to cooking. Salted sausage is susceptible to oxidative rancidity, but this is retarded by the antioxidant effect of nitrite in the cure.

Smoked Meat and Poultry

The primary function of smoking after curing is to provide flavor, not to preserve. Smoking (and accompanying cooking), depending on time and temperature exposure, will either kill or allow survival of microorganisms that do not form spores. Cold smoking, however, permits survival of most microorganisms. During smoking and accompanying or subsequent heating, the surface dries, thus reducing the water activity and concentrating salts. Wood smoking deposits phenolic and acidic compounds on surfaces, which lowers pH. Spoilage is usually caused by molds.

Fermented Sausage

Fermented sausages undergo a cure/fermentation process for a period of hours to days at temperatures ranging from 50° to 86°F (10° to 30°C), depending on the product. Fermented sausage having a low a_w can pose a risk due to the enterotoxin of S. aureus, particularly if it is made rapidly by fermentation at relatively high temperatures when the mix has a high a_w but before the product has been fermented and dried. Several outbreaks of food-borne illnesses have resulted from poorly processed Italian or Genoa salami (Barber and Diebel, 1972; CDC, 1975a, 1979).

Molds cause most of the spoilage of fermented sausage because they can grow in products having low water activity. Mycotoxins have been found on their surfaces (Frank, 1972), but apparently these toxins do not penetrate far below the surface. Enyzmes produced during multiplication of lactobacilli can result in a sharp off-odor and a bitter, cheesy flavor in sausage.

Dried Meat and Poultry

Commercial drying of meat, blood, and gelatin is usually done in hot-air tunnels or freeze driers, but some drying is done in the open air. Salmonellae, other Enterobacteriaceae, and clostridia are likely to be associated with meat, and staphylococci, Bacillus cereus, and C. perfringens may be introduced, if not already present, during the preparation and drying of these products. It is therefore essential that the drying rapidly decrease the a_w of these products to levels at which pathogens do not multiply. If these pathogens survive the processing, they can survive in the dried product for a long time. Multiplication of these bacteria in a dried product will be inhibited as long as the product is kept dry, but bacterial growth will then begin after the product is rehydrated and left unrefrigerated for 4 or more

hours. Spores, such as those of C. perfringens and B. cereus, can survive cooking (e.g., boiling for a few hours), freezing, and drying, and resulting vegetative cells can multiply when reconstituted products are improperly stored. Other pathogens, of course, can enter the product during or after reconstitution and subsequently multiply.

Properly dried meat is microbiologically stable, unless there is a relatively large uptake of moisture from exposure to moist conditions. When spoilage does occur, molds are the primary causes, and musty odors, off-flavors, and discoloration are the result. After rehydration, microbial growth is similar to that of the product before drying.

Rendered Meat and Fat

Rendering of meat trimmings and fat at low temperatures, i.e., approximately 120°F (49°C) or slightly lower, permits survival of C. perfringens and may not always kill vegetative forms of bacteria such as S. aureus and Salmonella. The conditions are anaerobic and ideal for the multiplication of C. perfringens, which can multiply at temperatures up to 122°F (50°C). This product is likely to be contaminated with a large number of bacteria. Spoilage is likely to be caused by anaerobes, including C. perfringens.

Dead and diseased animals, meat scraps, bone, feathers, blood, and viscera are rendered at high temperatures, between 239 and 270°F (115 and 150°C), to produce inedible fat and meals. Pathogens will be killed by this treatment, but the rendered product often becomes recontaminated in the rendering environment or sometimes during transit. Rendered meat, bone, blood, and leather by-products frequently harbor salmonellae.

Pasteurized Meat and Poultry

Uncured meat and poultry are often pasteurized--that is, cooked to internal temperatures of 130° to 167°F (54° to 75°C) for sufficient time to kill or inactivate most yeast, molds, parasites, viruses, and non-spore-forming bacteria. C. perfringens is the pathogen of most concern in pasteurized or otherwise low-heat processed meats and poultry. Cooking kills competitive organisms but allows heat-resistant C. perfringens spores to survive; it drives off oxygen, thus lowering the redox potential of the meat and skin; and it heat-activates spores, causing them to germinate when temperatures become favorable. Holding the cooked products for several hours within a temperature range optimal for multiplication of pathogenic bacteria permits their multiplication to numbers that could produce illness.

Salmonella are inactivated by proper heat processing (Bryan, 1980; Goodfellow and Brown, 1978), but cross-contamination readily occurs after heating when other products are packaged or repackaged by or on the same equipment, by the same persons, or in the same environment. Several outbreaks of salmonellosis have resulted from either

inadequately heat-processed or recontaminated "roast" beef (Bryan, 1980). Turkey rolls have also been a vehicle of salmonellosis outbreaks (Bryan et al., 1968).

When meat and poultry products are pasteurized after packaging, spoilage depends on the surviving flora and the product temperature during storage. Micrococci, streptococci, and lactobacilli are frequently involved. Recontamination occurs if the pasteurized product is repackaged or sliced. In such cases, spoilage may occur within a week and may be caused by a great variety of bacteria, yeast, or molds because cooked meat and poultry are excellent media for their growth. Thus, spoilage may be either souring proteolysis with repugnant odor or putrefaction with gas.

Cured meats (e.g., ham, wieners, bologna) are heated to internal temperatures of 137° to 167°F (58° to 75°C) to be pasteurized. S. aureus causes most concern in such cases. It rarely survives the heat process, but it is introduced by workers who handle and package these products. Once a food is contaminated, staphylococci can be readily disseminated by slicing machines and other equipment. The a_w and nitrite concentration in pasteurized, cured meats do not prevent the multiplication of S. aureus. Spores of Bacillus spp. and Clostridium spp. survive pasteurization. Salmonella and C. botulinum have not been a significant problem, probably because of the combined effect of salt, nitrite, and cold storage.

If pasteurized, cured meat and poultry products are stored in refrigerators, bacterial counts may not substantially change for months. Eventually, however, lactic acid bacteria and enterococci that have survived the heat process multiply and cause changes in flavor and odor. Products may become either putrid or acidic and sticky, depending on the concentration of fermentable carbohydrates. In oxygen-impermeable plastic pouches, lactic acid bacteria in some cases multiply despite the addition of salt and nitrite, and carbon dioxide may be formed and swell the package. The shelf life of pasteurized, cured products that are sold unpackaged or in oxygen-permeable films is only slightly longer than that of fresh meat (ICMSF, 1980). Psychrotrophic bacteria may cause slime formation, and molds may grow. Catalase-negative bacteria may produce hydrogen peroxide that causes either brown or green discoloration.

Low-Acid Canned Meat and Poultry

Uncured meat and poultry products (pH greater than 4.6) that are packed in tins or aluminum cans, glass jars, metal foils, or strong plastic containers are given a time-temperature exposure that will kill up to 10^{12} C. botulinum spores. On rare occasions, improper heat-processing or contamination during cooling has led to outbreaks of botulism (DHEW, 1979; Meyer and Eddie, 1965). Spores of such pathogens as C. perfringens and B. cereus are also killed by this "botulism cook." Salmonella and S. aureus only become problems if they gain

entrance through a seam or pin hole during handling or in cooling water after retorting.

Canned, uncured meat and poultry products may contain microorganisms from one of three sources: growth of bacteria before heat processing, survival of heat-resistant spores, and post-process penetration into cans. Some mesophilic spores (e.g., Clostridium sporogenes and putrefactive anaerobes) have greater heat resistance than does C. botulinum; surviving spores germinate and may cause cans to swell. Microorganisms from workers, equipment, or cooling water can enter cans through pin holes, faulty seams, or the mastic that seals ends to the can body. A variety of spoilage forms follows, depending on the type of contaminant.

Hermetically Sealed, Shelf-Stable, Cured Meat and Poultry

Hermetically sealed, shelf-stable, cured products are subjected to temperatures much lower than those required for a botulism cook. These products, however, are shelf-stable under normal distribution and storage conditions in temperate climates because of a combination of heat treatment, salt and nitrite concentrations, and storage temperature. C. botulinum spores can survive in hermetically sealed, shelf-stable, cured meat and poultry, but proper nitrite concentrations prevent outgrowth of spores.

Spoilage may be caused by a large quantity of mesophilic anaerobic spores, inadequate heat processing, a low concentration of curing salts, or a combination of these factors. As with any retorted product, spoilage can take place before canning, the process can fail, or contaminants can enter faulty cans after processing. If concentrations of curing salts are too low, and if pH and storage temperatures are favorable, C. sporogenes and other putrefactive anaerobes can germinate and multiply, producing gas that can make the can swell and sometimes turn the contents into liquid.

Fully Sterilized Cured Meat and Poultry

Fully sterilized cured meats are given a heat process higher than that required for the botulism cook so that putrefactive anaerobes and thermophilic spores are inactivated. These products would not spoil or become a health hazard unless post-retort contamination occurred, because the high-heat treatment either kills or injures heat-resistant spores, rendering them more sensitive to sodium chloride. These products are stable even when stored under tropical conditions.

Radicidized (Irradiation Pasteurized) Meat and Poultry

Doses of approximately 2.5 kilo Gray (kGy) in fresh meat and poultry and approximately 5 kGy in dried or frozen meat kill Salmonella. Irradiation is usually applied to packaged products and the products do not increase in temperature during treatment, so immersion in cooling

water is not necessary; there is little opportunity, therefore, for recontamination. This procedure could eliminate Salmonella from packaged raw meat and poultry and Trichinella spiralis from pork, but it is not yet an approved method of preservation in the United States for these products. C. perfringens would remain a concern, however, because the spores are not killed by this level of irradiation.

There are several causes of spoilage. Moraxella is a common cause of spoilage of irradiated meat and poultry stored at refrigeration temperatures. Enterococci may survive irradiation and be present in large numbers at the time of spoilage. Lactic acid bacteria cause spoilage in packages in which the atmosphere is anaerobic.

Radappertized (Commercially Sterilized) Meat and Poultry

Clostridium botulinum spores are highly resistant to radiation so either high-dose irradiation or lesser doses coupled with acidification or curing salts must be used to provide safety and shelf stability. A dose of 45 kGy for products that have not been acidified or cured is needed to provide a treatment that will kill up to 10^{12} C. botulinum spores.

INSPECTION RESPONSIBILITIES AND STRATEGIES

In the early days of meat inspection in the United States the primary concern was to keep meat from diseased animals out of food channels and to ensure that slaughter and meat processing operations were done under sanitary conditions (see Chapter 2). These objectives required continuous inspection at slaughter. Since World War II, increasing proportions of the meat supply have gone into processed products, and a significant portion of federal inspection has thus been devoted to processing. FSIS was required, therefore, to increase its degree of surveillance over a growing and increasingly complex system; budget restrictions, however, have not permitted commensurate growth in inspection activities. The expansion of responsibilities has been accommodated by increased efficiency, use of new methods, curtailment of unproductive inspection steps, and other measures.

All three of the broad inspection strategies discussed here (see Table 7-2)--the traditional approach, voluntary total quality control, and compliance-based inspection--are intended to ensure that

- sanitation is adequate;
- approved formulations are followed;
- only wholesome ingredients are used;
- products are not adultered; and
- products are truthfully labeled.

TABLE 7-2. Inspection Strategies[a]

Present

Traditional

The traditional inspection approach is to:

- search and detect, usually after the fact,
- evaluate finished products,
- conduct sanitary checks as a prerequisite to operating,
- examine ingredients on a case-by-case basis,
- check adequacy of processes, i.e., times, temperatures, etc., on a production-lot basis, and
- leave USDA personnel to bear the burden of compliance with the law and regulations.

TQC

Voluntary TQC emphasizes:

- prevention rather than remedial action,
- statistical methods for chart production,
- production patterns on charts that provide inprocess or online control, rather than lot inspection, as in the past,
- an orderly and systematic way to check critical control points, where loss of control would result in unacceptable product, and
- plants assuming responsibility for complying with the law and regulations.

Under voluntary partial quality control (PQC) programs, the plant establishes and FSIS approves specifications and control activities for given procedures.

Proposed

Proposal for compliance-based inspection reintroduced in 98th Congress. Proposal would give the Secretary of Agriculture authority to determine degree of inspection in meat, poultry and egg processing establishments.

Determination would be based on:

- nature and frequency of plant's processing operations,
- adequacy and reliability of its pr uct monitoring system.
- history of compliance with inspect requirements, and
- other factors the Secretary may de appropriate.

Inspectors would continue to sample product for laboratory testing, to se that sanitation requirements are met, and to monitor processing procedures.

The proposal would give USDA discreti to decide whether it is necessary for inspector to visit every processing p on a daily basis.

[a]From USDA, 1984a.

Inspectors have the authority to prevent adulterated products from entering commerce and to condemn any such products they discover at a processing facility.

Traditional Inspection

FSIS inspectors using a traditional inspection approach evaluate compliance with U.S. Department of Agriculture (USDA) meat and poultry regulations mainly by observing both the construction of plant and equipment and operations within the plant. The various responsibilities of the meat and poultry inspection program, as summarized by the Council for Agricultural Science and Technology (CAST, 1980), are:

- approval of all building plans and equipment used in the slaughter and processing of meat animals;
- anteslaughter examination of animals for health-related problems;
- carcass inspection for indications of health-related problems;
- sanitation inspection of equipment, buildings, grounds, and handling of meat products at all stages of processing;
- reinspection of all processed meat products to ensure that only approved items and procedures are used;
- quality inspection to ensure that only the appropriate amounts of moisture, fat, binders, etc., are incorporated into processed and cured meat items;
- destruction of condemned or unwholesome products to ensure that these items do not enter human food channels;
- examination of all ingredients used in meat items for appropriateness and wholesomeness;
- specification and application of identity (name of product) standards for inspected food products;
- approval and inspection of all labels to ensure informative and accurate labeling;
- inspection of foreign meat products that are imported into the United States;
- certification of domestic meat and meat food products for sale in foreign commerce;
- monitoring of meat items for drug, pesticide, and chemical residues;

- assurance that all pork used in processed products that may be eaten without adequate cooking is properly treated to destroy trichinae; and

- identification of causes of meat-borne hazards through epidemiology.

Labeling is an important part of inspection and is used as an enforcement tool. Inspectors' responsibilities regarding labeling (Libby, 1975; USDA, 1981) are to ensure that the principal display panel of a product contains the five essential features USDA requires:

- Name of Product. Each name represents a product for which there is a standard of composition. The standard may be established by regulation, or it may be developed by study of consumer expectations about a particular product.

- Ingredient Statement. The various ingredients in their order of predominance must be listed for products having more than one component.

- Identity of the Manufacturer. The name, address, and ZIP code of either the manufacturer or the distributor must appear on the label.

- Net Weight (Quantity of Contents).

- Inspection Legend.

In some cases, additional qualifying phrases and warning statements (such as "keep refrigerated" or "keep frozen") are necessary.

Labels are not required to provide information on how to handle the products, although many companies give instructions for thawing and cooking. Most outbreaks of food-borne diseases are related to mishandling after cooking, as noted earlier, and labels, stickers, or leaflets could be used to provide consumers with information to reduce this problem.

To meet their obligations, inspectors may make random checks of formulation and product weights and measurements of time–temperature exposures. They may also collect samples to be tested for fat, water, restricted ingredients (such as nitrites, phosphates, cereal, and nonfat dry milk), drugs, pesticides, or chemical residues. And they supervise the disposal of inedible meats.

To enforce these regulations, USDA's inspectors visit each meat and poultry processing plant at least an hour each day; larger operations are under continuous surveillance by at least one inspector. Products that pass inspection carry the USDA mark, which implies that they are wholesome, neither adulterated nor misbranded, but not necessarily free

of pathogens. When violations are detected, inspectors may tag the product (which necessitates correction and reinspection, causing slowdowns), talk with plant managers about the problem, report the situation to supervisors, or make out a schedule for compliance. Much of the success of the FSIS inspection program to date and much of the faith of the American public and purchasers abroad that meat and poultry are wholesome are due to these efforts of the inspectors and the FSIS.

Unfortunately, some items in the regulations are vague (e.g., "adequate," "satisfactory," "unsanitary," "clean," and "unwholesome"). This lack of specificity sometimes causes confusion about the relative importance of each requirement and leaves many important matters to the discretion of inspectors and their supervisors. Lack of discrimination between important and relatively unimportant requirements may result in overemphasis on unnecessary and relatively minor requirements, whereas operations critical to the safety of a product may be overlooked or underestimated.

Review and evaluation staff of FSIS oversee the work of inspectors by conducting onsite assessment of meat and poultry processing operations. Deficiencies associated with 10 "critical" control points specified by FSIS are used to monitor inspection control effectiveness. These are:

- facilities, equipment, water supply, and sewage disposal;
- sanitation of facilities and equipment, and personal hygiene;
- antemortem, postmortem, and dressing procedures;
- edible product handling procedures;
- total and partial quality control, acceptable quality level, and net weight programs;
- pest control, including rodenticides and insecticides;
- control of inedible and condemned material;
- control of product ingredients, formulation procedures, and labeling;
- control of retained, returned, and restricted products; and
- nonfood chemicals.

These inspection points relate to duties and responsibilities of inspectors to enforce 22 general items and 23 specific processing items, some of which do not have an impact on public health. Many of the "critical" control points currently used by FSIS are definitely control points in reference to aesthetic matters and compliance with existing regulations. But all of them cannot be considered critical to food

safety or public health (as delineated in Chapter 8). The committee notes that the word "critical" as used by FSIS needs to be reassessed and to be reserved for truly critical public health operations.

The traditional inspection approach is quite expensive. Despite continuous inspection since meat plants started operations, violations of regulations are encountered, as indicated by circuit staff reviews. Furthermore, outbreaks of meat-borne and poultry-borne illnesses occasionally result from processed meat and poultry products. In addition, the current approach is negative in that most of the communication with management is fault-finding; a more positive approach would identify possible problem areas before processing operations are affected.

Factors that have contributed to current problems of the traditional inspection approach were summarized in a Booz-Allen report (1977) as uncontrolled program growth and work load due to continuing state designations; lack of appropriate, accessible, and detailed information on the current system that can be integrated into budgeting, resource allocation, and other management processes to support management decision making and evaluation; and an inability to change with changing technologies, due largely to constraints imposed by existing regulations.

Industry Quality Control/Quality Assurance Approaches

Some meat and poultry further-processing plant managers have organized quality control/quality assurance programs. The general objectives are to meet specifications of buyers, decrease economic losses, and create or maintain product integrity and company reputation, which includes maintaining product standards and ensuring products have a reasonable shelf life. To attain these objectives, companies may set purchase specifications for ingredients, establish guidelines for various steps (control points) in the operation, establish their own critical control points, train staff, and test finished products. If ingredients, processing steps, or finished products do not match those specified in the guidelines, the management decides whether to distribute the product and accept any consequences, discard the product, reprocess the product, or modify subsequent processing steps, labeling, or distribution.

Quality control by the industry merits praise and should be encouraged. Some of these voluntary standards exceed USDA regulations, especially with respect to microbiological hazards and critical control points. Mainly on the basis of its site visits and discussions with FSIS staff at the plants, the committee noted that these efforts are not always complete. Some plants seem to use USDA inspectors as their quality control program and do not take major responsibility in this area. Others try, but their programs are poorly conceived or poorly managed, the committee observed. Therefore, some sort of official surveillance of products, processes, or plant seems necessary.

FSIS Total Quality Control Program

To help meet the increasing demands for continuous surveillance of meat and poultry processing operations yet remain within available resources, the FSIS has adopted a system of "continuous supervision" as well as "continuous inspection" (Angelotti, 1978). In this regard, Booz-Allen (1977) recommended that industry be made responsible for quality control of processing plant inspections, with the role of USDA being limited to monitoring and approval.

After a gradual phase-in, USDA recommended that this total quality control program (TQC) become mandatory, but because of legislative restrictions it was initiated as a voluntary system (CFR, 1980a,b; for further details, see Appendix B). Processing plant managers could ask for TQC inspection if they believed the system would be useful in their operations. Currently, many processing plants are not ready to change over to TQC because of lack of trained personnel to implement and comply with the program and the lack of management-perceived incentives to do so.

The proposed system places on the industry the burden of proof of compliance with federal laws and regulations. It is industry's responsibility to provide acceptable evidence of compliance to FSIS inspectors for monitoring and verification.

Such a system, in essence, suggests that industry quality control programs are the only acceptable means of providing this evidence under existing technology. This system would have four mandatory quality control programs: monitoring of microorganisms, fat and added water, net weights, and in-process temperature controls. All phases of the production cycle would be covered by these four programs, including incoming products, process controls, and outgoing products.

This monitoring system would be accompanied by frequent verification samples taken by FSIS inspectors, as well as by annual compliance ratings. Plants chronically not in compliance would meet with economic penalties that would levy a progressively greater burden on them.

The proposal for TQC recognized that small-plant operators lack both the expertise in quality control and the capital necessary to develop such programs and that these plants should continue to be inspected by traditional techniques. By using TQC where possible, FSIS can better utilize data to make less subjective judgments that can be supported and related to a progressive enforcement system. In addition, the proposal stated, FSIS will be better able to adhere to personnel ceilings while meeting its legislative mandates.

TQC is a major change in direction for the inspection of processed products. FSIS has therefore prepared manuals and visual aids that

provide guidance in developing quality control programs. Examples include a slide presentation "Total Quality Control Inspection, What it Means for You and for the Processor" (USDA, 1984c), a Quality Control Guidebook (USDA, 1984b), and a Chemistry Quality Assurance Handbook (USDA, 1982, 1983).

To satisfy USDA inspection requirements, processors must submit in writing their plans regarding 12 features of a TQC system (USDA, 1980):

- A plant profile must be developed that should include, though not be limited to, slaughter or processing operations, use of outside contractors for specific operational functions, plant laboratory capabilities, waste disposal, clean-in-place systems, continuous processing systems, product liability prevention, use of consultants or outside laboratories, water potability certificate, sources of meat or poultry, suppliers, and recall procedures.

- A list of plant management personnel--from the corporate head to persons responsible for making quality control checks--is needed, as is a flow chart showing lines of authority among plant officials. This chart must indicate adequate safeguards to ensure that quality control personnel can take action whenever a product is not in compliance with USDA inspection requirements.

- A list of raw materials, packaging materials, and nonfood supplies received by the plant or produced by the slaughter area of the plant should be submitted.

- A list of products produced in the plant must be categorized into classes that need specific controls to meet federal meat and poultry inspection regulations.

- By evaluating the raw materials and processed products used in the plant, a list of the meat and poultry regulations that are applicable to the plant's inspection should be developed.

- Hazards and control points of the processing of each product must be identified.

- Adequate records (such as receiving logs, product temperature records, formulation and processing procedure, mean-range quality control chart or similar quality control charts) are essential to the system's ability to provide necessary controls.

- A policy toward handling inedible materials must be in place.

- Specifics are required on a cleaning procedure for the different types of soils (e.g., fat, blood, dirt, and meat protein) and on the monitoring system, which would include preoperative inspection, operational inspection, general facilities inspection, personal hygiene, and pest control. Other items that would be helpful in documenting

sanitation include records on plant maintenance, environmental control and maintenance of environmental equipment, pest control, water supply, chemicals used for sanitation, product contamination control, cleaning instructions, personal hygiene, and daily inspections.

- Corrective action with an emphasis on long-range prevention should be recorded and made a matter of record.

- Statistical procedures should enable an examination at critical control points so that the process can be adjusted as it drifts toward undesirable features. The information provided will also be useful in making decisions concerning the "fitness for use."

- The plant's processing procedures from receiving raw materials to the finished product should be diagrammed.

In addition to a written plan, each company must submit a letter stating its reasons for seeking total quality control approval (USDA, 1984c). The plant must also indicate that it is willing to adhere to the requirements of the system after it has been approved, that all monitoring data will be available to representatives of USDA, that plant quality control personnel have authority to stop production or shipment of product when the need arises, and that plant officials will be available for consultation with representatives of USDA when necessary. If the total quality control application is approved, USDA guarantees production of products that are acceptable under USDA requirements for wholesomeness and labeling accuracy.

After a plant TQC program is approved, the USDA quality control inspector follows a prepared set of guidelines. This includes a plan of inspection and an inspection schedule. The plan is based on the plant's quality control plan that specifies (1) "critical" control points and elements; (2) compliance standards; (3) tests and inspections to ensure that "critical" control points are monitored and the standards are met; and (4) evidence that the plant is complying with the plans it produced. An FSIS Quality Control Inspection will verify that the system is being followed.

On an unannounced schedule, the plant's TQC program is evaluated by FSIS. If a plant frequently fails to operate according to its TQC system, if deficiencies recur, or if corrective action is not acceptable, the quality control inspector follows specific steps outlined in FSIS regulations. If this does not result in improvement, then the USDA quality control inspector issues a written notice to plant management. If the plant is still not responsive, further steps include possible termination of approval of the plant's TQC. All discrepancies and actions to be taken when the plant is not in compliance with its quality control system are noted and these matters are discussed with plant officials.

The TQC system is more systematic, objective, and organized than traditional inspection. Records and controls in plants that use TQC give both the plant management and the FSIS inspector a more complete picture of the processing procedure than presented by traditional processing inspection procedures. Problems can occur with any system, of course. Table 7-3 shows how possible problems can be minimized.

As of April 1, 1985, USDA had approved 475 TQC systems, covering about 7% of all meat and poultry processing plants and 9% of the processed products (FSIS, personal communication, 1985). Plans had been submitted for 115 more plants, but they have not yet been approved; 46 systems have been terminated by action of either the plant or FSIS.

In the judgment of the committee, TQC should lead to better compliance in plants that are committed to the approach, to a reduced need for FSIS supervision, and, therefore, to cost savings. Adequate data, however, are not yet available to confirm this view. A nondepartmental study team evaluated 15 establishments under the program (Temple, Barker, & Sloane, Inc., 1984). The team concluded that the TQC concept ensures compliance with USDA requirements and that it could provide even more confidence in such compliance than traditional inspection because it allows the inspector to review a much broader scope of plant operations. The team also concluded that the TQC program is hindered by the variable, and generally low, training in these areas of some meat packers and of federal inspectors in quality control, and that until this improves the resulting mode of inspection will in some cases be a hybrid of traditional and TQC approaches. In its final summary the team stated that TQC offers potential benefits to plants, the public, and FSIS by improving quality and production efficiency. Essential for its success is the commitment of plant management to the program and the practical understanding of a good inspector and plant staffs of quality control concepts and tools.

SUMMARY AND RECOMMENDATIONS

"Processed" meat and poultry products are defined as those in which the carcass identity is lost or subjected to some treatment that affects its texture, color, and flavor. The nature of microbial hazards and the extent of spoilage depend on the specific process used. Proper processing and storage can minimize or prevent risks to health and prolong shelf life. Spoilage or outbreaks of food-borne disease from processed meat and poultry products result from process failures, contamination of the product after processing, or from improper storage. It should be kept in mind that the microorganisms that are potential pathogens are not necessarily the same as those that cause spoilage and that spoilage might be due to microorganisms that are not pathogens.

Some processing plants have their own quality control/quality assurance programs to maintain product consistency and standards and to

TABLE 7-3. Potential Problems and Safeguards of the Total Quality Control (TQC) Program

Possible Problems	Safeguards
Falsification of quality control data or failure to follow the control plan	Make unannounced inspections with appropriate penalties for violations
Plants improperly learning of unannounced inspection	Send a second inspection team unannounced to both plant and local inspectors
Inspectors insufficiently trained to handle quality control inspection	Upgrade educational levels for inspectors who enter quality control inspection and give extensive USDA-sponsored training to inspectors
Collusion between inspectors and plant personnel	Take the same preventive action as taken for traditional inspection
A large amount of data, which dilutes crucial critical control points	Stress critical control points in the TQC plan and at each review session; deal with violations promptly and appropriately
Plans adopted without total corporate commitment to avert conventional inspection or management's failure to give quality control personnel sufficient authority to perform their responsibility	Get a written TQC plan that is approved by USDA, and terminate the program if the plan is not followed
The "newness" of the quality control system wears down and the plant loses its enthusiasm	Observe this situation during the unannounced inspections and if it occurs either rejuvenate or terminate the plan; if rejuvenated, more-frequent inspections should be made to verify that the system is working
A system so complex that only large plants can take full advantage of this approach	Provide consultation and assistance to smaller plants and emphasize the "crucial" critical control points
Concern over the ultimate cost of the product	Confirm that TQC systems reduce the cost of operation by increasing uniformity (Theno, 1981)
Concern that the system may become mandatory for all processing plants	Keep the system voluntary because enthusiasm of plant management is essential to a successful program

protect the reputation of the company. This is also done to meet buyer specifications and to decrease losses. These plant-initiated quality control programs, which frequently exceed FSIS guidelines, merit praise and should be encouraged. However, some plants use the FSIS inspectors as the basis of their quality control efforts and do not take major responsibility in this area. Thus continuous inspection of products, processes, and the plant by FSIS is required in many cases.

Processing plants with the capability or proven practice of instituting their own effective quality control programs reasonably might not require continuous inspection by FSIS. With this as an important consideration and with the increasing demands on the resources of FSIS, the total quality control program was proposed and instituted on a voluntary basis. In this program, the managers of the processing plant are made responsible for quality control procedures and for day-to-day and process-by-process inspection. The role of FSIS in TQC is one of monitoring and verifying that the processing procedures comply with federal laws and regulations, on the basis of evidence provided by plant managers and FSIS's own validation. As of April 1985, USDA had approved TQC systems in 7% of the meat and poultry processing plants, which produce 9% of the processed products in the United States.

- The committee recommends that FSIS inspection approaches (traditional and total quality control) be strengthened in the areas of establishing and letting inspectors and plant personnel know about priorities in terms of which facets of inspection are the most important. Some aspects of USDA regulations are more important than others in providing assurance of food safety and product wholesomeness, a distinction that is not always reflected in regulations or during inspections.

- The committee recommends that FSIS reevaluate the use of the term critical control point and restrict its use to those operations that if incorrectly performed could increase food-borne disease or food spoilage. More minor items may be referred to as control points or noncritical regulated items. (See Chapter 8 for examples of critical control points.)

- The committee recommends that the recruitment and training of inspectors be made appropriate to the expanding technical aspects of their role in total quality control and the hazard analysis critical control point approach. An internal working group augmented by outside consultants should be created and used to evaluate FSIS personnel needs as policy and technology changes.

- It is recommended that FSIS and the meat and poultry processing plants under their supervision use state-of-the-science technology (e.g., thermocouples and potentiometers) for measuring and recording time-temperature exposure of foods during processing (heating and cooling).

- Methods should be developed to minimize the microbial load of meat following initial processing, prior to packaging and distribution. Not only would this prevent the spread of disease from animals to humans, it would also prevent spoilage and prolong shelf life.

- From a disease-control standpoint, the committee recommends that labels, stickers, or inserted leaflets be used to provide useful information, when appropriate, on safe ways to thaw, cook, and handle (e.g., cool and reheat) cooked products and should list precautions to avoid cross-contamination.

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8
The Hazard Analysis Critical Control Point Approach to Food Safety

This chapter describes the basic principles of the hazard analysis critical control point (HACCP) system and reviews general critical control points for typical processing operations.

THE PRINCIPLES OF HACCP

The HACCP system for meat or poultry consists of an assessment of hazards associated with such operations, the determination of critical control points necessary to prevent or control the identified hazards, and the establishment of procedures to monitor (check or verify) the critical control points.

This approach is applicable to the handling of meat and poultry in homes (Zottola and Wolfe, 1980), in food-service establishments (Bobeng and David, 1977; Bryan 1981a,b; Bryan and McKinley, 1974, 1979; Unklesbay et al., 1977), and in any type of food processing plant (Bauman, 1974; DHEW, 1972; Ito, 1974; Kauffman and Schaffner, 1974; Peterson and Gunnerson, 1974; WHO/ICMSF, 1982). The Subcommittee on Microbiological Criteria for Foods and Food Ingredients of the National Research Council's Committee on Food Protection has endorsed (NRC, 1985) HACCP as an effective and rational approach to the assurance of food safety and prevention of spoilage.

According to D.L. Houston, Administrator of the Food Safety and Inspection Service (FSIS) (personal communication, 1984), HACCP is being incorporated as part of the quality control approach of FSIS and this committee endorses the usage of the HACCP concept in that approach. The HACCP approach emphasizes those aspects of an operation that are critical to ensuring food safety and preventing spoilage; it therefore relates more specifically to health hazards than to other aspects of the total quality control (TQC) approach, such as aesthetic considerations, quality, or compliance with a set of regulations.

A hazard analysis is an evaluation of all procedures during the production, processing, distribution, and use of raw materials or food products. It includes:

- identification of potentially hazardous raw materials and foods that may contain poisonous substances, pathogens, or large numbers of food spoilage microorganisms, and identification of substrates or conditions that can support microbial growth;

- determination of sources and specific points of chemical and microbiological contamination through observations of each step and operation in the process;

- determination of the potential for microorganisms or toxic substances to persist during a process; and

- determination of the potential for microorganisms to multiply (WHO/ICMSF, 1982).

Hazards, therefore, mean unacceptable growth of, survival of, or contamination by microorganisms of concern to safety or spoilage and the unacceptable production or persistence of microbial metabolic products in a food. The analysis is carried out on all existing products, on any new product that a processor intends to manufacture, and whenever substantial changes in raw materials, product formulation, processing, packaging, distribution, or intended use could adversely affect the safety or shelf life of a product.

Certain key questions need to be addressed during a hazard analysis:

- Product formulation and packaging--What are the ingredients? What is the pH? Are toxic substances added? If so, what is the concentration? What type and numbers of microorganisms are likely to be present? What is the water activity? Are preservatives used? If so, what is their nature? What type of packaging is used and is this integral to product stability?

- The process--Are live animals or raw products likely to be contaminated with pathogens? Are these likely to be spread to carcasses and cuts of meat during processing? What is the likelihood that the microorganisms of concern will be killed during processing (e.g., cooking, retorting)? Is there a likelihood of contamination after processing, or that the microorganisms will multiply during processing or storage?

- The conditions of intended distribution and use--Is the product distributed under ambient, hot, or cold storage temperatures? What is its expected shelf life during distribution, storage, and use? How

will the product be prepared for consumption? Is it likely to be cooked and then held for a period before consumption? If so, is it likely to be held hot, cold, frozen, or at warm temperatures? What mishandling of the product is likely to occur during marketing or in the hands of the consumer?

The answers to these questions, along with other available information, allow a preliminary assessment of the potential hazard(s), including an evaluation of the effects of mishandling on product safety and stability.

It may be desirable and in many cases necessary to check the assessment by testing for the presence of microorganisms or chemical substances of concern or by inoculating the product with appropriate food-borne pathogens and potential spoilage organisms. The inoculated food must be subjected to a simulation of routine processing and packaging under intended marketing conditions and then be subjected to anticipated storage, distribution, and expected-use conditions. This assessment should include evaluation of the effects of mishandling on product safety and stability. Test protocols, including the nature and size of the inoculum as well as other details, should be under the direction of an expert food microbiologist or toxicologist, as appropriate (WHO/ICMSF, 1982).

Critical Control Points

Hazards that are detected at one or more points of a process or stages of the food chain may be eliminated at certain key junctures referred to as critical control points. In this context, these are defined as locations or processing procedures at which control can be exercised over parameters that if not controlled properly could lead to unacceptable contamination, survival, or growth of food-borne pathogens or spoilage organisms or to the unacceptable production or persistence of microbial metabolic products.

Incoming raw materials, for example, may constitute critical control points, particularly if there are no subsequent operations to eliminate the hazards or if the contaminants are likely to be heat-resistant spores. The time and temperature of heat processing are obvious critical control points. Similarly, the temperature at which products are held prior to and during cooling and freezing, the volume being cooled, and the length of time products are held are critical control points. The cleaning of equipment that contacts products, particularly heat-processed products, is often a critical control point, as is the handling of cooked products by workers. (Further details of the critical control points in meat and poultry production, slaughtering, and processing are given later in this chapter.)

Sometimes critical control points are obvious from the hazard analysis or from investigations of disease outbreaks that occur when similar procedures have been followed. At other times, however, more

extensive research on the food or the process may be necessary to establish appropriate control points. Statistically valid sampling procedures may need to be used and repeated several times in order to identify stages in processing and the environment when contamination, survival of contaminants, or microbial growth may occur (WHO/ICMSF, 1982).

These critical control points differ somewhat from those described in Chapter 7 in the section on total quality control in that HACCP critical control points only relate to operations that if not satisfactorily carried out could lead to food-borne disease or spoilage and they are not directly concerned with aesthetics or quality. Thus, they are crucial (critical) to ensuring safety and to maintaining a satisfactory shelf life of a product. Critical control points as applied in the total quality control program refer to measures taken to comply with regulations. These may relate to concerns about safety, wholesomeness, quantity, aesthetics, or standard operating procedures that are referenced in a regulation, and some are either unrelated or indirectly related to food safety.

The hazard analyses and critical control point determinations might be done by qualified plant personnel, by hired consultants, or by qualified FSIS staff or they might be done jointly. Review of the system and final approval, however, needs to be done by qualified FSIS supervisory and technical staff.

Monitoring

Critical control points must be monitored continuously or periodically, as appropriate, to ensure that they are under control. This monitoring may involve making observations, taking temperature measurements, collecting samples, and performing appropriate chemical, physical, or microbiological analyses. Appropriate monitoring tests must be determined for each critical control point, the frequency of evaluation must be specified, and data must be recorded. FSIS personnel will need to verify that the monitoring is carried out properly by plant personnel.

The type of monitoring depends upon the nature of the critical control point under consideration (WHO/ICMSF, 1982). For example, if a raw material is a critical control point, a specification can be set for that raw material detailing the microbiological, chemical, or other test, the sampling plan, and the limits to be used. Ideally, the supplier will perform the required tests and ensure that the materials comply with the specifications before the product is delivered to the user. It may be advisable, however, for the user to test the consignment upon receipt, particularly if it is from a new supplier. Raw material storage conditions should be monitored to ensure that the quality of the material is maintained satisfactorily until it is used.

Monitoring the critical control points of processing operations is usually achieved by physical and chemical tests, because the results of these are available more rapidly. There are, however, situations where in-process microbiological monitoring is necessary. For example, it may also be necessary to monitor the effectiveness of sanitation measures by the use of microbiological tests. In situations where a heat-stable toxin is a potential hazard, a product of concern should be examined for toxicogenic organisms prior to a heat process to assess the likelihood of a hazard.

Visual observation is an important means of monitoring critical control points of many slaughtering and processing operations. Personnel responsible for such monitoring need appropriate training. Checklists should be used to monitor critical control points. These should detail the locations of critical control points, the monitoring procedures, and monitoring frequency, and they should specify criteria for satisfactory compliance.

End-product monitoring by microbiological testing is generally very limited. More often, determination of product attributes (such as pH, water activity, preservative level, and salt content) will give far more information about safety and stability. There are situations, however, where microbiological examination of the finished product (e.g., the examination of cooked "roast" beef for Salmonella) would provide valuable information.

HACCP is intended to provide a high degree of food safety assurance. To be implemented effectively, however, those who conduct the analyses, identify critical control points, and select monitoring procedures must be well versed in food science, food microbiology, and perhaps toxicology as well as in meat and poultry technology and processing. Staff who monitor critical control points or who evaluate the monitoring of these points do not need as much education in the sciences, but they must have other skills to carry out appropriate organoleptic, chemical, physical, or microbiological monitoring.

CRITICAL CONTROL POINTS IN THE MEAT AND POULTRY INDUSTRY

Most of the rest of this chapter highlights some of the critical control points for production, slaughtering, and processing operations. These and other critical control points that are unique to a particular operation or plant need to be used as the prime focus of an HACCP system, a traditional inspection, or the TQC programs used in plants.

Animal Production

Wholesomeness and safety of meat and poultry are based in part on the health of live animals, their feed, and the environment under which they are raised. Drug and pesticide residues in meat and poultry may

constitute a health hazard to some people. Therefore, the use of pesticides in the immediate environment of animals and in animal dips is also a critical control point. The type, quantity, and time of application of antibiotics on farms constitute critical control points that often can be monitored. Antibiotic-resistant strains of pathogens may emerge as a result of treating animals or using antibiotics in feed (see Chapter 4). These applications do not obviate the carrier state, and other animals can be infected with food-borne pathogens without showing signs of illness. These animals carry pathogens into slaughterhouses, where they may be spread to carcasses and processed products. This situation is difficult to control.

Feed and water containing infectious agents, toxic chemicals, or mycotoxins are also hazards. Use of Salmonella-free feed, for example, is a husbandry practice that can have a major impact on preventing livestock from becoming infected with this pathogen. The way grains and meals are stored can either promote or prevent mold growth and mycotoxin production and is thus a critical control point, as are the sanitation of the animal housing facilities and proper manure disposal.

Although these general points hold for all production facilities, other critical control points are unique to hatchery or farm practices for the species of animal being produced.

Slaughtering/Dressing

Generalized critical control points in slaughtering operations for all species of food-animals include the health of the live animals; sanitary conditions during transport, slaughtering, and dressing; the rate of carcass cooling; and time-temperature conditions of storage and distribution of the carcasses.

Antemortem inspection to detect sick and dying animals and to diagnose certain diseased conditions in animals is an example of monitoring a critical control point. Skinning or dehairing slaughtered animals and removing intestines are the operations that lead to carcass contamination. A microbial count similar to that found on dressed carcasses is established during these operations. The temperature of scald water becomes a critical control point in poultry and swine slaughtering operations. Thorough washing of poultry carcasses after picking and washing of swine carcasses after dehairing are also critical control points because of the transfer and cross-contamination of Salmonella and other microorganisms during picking and dehairing.

Processed Products

Raw Meat. The surfaces of carcasses and of primal, subprimal, and retail cuts of meat are contaminated by a variety of microorganisms, including low levels of some pathogens. Salmonella, Campylobacter spp., Clostridium spp., and Staphylococcus aureus are frequently on these surfaces. When carcasses are cut, these microorganisms can

cross-contaminate workers' hands, cutting boards, knives, table tops, saws, and other pieces of equipment and can then be transferred from the equipment, via cleaning cloths, to other equipment. The critical control points in processing are, therefore, the areas where steps can be taken to minimize this cross-contamination and the sanitation of utensils and equipment. The temperature in rooms of deboning and storage and the duration of storage are also critical control points.

Raw, Ground Meat. Critical control points in the production of raw, ground meat are similar to those for retail cuts--equipment sanitation, prevention of cross-contamination, and time-temperature control. In addition, the condition of ingredients (trimmings) are also important. Good quality ingredients and effective cleaning of equipment are essential. Different grinders (or adequate cleaning between uses) need to be used for pork products and other types of meat products to prevent cross-contamination with Trichinella spiralis. Ingredients should be cold and ground at temperatures as near freezing as practicable. Short-term storage for holding ground products at temperatures near 32°F (0°C) is a critical control point.

Raw, Frozen Meat. For frozen products, critical points up to the time of freezing are the same as those for chilled products. In addition, proper packaging, rapid freezing, and the time and temperature the products are kept frozen and thawed are critical control points.

Vacuum-Packed Raw Meat and Poultry. Anaerobic conditions in vacuum-packed meat and poultry in a carbon dioxide or nitrogen atmosphere inhibit growth of aerobic flora that commonly spoil unpackaged raw meat. In vacuum-packed products this flora is replaced by lactic acid bacteria, which multiply at different rates and produce different metabolic products, and the shelf life of these products is therefore prolonged. Vacuum packaging, the integrity of the package, and the time and temperature conditions of storage are critical controlling factors for prolonging the shelf life of these meat and poultry products.

Raw, Cured Meat. Critical control points for raw, cured meats are the quality of the meat (e.g., beef briskets for corned beef and pork bellies for bacon), the salt and nitrite concentration of the brine, and the microbiological load of the pickle solution (containing salt, nitrite, and perhaps nitrate). If salt and nitrite concentrations and pH are not controlled, spoilage organisms can multiply. Bacon is subjected to a mild heat treatment (128° to 130°F/53.3° to 54.4°C) to fix the cured-meat color, but this temperature is insufficient to kill either trichinae or vegetative forms of pathogenic bacteria so it is not a critical control point. If cured meats are to be packaged in oxygen-permeable films, which is uncommon today, the air of the packaging area becomes a control point. Time and temperature of storage are also critical control points for raw, cured meat products.

Critical control points of shelf-stable (low water activity) salted raw and salted cured meats (e.g., salt pork, dry-cured bacon, and dry-cured "country-cured" hams) are proper penetration and equilibration of the curing salts (sodium chloride and nitrite) to achieve appropriate moisture loss resulting in proper water activity levels. Control of temperature during drying of salted meats is also a critical control point to prevent growth of Staphylococcus aureus or spoilage flora before the curing salts diffuse into the product.

The concentration of chemical additives, particularly nitrites, in cured meat and poultry products is a critical control point that requires careful monitoring.

Fermented Sausage. The most critical factor in the processing of fermented sausages is the rapid production of acid by microorganisms to prevent the formation of staphylococcal enterotoxin. This can be achieved by a proper fermentation, which is promoted by rapid growth of lactic acid bacteria through carefully controlled environmental conditions.

Controlling such undesirable growth includes a rapid decrease in pH, a decrease of water activity, and buildup of flora that are competitive with or inhibitory to pathogens. Critical control points vary with the method of fermentation, which is selected on the basis of tradition and the type of product being produced. The greatest risk occurs if products are naturally fermented directly after stuffing if product temperature rises. Critical control points are product temperature, pH, and the speed of pH decrease. (Glucono- δ -lactone is sometimes added to effect a more rapid decrease of pH.)

Risk with fermenting meat is reduced by lowering the temperature of the stuffed product through cold storage before fermentation or by selecting a natural lactic microflora before transfer to the fermentation room. The risk is further reduced if a sufficient amount of previously fermented product is added. Addition of a pure culture of fermenting organism is, however, the most dependable control. Monitoring of the finished product is achieved by examining the appearance of the product, its firmness, and the pH.

Smoking might be used to further dry (reduce the water activity of) a product, which concentrates the curing ingredients, but this process alone without sufficient heat cannot be relied upon to kill either trichinae or vegetative forms of pathogenic bacteria. After fermentation, pork products must be heated to a minimum of 137°F (58.3°C) or frozen to destroy trichinae. Those conditions, which are considered critical to assure safety of fermented products, must be monitored. Further control is achieved by refrigerated storage.

Dried Meat and Poultry. The quality of the raw product and the control of contamination prior to drying are essential. Control of time and temperature is critical during drying to lower the moisture

content enough to provide shelf stability. Temperatures during many drying operations, however, are not always high enough to kill pathogens. Dried products must be protected from reabsorption of moisture by suitable packaging. Time-temperature control of the product after rehydration is also critical to minimize microbial growth in the reconstituted product.

Pasteurized Meat and Poultry. The critical control points of cooked, uncured products, in addition to the quality of the raw ingredients, are the time and temperature of the cook, the rate of cooling, the way products are handled after cooking, equipment sanitation, and subsequent cold storage. Time-temperature requirements for cooked products should be continuously monitored and the measurements recorded. Monitoring the rate of cooling is also essential, as is the chlorine level of water when water-bath cooling is used.

Sampling products after heat processing and testing them for Salmonella or other microorganisms for which a microbiological standard, specification, or guideline has been developed is another way to monitor these critical control points. Spores such as those of Clostridium perfringens, however, are not inactivated during pasteurization. A negative test for Salmonella does not indicate safety from spore-forming bacteria.

Repackaging, boning, slicing, and other handling operations are critical control points that require monitoring. This monitoring might be supplemented by testing products for Escherichia coli if cross-contamination is possible or for Staphylococcus aureus if contamination by workers is likely. Cooking operations should be physically separated from raw meat and poultry processing areas and, if practicable, different equipment and utensils should be used and different workers employed to prevent cross-contamination.

The critical control points for uncured products also apply to cooked cured products. In addition, the time and temperature of heat processing (e.g., water baths for canned hams and plastic packaged beef or smoke ovens for wieners) are control points that require continuous or terminal monitoring. Cooked products must be chilled rapidly enough to preclude germination of spores and multiplication of resulting vegetative cells. Chlorine levels of chill water should be monitored. The cleanliness of equipment used to convey, slice, strip, or package, or that otherwise comes into contact with, cooked products is a critical control point.

Canned Uncured Meat and Poultry. Time-temperature control of the heat process and pH evaluation of these products are essential critical control points. Products having pH values of 4.6 or below are considered high acid products and need only a heat process that assures shelf stability.

Low-acid, canned foods (pH greater than 4.6) must be given time-temperature exposures that will kill up to 10^{12} Clostridium botulinum spores. Critical control points for this "botulism cook" include exhaust-product temperatures and retort equipment checks before processing, as well as the time, pressure, and temperature evaluation and recording during retorting. Heated cans must be cooled in an adequately chlorinated water bath in case the cans have pin holes or the seam or mastic allow water to enter during cooling. Processed product containers should also be inspected for seam and other defects. Samples of the canned product are often incubated at elevated temperatures to determine shelf life.

Shelf-Stable, Canned Cured Meat and Poultry. Critical control points are proper curing (including proper salt and nitrite concentrations), microbial quality of ingredients, level of spore contamination, proper heat processing, container integrity, and proper cooling. Specific critical control points depend on the physicochemical nature of certain products. The stability and safety of canned hams and luncheon meats, for example, depend on the presence of nitrites and salt and on minimal contamination with C. botulinum as well as a thermal process that injures surviving spores so that they cannot germinate and multiply in the cured meat. Low water activity is a critical control point for products such as canned sausages in hot oil, sliced dried beef in vacuum-sealed jars, and canned fired bacon. Brine and acid content, integrity of airtight containers, and temperature control during storage are important for products such as pickled pigs' feet and pickled sausage that are immersed in vinegar brine.

Radicidized (Irradiation Pasteurized) Meat and Poultry. Radicidized products should be packaged prior to irradiation. The proper dose of radiation depends on the nature of the product (e.g., the size of its container and whether it is raw, dried, or frozen). Further control points are package integrity and the manner and temperature of storage.

Radappertized (Commercially Sterilized) Meat and Poultry. The most important critical control point of radappertization is the strict assurance that the radiation dosage is high enough to sterilize the product (equivalent to a botulism cook). Because cooling is not necessary, post-radappertizing contamination is unlikely unless a package breaks.

Meat and Poultry Products After Processing

Critical control points in the shipment of carcass meat and poultry are the microbial load at the time of shipment, the internal temperature at the time of loading, and the air temperature and movement in the transport vehicle and storage warehouse. Insect and rodent control may be critical during storage of paper- and plastic-packaged dry products. Storage temperature, methods of loading

walk-in refrigerators and display cases, and cleanliness of cutting boards and blocks, grinders, saws, tenderizers, and cutting utensils are key points in retail stores.

The critical control points during preparation in food-service establishments and homes vary with the product, equipment, and food-service system. Cooking, hot-holding, and handling afterward are often critical. For foods left over or prepared hours before they are to be eaten, cooling and reheating are critical control points. Prevention of cross-contamination within kitchens and proper cleaning of kitchen equipment are also critical.

TRAINING

Processing operations and the variety of processes applied to meat and poultry are complex and becoming more so. Personnel in charge of quality control operations and those who conduct hazard analyses and identify critical control points must have appropriate educational backgrounds, including understanding of HACCP principles, food (meat and poultry) science, food microbiology (and possibly toxicology), and step-by-step processing operations.

Inspectors will need at least an overview of this information as well as specific training in skills required to monitor critical control points. Quality control personnel need to know how to develop quality control systems appropriate for their operations. Plant personnel must know the hazards that may be associated with the products they process, the critical control points, and ways to monitor these points.

SUMMARY AND RECOMMENDATIONS

The principles of the hazard analysis critical control point approach were applied to the hazards associated with any operation involving meat or poultry, to determine the critical control points (CCPs), and to establish procedures to monitor them. These CCPs are related to public health and food spoilage aspects of the operation and need to be controlled carefully to eliminate health hazards. The methods of analyzing hazards, determining CCPs, and monitoring them at each phase of meat and poultry production, slaughter, and processing are described in this chapter.

Public health protection is one of the broad goals of the Food Safety and Inspection Service. In a communication from FSIS Administrator Donald L. Houston, it is stated that the concept of HACCP is now part of a strategy of FSIS, particularly in reference to "the Department's procedures for approving quality control plans in processing plants ..."(emphasis added). The committee, recognizing the implementation of the strategy of HACCP into the FSIS program,

encourages FSIS to move as vigorously as possible in the application of the HACCP concept to each and every step in plant operations, in all types of enterprises involved in the production, processing, and storage of meat and poultry products.

The critical control points described in this chapter, and others that are appropriate to an operation, need to be carefully identified, controlled, and monitored. The committee emphasizes the special significance of the term "critical" in this phrase in order to restrict the term to the control points related to public health and food spoilage. Critical control points are specific for each product and each operation within each plant. For inspections to be scientifically sound, these critical points must be given foremost importance over other control points related to aesthetic considerations or those considered as violations of regulations. By emphasizing the critical control points related to public health and food spoilage over those that are unrelated, FSIS could attain the highest degree of food safety within its available resources.

Hazard analyses for each product within each phase of the operation must be performed by qualified persons and must either be developed under FSIS supervision or reviewed by FSIS. The elements of the HACCP system need to be emphasized during the continual education of inspection personnel so that they can evaluate monitoring systems and detect new or missed hazards. FSIS technical staff (such as meat and food scientists, meat and food technologists, meat and food microbiologists, and toxicologists) should be trained to conduct hazard analyses, identify critical control points, and recommend control measures and monitoring procedures, so that they can effectively review HACCP systems that are submitted by industry and can act as technical consultants for inspectors.

Continuous inspection is not needed to ensure food safety in meat and poultry processing plants in which hazards and critical control points have been identified and monitored by qualified staff. (In slaughter facilities, however, continuous inspection is currently needed.) Depending on the hazards (which should be based in part on epidemiological data, if available) and the reliability of plant personnel in monitoring critical control points, a variable-time inspection approach is recommended. As long as there is evidence that the critical control points have been identified and monitored and that appropriate standards and guidelines are met, a high degree of safety can be assured. In plants that have had problems in the past or that are not monitoring critical control points, there may be reasons to have continuous inspection. Therefore, the committee suggests that the critical control points be confirmed by FSIS and monitored, as applicable, by plant personnel and verified by trained FSIS inspectors.

Furthermore, FSIS regulations should be considered for systematic review to see that critical control points and appropriate monitoring procedures are specified to prevent hazards during production,

slaughtering, and processing operations. Consideration should be given to making specified critical control points and recommended monitoring procedures an integral part of all future regulations.

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9
New Technology
Approaches to Meat and Poultry Inspection

The procedures and techniques used by the staff of the Food Safety and Inspection Service (FSIS) have for the most part been in place for many years. These traditional methods are used to detect zoonotic and other animal diseases at slaughterhouses and to analyze meat and poultry samples as part of the National Residue Program. To date, only slight advantage appears to have been taken of electronic and technologically advanced devices and instrumentation.

Some of the current technologies available and in use that have proved useful in the separation and identification of deleterious agents, both chemical and infectious, are briefly described in this chapter. Several new technologies that are becoming useful for this purpose are also detailed--in part to illustrate for the nonscientist the techniques that might be adapted to meat and poultry inspection, and in part to alert policymakers to the potential for improvement. Physical methods, particularly imaging techniques, are considered, for some of them could have a significant and direct impact on the inspection process. Finally, the considerable advantage of using computer-based information systems is discussed.

SEPARATION AND IDENTIFICATION METHODS

Current Technologies

Thin-Layer Chromatography (TLC). This method, developed in the 1930s, is widely used because of its speed, low cost, and ease of adaptation to a variety of laboratory conditions. The principles involved in TLC include the adsorption of test compounds onto a thin layer of adsorbent and the selective solubility of the test compounds in solvents that are allowed to migrate through the adsorbent. TLC results can be obtained in a short time (between 30 minutes and 2 hours) and the technique is nondestructive with regard to the test compounds. Detection of test compounds is limited to their absorption of ultraviolet light or by visual observations after spraying with chromophoric reagents (Mendoza, 1981).

Gas-Liquid Chromatography (GLC). First introduced in 1952, GLC has become the analytical methodology most closely associated with the

detection of chemical residues in food products. A capillary column technology has greatly improved the resolution and sensitivity of the GLC method. A sample is introduced into a heated injection port, rapidly converted to a vapor, and swept by a continuous flow of carrier gas through the system. Sophisticated, highly selective detectors have been developed for GLC and it is possible to rapidly resolve, identify, and measure complex mixtures. The volatility of test compounds is sometimes a limiting factor for GLC applications, and several of the detectors destroy the test compound (Grob, 1977).

High-Performance Liquid Chromatography (HPLC). Liquid chromatographs that use some pressure device (such as a pump-direct drive) for fluent mobility and are equipped with low-volume detectors are described as high-performance liquid chromatographs. Basically, HPLC is TLC in a pressurized system; solvents that will affect the separation of test compounds on TLC plates are also used in HPLC. Since the early 1970s, the use of HPLC has grown rapidly, based on the development of specific detectors and column packing materials. Compounds do not need to be in a vapor phase for HPLC, and they can be recovered from the column effluent for conformation analyses. HPLC is currently one of the more widely used analytical techniques (Hanks and Colvin, 1981).

Ultraviolet, Infrared, and Atomic Absorption Spectrophotometry. Analytical techniques in this grouping are designed to use quantized energy changes that occur when electromagnetic energy (a photon) is absorbed by molecules or atoms. In general, these procedures take advantage of one or more of the three energy levels that exist in molecules (electronic, vibrational, or rotational). Ultraviolet and infrared spectrophotometry is applicable to functional or resonating groups in organic or biological molecules and does not destroy the test compound. Atomic absorption uses high temperatures to excite atoms of metals and metalloids, which in turn absorb light energy. Atomic absorption spectrophotometry destroys the test sample. Modern spectrophotometric instrumentation contains a primary light source, a precise monochromator to isolate a specific wave length, a sensitive detector to measure the light, and electronics to receive the signal and display the results (response) (Holmes and Reddy, 1981b).

Mass Spectrometry (MS) and Interfaced Instrumentation. Mass spectrometry (MS) involves the fate of gaseous molecules under reduced pressure conditions. In MS, a test compound is introduced into an ionizing chamber that is under high vacuum conditions, heated until it becomes gaseous, and then bombarded by high-energy electrons. The test compound is thereby fragmented into a series of lower-molecular-weight ions. These positively charged ions are then separated, collected, and displayed according to their mass. MS has become a versatile and sensitive tool in the analysis of chemical residues and pollutants. It is, however, somewhat expensive with regard to both initial and operating costs. The mass spectrum of a test compound is perhaps the ultimate residue identification technique (Safe and Boyd, 1981).

The primary limitation of MS is that positive identification of an unknown compound, on the basis of its mass spectrum, can be made only with pure compounds. Thus the application of MS to food and chemical residues requires sophisticated separation techniques to remove impurities that are extracted at the same time as the test compound from complex biological matrixes. GLC and HPLC, the most effective separation techniques, have both been used with the ionization chamber of mass spectrometers. Similarly, GLC has been combined with thermal energy analyzers as interfaced instrumentation and is the analytical technique used by the meat and poultry inspection service for the detection of nitroso compounds.

Radioimmunoassay. This methodology has been closely associated with hormone studies, but the principles involved can be applied to a wide variety of antigenic substances. To determine the concentration of any antigen, a source of the antigen that contains a radiolabel is needed. The test compound, the labeled test compound, and the antibody to the test compound are allowed to equilibrate in a series of tubes. The antigen-antibody complex is separated and the radioactivity is measured. Instrumentation for measuring radioactivity is a necessary part of this technique (Metzler, 1977).

Direct and Indirect Fluorescence Antibody Techniques. The direct fluorescence antibody technique is a much simpler test than the indirect procedure just described. The direct procedure consists of labeling the test antibody with a fluorescent dye (usually fluorescein isothiocyanate) and applying the labeled antibody to the antigen, which is fixed on microscope slides. After the system has reached equilibrium, the excess antibody is washed away and the preparation is examined with a fluorescence microscope. In indirect fluorescence, the unlabeled antibody produced in a rabbit, for example, plays a dual role. It forms an unlabeled product in the primary antigen-antibody reaction, but it is also used as an antigen in a second animal (a sheep, for example). The resulting sheep anti-immunoglobulin is labeled with a fluorescent dye. This labeled material is then directed toward the initial unlabeled product and viewed under the microscope. Such techniques are used primarily as diagnostic tests in parasitology, bacteriology, virology, and mycology (Cherry et al., 1960). Several immunoassay procedures were developed recently for specific pesticide residues (Schwalbe et al., 1984; Vallejo et al., 1982; Wie and Hammock, 1982).

New Technologies

Recent advances in biotechnology have provided an increased ability to utilize and direct microorganisms to produce specific compounds. Furthermore, these approaches can be used to identify with high specificity infectious agents by means unheard of just 5 to 10 years ago.

Recombinant DNA. Gene splicing (recombinant DNA technology)--which has been described as the most important emerging technology of the

1980s--involves the manipulation and control of the intricate chemical reactions a cell uses to synthesize new cellular parts. Recombinant DNA molecules (spliced genes) consist of DNA fragments from two different species that have been joined together. The splicing is accomplished by highly selective enzymes. The new, hybrid DNA is inserted into a host cell (a process called transformation), and when this cell divides, a copy of the hybrid DNA is passed along to its daughter cells. If the new gene is "expressed," each daughter cell will begin producing a new protein. Most recombinant DNA research has focused on applying the technology to pharmaceuticals, agriculture, and chemicals (Gilbert and Taunton-Rigby, 1984).

The technology has been used extensively in recent years to develop several bioprobes, including DNA probes. DNA probes (small pieces of DNA that recognize specific genes) can be used to identify the genetic information of any organism. This provides a powerful tool for diagnostic purposes because it offers a high degree of specificity, sensitivity, and accuracy and can be applied to a variety of formats. The ability of avidin to bind firmly to biotin, for example, is used in developing bioprobes that utilize a biotinylated derivative of deoxyuridine triphosphate in the place of thymidine triphosphate in several DNA-labeling reactions (Langer et al., 1981). The resulting bioprobes hybridize normally to complementary DNA. The bioprobes are chemically stable and have shelf lives in excess of a year. Some of these probes are now being commercially developed into ready-to-use kits for the detection and identification of specific infections.

Monoclonal Antibody Technology (Hybridomas). Recognizing and removing foreign substances (antigens) from the bodies of higher animals involves a complex series of events called the immune response. When a foreign substance is recognized, the body produces a product (antibody) specifically designed to bind to the antigen. This specific and unique binding of antigen to antibody is the basis for detecting and diagnosing many diseases. Antibodies produced by conventional methods are polyvalent, containing a mixture of antibodies directed against different regions of the antigen (OTA, 1984).

In the production of monoclonal antibodies (MABs), a mouse and an antibody-producing tumor (myeloma) play important roles. An antigen is injected into a mouse to elicit an immune response. Antibody-producing cells, growing in tissue culture, are then fused with the B-lymphocytes. The fusion products that survive contain genes from the antibody-producing cells and are called hybridomas. Hybridomas are cloned and screened for their antibody production and are used to produce MABs in large quantities. The antibodies produced by this technology are homogeneous and monospecific, i.e., they react with a specific region of the antigen. The hybridoma-monoclonal antibody technique can also yield a specific antibody directed against a single antigen even when a mixture of antigens, such as an impure protein preparation, is injected into the mouse.

Enzyme-Linked Immunosorbent Assay (ELISA). ELISA, sometimes called the "double antibody sandwich" technique, is used to detect and measure antigens or antibodies. Several procedural variations of this technology have been used for the last decade. ELISA is mentioned here as an emerging technology in view of the added diagnostic specificity and potential applications available when MABs are used in the process (Finegold and Martin, 1982).

In one type of ELISA, the antigen (such as a virus or bacteria) is immobilized in wells formed in a plastic plate. This is done in an alkaline buffer (pH of 9.0) and remains attached throughout the manipulations at a near neutral pH. A specific antibody is then added, and it forms a tight complex with the immobilized antigen. The excess antibody is removed; this is followed by the addition of an antibody produced against the initial antibody. Covalently linked to the second antibody is an enzyme (horseradish peroxidase or alkaline phosphatase). The removal of the excess second antibody is followed by the addition of reagents that produce a color through enzymatic action. Color production above the control wells indicates the presence of an antibody and the amount of color is directly related to the quantity of antigen under consideration.

Unlike radioimmunoassays, the handling, counting, and disposal of radionuclides are not required, and there is no need for specially designated radiation laboratories. The ELISA technique has been used recently as a diagnostic tool in the food and agricultural markets. Under development are applications for detecting brucellosis in cattle (serum and milk), salmonellosis in dairy cattle, and toxoplasmosis in pork (N.C. Vail, Idetek Inc., personal communication, 1984). The technique has also been successfully used to detect minute quantities of mycotoxins such as aflatoxin M_1 at the parts per trillion level (Fremy and Chu, 1984).

IMAGING TECHNIQUES

A number of technological developments involving physical methods of diagnosis in human and veterinary medicine have considerable potential for application within FSIS. Taken together, these could prove to be almost as important in the diagnosis of certain diseases as the introduction of the x ray was in the first quarter of this century. The new methods include improved x-ray techniques, ultrasound, nuclear magnetic resonance, and computerized methods for image collection and comparison to an established normal baseline.

Nonphotographic Visualization of X-ray Images

Although conventional x rays remain a useful diagnostic technique, they are expensive and can be hazardous. This well-established technology has been improved by recent developments in electronics and imaging and by application of computer technology. One example is the

electronic amplification of x-ray images, which allows a reduction in exposure to radiation, the capturing of the image on digital imaging equipment, and the storage of the captured image on magnetic tape. The images are subjected to computer-assisted interpretation. These changes have reduced radiation hazards, eliminated expensive silver halide film, and permitted enlargement of selected areas of interest by amplification.

The addition of computer technology to diagnostic procedures has permitted the development of new and novel approaches to old problems. The data are generated in a form that can be readily transmitted to distant facilities for interpretation, collation, and storage with a speed and accuracy unimaginable earlier.

X-ray Visualization by Digital Subtraction Methods

This technique uses a preliminary x-ray image that is converted to an electronic signal stored on magnetic tape. The stored image is then used for electronic comparison to a subsequent contrast anglograph, and the initial image is erased electronically. As a result, the blood vessels appear in the final picture as the naked vascular tree, and visual interference by nonvascular structures is eliminated. The clean, simple image is easy to interpret, and the required dose of contrast material is greatly reduced. Electronic amplification of the signal permits low-dose x-ray exposure even with repeated studies. Because of the electronic nature of the image, the observer can look at the vascular structures from other angles without taking new x rays.

Although this technology may seem remote from the needs of FSIS, if the principles involved are properly understood and applied they may offer a new approach to the problem of repetitive inspection of objects with a low frequency of abnormal findings. For example, some organs might be routinely examined for abnormalities such as tumors or abscesses. A computerized image of a normal organ could be used as a standard for either x-ray or ultrasound examination. This would reduce the need for hand palpation of normal organs, allow faster processing, and reduce the need for personnel committed to a dull job.

Ultrasound

Ultrasound equipment for diagnosis has been available for about two decades, but it did not become clinically useful until the general development of electronics and of compact equipment that uses only small amounts of energy (Stouffer and Westervelt, 1977). Ultrasound can detect differences in density in tissue and fluids, measure depth, observe contours, and detect motion. It is not hazardous and is much cheaper than many other diagnostic instruments. It can be operated to provide three-dimensional images. Computerization allows both visual and nonvisual interpretation of data, and computer-assisted interpretation is possible. Because ultrasound does not penetrate solids, its clinical use in evaluating abnormalities of the lung,

brain, or other bone-covered organs has been limited. In the animal carcass, however, images of soft tissue in these areas can be obtained since overlying solid structures can be removed.

Ultrasonic imaging techniques were originally applied to detect abnormalities of soft tissue. A recent technological breakthrough with real-time ultrasound has permitted instantaneous, accurate cross-sectional images that can be read and analyzed by computers. This technology can be applied to the postmortem inspection of meat and poultry carcasses and organs. The detection of abscesses without the incision of intact livers and other organs at the rate of several hundred per hour would save labor and valuable products and would improve the effectiveness of meat inspection. Intact carcasses on moving chains could be scanned with real-time ultrasound for such abnormalities as infected lymph glands; abscesses in hams, jowls, or other locations; and liver flukes in bile ducts. Applying this technology to meat inspection might improve efficiency, reduce public health risk, and be cost effective. Recently, this method has been used for evaluation of beef carcasses (Cross et al., 1983).

Ultrasound could be effective in detecting metallic particles (ferrous or nonferrous), bone spicules, or glass or plastic particles in meat and meat products prior to packing or even after the meat has been placed in containers. This kind of detection program might be partially or fully automated.

Computer-Assisted Axial Tomography (CAT)

CAT scanning has revolutionalized body and head imaging in human diagnostic medicine. It can provide a three-dimensional image of the whole subject, showing bone or major organ disease or displacement by disease. It is expensive and not readily amenable to automation, at least at the moment. It could be valuable in the future, however, if the special needs of FSIS were considered in the design of new instruments.

Nuclear Magnetic Resonance (NMR)

An even newer imaging technique is nuclear magnetic resonance (NMR) or magnetic resonance. The development of NMR imaging spectrometers in recent years made it possible to apply imaging technique to whole live animals or parts. It does not use radiation, can visualize abnormal concentrations of enzymes, fluids, or organ contents, and is not affected by bone or nonferrous covering. Moreover, abnormalities in tissues or organs and lesions can be detected by this technique. It is currently extremely expensive, and many phases are still in the developmental stages, but it clearly holds potential for improving meat and poultry inspection procedures (Wilson, 1981).

ROBOTICS

The Tin Man from The Wizard of Oz and, more recently, C3PO and R2D2 from the film Star Wars are perhaps our most well known robots. Some 20,000 industrial robots were produced in 1983. Today they consist of an arm, hand, small brain (computer), and sometimes an eye. The eye uses reflected light to recognize, sort, and pick out objects according to size and shape. Most industrial robots are manufactured in Japan and are used extensively for welding in the production of automobiles and heavy equipment. The electronics industry also makes considerable use of robots. Today, the ability to produce robots with larger brains (computer components) is much greater than that of producing the mechanical features. As these technologies merge, the economical potential for the commercial exploitation of robots appears unlimited (Fredkin, 1984). In the meat and poultry industry, assembly-line type of robots could be employed when appropriate sensory devices are developed to replace organoleptic techniques.

COMPUTER AUTOMATION: DATA GATHERING, PROCESSING, AND DISTRIBUTION

FSIS's responsibility stretches from a central administrative group in Washington, D.C., to the on-line field inspectors in slaughter and processing plants throughout the country. Data and information must flow in both directions. Directives from administrators must reach the various subordinate levels while data, queries, and other forms of information should pass from the field back up the administrative ladder to the appropriate office. This feedback of data and information to central points is essential for monitoring the efficiency and effectiveness of the nation's meat and poultry inspection programs. Such information is also required for determining changes in current and future policies and for developing directives and memoranda for the field offices and inspectors.

Computer-Based Information Systems

Decisions can only be as good as the data and information on which they are based. And conclusions drawn from statistical analyses of monitoring and surveillance data are only as good as the correctness of the information fed into the system and the availability and accessibility of data. The automated computer-based information systems now widely used in the industrial world are immeasurably facilitating the rapid collection of high-quality data. Computer terminals at strategic locations that use programs with well-defined terminologies and data-input control features in conjunction with computer-mail capability can reduce the chance of error in the transfer of data and information. Computer compilation of monitoring and surveillance data, in the appropriate form, provides a ready source of information for regulatory decisions and legal actions. It could also identify problematic field inspection operations and monitor plants and slaughterhouses with respect to procedures, facilities, and violations.

FSIS is giving some attention to incorporating automated computer-based information systems in its operation (USDA, 1983). The Mathematics and Statistics Division of the Science Program, for example, intends to upgrade the Microbiological and Residue Computer Information System (MARCIS) and convert the information systems of accredited analytical laboratories to MARCIS.

The Field Services Laboratory Division analyzes samples for chemical residues, food additives, nutritional values, contamination with microorganisms, and parasites. The data generated cover 38,000 residue samples and 95,000 nonresidue samples analyzed in FSIS field laboratories. Additional samples are analyzed through contracts with non-FSIS laboratories. With appropriate instrumentation and more data-transfer capability, the results of field laboratory analyses could be transmitted by computer mail (with onsite hard-copy capability) to field inspectors and central administrative offices. Computer mail is preferable to telephone conversations because of a decreased possibility of error.

Automated Laboratory Methods

The use of automation in the analysis of samples lies at the heart of most medical laboratories. Many businesses have been launched in recent years to develop and market automated analytical equipment and procedures. Routine analyses, such as for protein and other components of food and feeds, using traditional "by-hand" analytical procedures are prone to considerable error--the degree of error depending on the expertise, experience, and day-to-day motivation of each laboratory technician. Automation in laboratory analysis, though not without potential problems and requiring adequately trained personnel, constitutes a considerable advantage. Correctly installed and operated, there is less chance for error and the data can be fed directly into a computer-based information transfer system. FSIS is now considering the cost of installing, maintaining, and operating automated equipment.

SUMMARY AND RECOMMENDATIONS

The committee recognizes that FSIS has introduced some new technologies into its programs, as committee members observed during site visits to the regional field laboratories in Georgia, Missouri, and California. Furthermore, FSIS plans to use more advanced technologies in other segments of its total inspection program. One primary example is the Live Animal Swab Test (LAST), which is being used on the farm to test bovine urine for antibiotic residues. This type of farm testing could well become a required initial screening procedure for all meat and poultry inspection. Several emerging biotechnologies (DNA probes and monoclonal antibodies) lend themselves to this. Prepackaged tests in the form of simple reagent kits or impregnated ELISA-card tests are currently available and routinely used

for diagnostic purposes. Identifying potential residues and infectious diseases on the farm is a far more reasonable inspection process than allowing these animals into slaughtering facilities, a point that comes through clearly in the FSIS Program Plan for 1984 (USDA, 1983).

The committee notes that the techniques with the greatest possible future impact on FSIS procedures appear to be imaging technologies, state-of-the-science computer-assisted information transfer, and automated laboratory methods for analyses and quantitation. Imaging techniques appear to have considerable potential for future impact on the traditional antemortem and postmortem segments of meat and poultry inspection. Computer-assisted ultrasound seems particularly well suited to these phases, and its use should be investigated as an alternative to visual and physical examination of cervical and mesenteric lymph nodes. Detecting bone fragments or other dense materials that may occur in processed meat products is also amenable to imaging methods.

The technologies discussed in this chapter can assist FSIS to establish a modern, technology-based system capable of safely screening a large number of apparently acceptable products in order to identify a small number of unacceptable ones. The recommendations that follow are offered with that broader goal in mind.

- The committee recommends that FSIS directly manage an in-house and out-of-house research program relevant to its mission.

- The committee recommends that FSIS establish a science advisory committee composed of representatives from government, industry, academia, and research organizations and that the agency continuously use the expertise of this group.

- The committee suggests that FSIS use a computer-assisted system extensively for inspection and for the acquisition, transfer, analysis, and wider dissemination of data on meat-borne hazards.

- The committee suggests that FSIS rapidly develop a more efficient automated laboratory analysis system. New automated methods could be introduced into onsite and Field Service Laboratories without extensive training of personnel. Consideration, however, must be given to the level of FSIS operation at which automated analytical equipment would be advantageous.

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10
New Directions for Decision Making in Meat and Poultry Inspection
Evidence Required for Quantitative Health Risk Assessment

The committee was asked to examine the scientific foundation for the meat and poultry inspection program in the United States, to look at different inspection strategies, and to consider the role of technological development as it affects these strategies. Yet early in its deliberations the committee noted that its efforts would be of more value to the Food Safety and Inspection Service (FSIS), to the U.S. Department of Agriculture (USDA), and to the public if they were placed in the context of an effort broader than the mission of FSIS. The success of FSIS in dealing with the gross disease and contamination problems that it was established to address creates an opportunity for the agency to give more attention to newer challenges using open, rational, structured decision-making processes and updated scientific methods.

This final chapter presents the committee's consideration of the characteristics, from a scientific perspective, of an optimal meat and poultry inspection program; new, more structured ways to analyze FSIS problems and to develop policy from factual evaluations; and a comprehensive set of steps that the entire federal government--not just FSIS--needs to take to ensure the existence of a meat and poultry inspection system that justifies continuing public support.

The reconsideration of the scientific and technical role and procedures of FSIS suggested herein must and can be done by the agency itself, although with substantial outside participation from persons with a broader range of skills in diverse disciplines ranging from management to law, from economics to human behavior.

AN OPTIMAL MEAT AND POULTRY INSPECTION PROGRAM

In evaluating the current U.S. meat and poultry inspection program, the committee noted the absence of objectives stated in a form that could be used by FSIS to measure its success in protecting the public health. In light of the committee's recommendation for a new decision-making system at the agency, it is important to set out initially the characteristics of a system that would adequately protect

the American public. Once reasonable objectives have been defined, a program for action can be modified as needed, and progress toward the objectives can be assessed.

As budgeting constraints, technologies, and industry economics change, new kinds of inspection techniques and systems with various mixes of industry inspection and certification need to be identified, defined, and tested. Ideally, new approaches to inspection should not be implemented nationally until they have been validated by objective assessments of their health impact or until their continuing health impact after adoption can be evaluated against some reasonably objective criteria. This development of criteria, or even of proxy criteria, is a prerequisite to setting any new objectives for FSIS. If continuing research, development, testing, and evaluation of new methods become a hallmark of the agency, the public can continue to have confidence in changes introduced at the initiative of FSIS.

Beyond this devotion to the development of objective measures, an optimal meat and poultry inspection program should have the following characteristics, many of which are already a part of FSIS policy:

- A trace-back and recall system from producer to final sale for all animals and products destined to enter the human food supply, both to produce epidemiological data based on animals that are important for the prevention of human disease and to enhance the ability of processors and the government to respond to problems in the food chain as they occur.

- The maximum use of producer or processor certification of product compliance with all critical regulations, consistent with established good manufacturing practices in food processing and with adequate governmental oversight. An industry that is fundamentally responsible for its own compliance will in time learn to encourage the development and application of new technology, responsible and accountable personnel, and a cost-effective implementation of food safety regulations. The committee notes that the present role of FSIS in effect relieves producers of many important responsibilities that they would otherwise have to shoulder. Furthermore, the current intensive inspection by FSIS actively discourages the development of an industry-wide ethic that producers and processors must be responsible for the quality of their own products. Marginal processors, currently the source of most detected problems (USDA, 1984a), are largely protected by a public perception that governmental inspection is fully effective.

- Adequate technical support for inspection operations from a team of qualified personnel, including substantial emphasis on veterinary medicine, food science, public health, food engineering, food technology, epidemiology, pathology, toxicology, microbiology, animal science, risk analysis, systems analysis, statistics, computer science, and economics. Similarly, managers should have expertise in several

relevant disciplines, including veterinary medicine, food science and technology, nutrition, public health, and public management; no one discipline should dominate.

- An inspection system in which the intensity of inspection depends on a variety of factors, including the risks involved in specific processes, the reliability of the monitoring system, the compliance history of the plant, and the special needs of the intended consumer (e.g., military personnel and schoolchildren). Where inspection is less than continuous, it should be unpredictable (i.e., effectively random).

- A list of the diseases that can be identified by each step in the inspection procedure. A determination should then be made about whether the steps are: (1) useful for human health purposes either by detecting infections or residues that can be transmitted to humans or by maintaining basic levels of food hygiene; (2) useful for animal health purposes, for the surveillance and control of diseases transmitted between animals during production or by other means; (3) useful for detecting aesthetically objectionable conditions; (4) necessary to prevent fraud of consumers; or (5) able to provide other identifiable benefits. Classifying the steps in the inspection process in this way would help FSIS identify efforts that are redundant or that could for other reasons be eliminated without increasing risks to human health. It would also identify areas in which FSIS needs to give more attention to diseases of major importance to human health, as well as opportunities to use data on meat inspection for surveillance of animal diseases.

- A random sampling system to test retained or condemned carcasses and parts of carcasses in order to establish and report definitive diagnoses that can be used to control and prevent future hazards. The sampling system should include pathology correlation sessions as part of continuing education, so it would have an educational as well as surveillance function.

- Rapid, inexpensive screening tests to detect a broad array of hazardous chemical compounds and biological products that may be hazardous to the consumer.

- An adequate sampling plan, designed to protect the consumer, for chemicals that are not randomly distributed across the entire country.

- An emphasis on hazard analysis critical control points in production, slaughter, processing, and distribution, with more limited inspection in selected processing areas within plants where the historic yield of violations is low and where public health risks are negligible.

- The documented assurance, backed by substantial compliance enforcement, of the sanitary wholesomeness of all meat and poultry products.

- The enforcement capability to impose a broad range of penalties upon violators, including the withdrawal of inspection. The penalties must be sufficient to ensure voluntary compliance by plants and be readily tailored to deal with specific kinds of problems.

- Adequate resources to ensure the development of new inspection technologies that will reduce cross-contamination of carcasses, to develop new techniques, to undertake toxicological assessments, and in general to continue improving the technological base of the agency.

- A mandatory system of initial and continuing education for inspection personnel that emphasizes food science, food technology, pathology, and public health. Such a system should also ensure that all inspection personnel be recertified on a continuing basis to ensure continued competence.

- An augmented scientific and technical FSIS staff who have a considerable consultative role in the development of policy.

- The presence of standing advisory panels composed primarily of outside experts to provide consultation on both policy and practice regarding meat and poultry safety. Although such panels might best be organized along problem lines, each must be multidisciplinary. Some of the relevant disciplines are food science and technology, computer applications, microbiology, biostatistics, epidemiology, veterinary medicine, toxicology, systems analysis, animal health, economics, marketing, nutrition, and risk analysis. No one discipline should dominate any panel. All major regulatory proposals should be reviewed by appropriate standing advisory panels prior to finalization.

- Strong liaison with other relevant animal-health agencies of the federal, state, and local governments, so that FSIS has sufficient and current knowledge of hazards emerging in the food supply.

- Substantial use of a rapid, timely, and flexible system to acquire, transfer, analyze, and make more widely available data related to inspection and to meat-borne hazards. Such a system is likely to be computer-based.

An ideal meat and poultry inspection system will ensure that adequate public protection measures are located throughout the food system, from animal production to the final sale of the food product. The best system would also encourage individual consumer responsibility for food safety through effective education programs aimed at the general public, beginning with the school-aged population. Finally, and perhaps most importantly in the context of the charge to this committee, the allocation of food inspection resources should be based on an evaluation of degrees of public health hazard and on the availability of cost-effective methodologies to eliminate or control these risks.

IDENTIFYING AND ADDRESSING RISK THROUGH QUANTITATIVE HEALTH RISK ASSESSMENT

The committee was concerned about two key measures that are missing from the present FSIS approach to inspection: a comprehensive assessment of the kinds of public health hazards that face the agency and the American public, and objective criteria to determine whether identified problems are being appropriately and successfully addressed. One of the major justifications for the inspection of meat and poultry is the need to protect human health. The committee could find, however, no comprehensive quantitative technical analyses of the hazards to human health of specific agents or of the benefits that would follow the adoption of new techniques. Examples of the new approaches include methods of inspecting the slaughter of poultry, the voluntary quality control system, and the testing for pesticide residues on a sampling basis. Without any formal assessments that compare the risks being attacked with the residual risk after control programs are implemented, the committee was unable to evaluate adequately whether these new programs are beneficial to the public or whether the agency has allocated sufficient and appropriate resources to them.

As mentioned earlier, the establishment of reasonable, measurable objectives for the nation's meat and poultry inspection program is imperative. To that end, the committee recommends the adoption of quantitative health risk assessment, which it believes will aid FSIS in improving its program and achieving specific objectives. Quantitative health risk assessment has most recently been discussed in connection with toxic substances (NRC, 1980), yet its roots go much deeper than that, into areas as diverse as transportation, national security policy, and business decision making (NRC, 1983). Although specific elements of this analytical tool may have to be adjusted to the meat and poultry inspection process, the concept is universal. Indeed, its application in food inspection and regulation is already much discussed in relation to the Federal Food, Drug, and Cosmetic Act. The courts, including the Supreme Court, have indicated their willingness to accept the notion of quantitative health risk assessment in the context of indirect food additives (Monsanto v. Kennedy, 1979; Scott v. FDA, 1984).

The Elements of Risk Assessment

Risk assessment is part of the larger discipline of decision analysis. In the context of federal health and safety regulatory programs, it forms a basis for other kinds of decision analysis. Whether using cost-effectiveness analysis, cost-benefit analysis, or other forms of policy analysis that attempt to quantify elements of the decision-making process, health risk assessment must form part of the equation. The emerging discipline of risk assessment (NRC, 1983) has a language of its own that can be reduced to the following four elements: hazard or problem identification, exposure assessment, hazard assessment, and quantitative health risk assessment. Each

merits some discussion in the context of meat and poultry inspection. The comments here follow the National Research Council report in principle, with minor modifications.

Hazard or Problem Identification. The most important first step in any risk analysis is the identification of the hazard or problem. For meat and poultry inspection, this entails identifying precisely the kinds of public health problems FSIS continues to face. With regard to poultry inspection, for example, it is vital to know which diseases or conditions are important to detect and which are trivial. Which inspection procedures relate in what degree to which diseases or conditions being sought? The problems must be broken down into operational components, into issues that can be managed by FSIS and for which some objective data exist or can be developed.

Exposure Assessment. After the problems FSIS is to address have been adequately identified and characterized, it is critical to determine their likely magnitude. How many and what kinds of people--the very young and the very old, for example, and other possibly sensitive populations--are likely to be exposed to components of a problem or to particular levels of toxic substances? The statistical distribution of exposures must be estimated, at least roughly, because average exposures may have little relevance for persons who are unusually sensitive or highly exposed. The range of exposures at the time of consumption may be especially important. For example, trichina larvae in pork may theoretically be a major public health problem inasmuch as organisms still exist in some proportion of pork on the market. Yet if prior campaigns have led producers to avoid hazardous hog-feeding practices and have led the public to cook pork products thoroughly, then the exposure to risk may be too small to warrant further action. In some cases, however--Salmonella may be one--FSIS simply lacks definitive evidence on which to make an adequate exposure assessment. This second step in the risk assessment process would identify these critical gaps in the data.

Hazard Assessment. The third step is a quantitative estimation of what happens, or what might happen, under certain kinds and levels of exposure. In statistical terms, this is a study of conditional probabilities: If a human population receives a certain statistical distribution of exposures, then what is the probability of one or another set of health effects? Hazard assessment is basically a generic term for the concept in toxicology of developing a dose-response relationship. It attempts to define the effects of exposing a human population of a specified size to particular levels of an identified risk, including the approximate distribution of high and low exposures as well as the approximate proportion of sensitive and resistant persons. Hazard assessment includes the study of how sensitive the analysis is to different assumptions and how much uncertainty about information can be tolerated, given the potential health effects of the condition under consideration.

Quantitative Health Risk Assessment. The last step is the integration and interpretation of the preceding three steps to evaluate the overall consequences imposed by exposure to a particular agent under a particular set of circumstances.

In theory, by using this model across a variety of problems FSIS would produce a set of quantitative assessments that could be directly compared, so that current programs could be evaluated and resource allocation could be improved. In practice, risk assessment is an evolving science, in which a variety of information should be given both to the decision maker and to the public before action is taken,including a best estimate of risk, bounded by statistical confidence limits, and a broader statement concerning other kinds of uncertainty about the risk. Common statistical tests deal only with random error. In the real world, a whole range of uncertainties exist, from problems concerning bias in measurements to the use of the wrong test system.

The committee endorses the clear distinction between risk assessment and risk management that others have proposed and developed (NRC, 1983). Quantitative risk assessment is not designed to remove judgment from the decision-making process, but rather to assemble and organize the information that decision makers use (or should use). The difficult question of how much evidence is enough must always be addressed before taking action. Quantitative risk assessment specifies both the state of knowledge and the uncertainties in a rigorous, scientific fashion, so that decision makers can understand the level of uncertainty inherent in the problem. For many policy purposes, a risk assessment must have at least two parallel components--one based on present circumstances (a control) and one expected after some possible change, so that effects of the change can be estimated by any differences between the two.

Applying Risk Assessment to Meat and Poultry Inspection

FSIS already makes implicit risk assessments in deploying its resources. The committee recommends that this process become explicit, that the results of assessments be reviewed by appropriate expert advisory panels, and that formal quantitative risk assessment have a substantial and well-defined role in FSIS policy decisions that affect human health.

The public health risk that justifies each of the inspection program's major efforts needs to be assessed. For example, risks in the following areas need to be identified and compared:

- the human health consequences of animal production practices in the United States,
- the human health consequences of zoonotic agents in food-animals,

- microbiological contamination of processed meat and poultry products,
- other problems caused by inadequate sanitation,
- drug residues,
- pesticide residues and environmental contaminants,
- imported versus domestically produced products in all the above categories, and
- the human health consequences of meat and poultry handling practices subject to current FSIS jurisdiction.

Only in the presence of formal assessments such as these can the implications of change be judged and can experiments be designed to justify future changes. For example, if the current health risk inherent in zoonotic diseases in poultry at slaughter is not material, then the extent and quality of data brought to bear to justify change in the speed of poultry lines is immaterial from a human health perspective. If the major risks in poultry are those of contamination by Salmonella and Campylobacter spp., then efforts must be made to assess how changes in inspection might have implications for Salmonella risks. Similarly, only after a thorough quantitative health risk assessment will it be possible to know whether the relative allocation of resources to poultry slaughter--$120 million in fiscal year 1985 (Executive Office of the President, 1985)--is reasonable in comparison with the much smaller resources devoted to residue control. If the allocation of resources is not optimal from a health perspective, then the analysis lays the scientific and technical base for appropriate changes. In the interim, the committee recommends that FSIS implement new initiatives as rapidly, but only as rapidly, as they can be supported by the analytical approaches outlined here.

The committee urges FSIS to begin promptly to develop a formal and open risk assessment process for all significant areas of policy change. For example, if it wishes to change a red-meat inspection procedure, it should undertake a risk assessment along the lines described here and submit the results for peer review to one or more of its own scientific panels (see above) and then to the relevant scientific communities prior to implementation. If it wishes to bring more plants into its voluntary quality control program, it should likewise attempt to quantify any resulting changes in risk and incorporate its analyses in a proposal to the scientific and public communities. This would put the agency in a stronger position to ask Congress for the authority and flexibility to deal with the problems and establishments that present the greatest risks.

The committee notes that the kind of rigorous overall risk assessment proposed here requires considerable time and resources.

Even findings that data are seriously inadequate may have much value in delaying unjustified changes and in pinpointing needs for prompt data development. An FSIS program of quantitative health risk assessments would have many parallels to programs in other agencies, and their experience might be helpful. Quantitative risk assessments are feasible, and it appears that they could be done for a very small part of FSIS's current appropriation. This seems a good investment for analyses that may lead to substantial improvements in the impact of each dollar spent on inspection.

BUILDING TOWARD AN OPTIMAL SYSTEM

Current Constraints

The first part of this chapter listed several characteristics of an optimal meat and poultry inspection system. Substantial evidence from FSIS, in terms of both structure and process, indicates that the inspection program is already good in many ways.

With respect to outcome, however, neither the committee nor FSIS knows how many diseases or infections the program has prevented. Only rudimentary guesses can be made of the economic costs that have been imposed or avoided. The committee's pursuit of its fundamental charge to examine the scientific foundation of this program has been hindered by the lack of data on major issues. It is not known, for example, whether the nation's current online poultry inspection protects consumers against any diseases of public health importance.

Significant problems of evaluation, therefore, plague the meat and poultry inspection program. The situation is not unique--many federal programs face the same problems. When they are established, the initial impetus is the requirement to take action against some problem. Often, as in the case of FSIS, Congress prescribes the ways in which the agencies will do their business. The necessity to inspect every food-animal under USDA jurisdiction--in contrast with the goal-oriented system established for the U.S. Food and Drug Administration, for instance--places major constraints on the system. In particular, it requires great resources at the point of slaughter and a line-management system that must be able to make complicated judgments quickly. The speed of the line, the necessity to positively inspect each product before it leaves the regulated environment of the plant, the ethic of being on the spot with the problem--these forces and more tend to create a bias toward immediate decision making and away from critical analysis.

This tendency is exacerbated by the very difficult job given to USDA. The various federal meat and poultry inspection acts clearly give USDA multiple responsibilities with respect to the food supply. While FSIS has public health objectives, the laws also require that

USDA assist in the marketing of products and that FSIS be concerned with aesthetic quality. For reasons that go beyond health and stretch far back into the history of Western culture, people are concerned with the way in which animal flesh reaches their tables. They are also concerned that foods not be adulterated in ways unknown to or not recognizable by the purchaser and consumer, and that food products not contain organs or other matter not normally considered fit in U.S. culture for human consumption.

Neither law nor history provides FSIS with any good guide on which of these tasks--health protection, market assistance, or aesthetic control--should predominate, or how conflicts should be resolved. Consequently, the agency attempts to use a single set of programs to achieve these many different objectives. From an analytical perspective, it is not surprising that the result is a general inability to measure the outcome of these programs.

On the basis of discussions with USDA personnel and a survey of inspectors and inspection facilities, the committee believes that the difficulty in defining the FSIS mission, combined with the necessity to make multiple regulatory decisions, reduces the opportunity and the incentive for a comprehensive analysis. Even if objectives could be better defined and program officials were more cognizant of the need to step back and evaluate methods, other constraints must also be overcome to improve the decision process. Foremost among these are:

- the tendency to continue to define health, aesthetic, or economic objectives in terms of visible pathology, rather than recognizing the changes that have occurred in both the makeup of the food supply and the hazards likely to be present;

- the orientation of FSIS more toward the meat and poultry industry as its peer group than toward the broader scientific and public policy communities; and

- the lack of sufficient scientific and technical commitment from the research components of USDA or of assistance from the university community to help FSIS address major technical problems.

The Veterinary Medical Influence. The history of meat and poultry inspection is, by and large, the history of the veterinary medical community's attempt to intercept visibly diseased animals and prevent adulteration of meat and poultry products. As pointed out in Chapter 2, the methods used in inspection are primarily those developed in Europe during the last part of the nineteenth century. They are highly focused on observation of gross lesions or abnormalities that would be direct indicators or markers of disease. Sanitation was and is considered important, of course, and sanitation has often been emphasized in the context of ensuring that the abuses described in The Jungle (Sinclair, 1906) do not occur.

The FSIS professional roster gives a good indication of the agency's emphasis: The number of chemists, microbiologists, quality assurance technicians, and other professional personnel is dwarfed by the number of veterinarians at work in the program (USDA, 1983). This emphasis may be compared with the description in Chapter 7 of inspection responsibilities and strategies. It is immediately clear that nonveterinary expertise dominates a majority of the tasks that face FSIS in traditional processing inspection. That emphasis is even further shifted from veterinary science per se in total quality control and other, newer inspection strategies for processing operations.

It is clear that veterinary medical officers bring a variety of essential skills to meat and poultry inspection. Yet the number of FSIS professionals who have specialized skills in the design, performance, and interpretation of analytical studies needs to be increased if the agency is to meet its future responsibilities in light of rapid change. In the absence of these specialized skills, it is not surprising that FSIS has had difficulty providing its inspectors with enough background to deal effectively with new tasks and problems, such as toxic substances, and the principles underlying the new quality control programs. These principles are best taught by professional experts in such disciplines as food science and toxicology--experts who are in short supply within USDA.

The Industrial Orientation. An additional obstacle to analysis is the peer group with which FSIS is most closely associated. Many federal agencies have strong relationships with their industrial and business constituencies. It is a measure of a democratic government that it be accountable to all the people and groups it affects. For meat and poultry inspection, the relationship to industry is particularly close--of necessity. Honest or dishonest, good compliance record or bad, slaughterer or soup maker, every operator of an establishment is subject to federal oversight every working day. The potential for conflict is always present.

The close relationship with the industry FSIS has had to develop sensitizes program officials to the effects of their program upon the manufacturers. This is not to suggest that FSIS ignores the public interest in the execution of its duties or that it makes decisions that are inevitably industrially oriented. Indeed, conflict occurs at both the plant level and the policy level.

Historically, FSIS has published many policies only in its internal policy book, without giving the public or the scientific community a chance to comment or fully understand new policies in depth. Nor has the agency sponsored or encouraged active debate on the shape of its program. FSIS seldom describes to a scientific or broader public policy audience the underlying rationale for its decisions. In some cases, this low level of communication with communities outside industry can lead to inappropriate decisions that may affect public health.

Insufficient Research. Closely linked to FSIS's failure to sufficiently broaden its view is insufficient research related to the problems underlying meat and poultry inspection. Most investigators in food technology and other relevant sciences find it difficult to conduct research because of a lack of support. It is not sufficient to develop a sophisticated apparatus for policy analysis if the data and technology gaps are so broad that they render analysis meaningless.

The problem of implementing rapid test methodologies, for example, has been recognized for more than a decade. As of 1984, only a few quick tests have been developed (USDA, 1984b), although it is widely recognized that online serological testing of animals could dramatically reduce the need for subjective decision making that has marked meat and poultry inspection for nearly a century. The committee maintains that much more could have been done by now.

Given the current $805-million federal investment in research funded by USDA (Executive Office of the President, 1985) and the major place of meat and poultry products in the department's programs and in the American food supply, it would be appropriate if the USDA could give more attention to research on problems of meat and poultry inspection. The department urgently needs to obtain the kind of research backup for its program that would both enhance its scientific and public credibility and provide the technical base required for sophisticated policy analysis. The committee suggests that FSIS, with substantial support from USDA, develop its relations with the scientific research community. One step toward this goal would be the creation and use of expert panels of outside scientific advisors. Another would be to expand FSIS encouragement and support of investigator-initiated research proposals developed in response to problems identified by FSIS. These problems may indicate needs for basic as well as applied research.

A Source of Optimism: The Will to Change

Overall, several trends in FSIS have made the committee quite optimistic about the future of the program and improvements in the decision-making process. Through a combination of budget increases and reallocations, the agency has taken concrete steps in the last few years to deal with the problems of contamination in the food supply. This demonstrated willingness and ability to reallocate priorities and resources is important because it shows that FSIS can and will make changes when the need is clear and the tools are available. It also indicates that the leadership of USDA and FSIS recognizes and will deal with the changing nature of the inspection problem.

FSIS has additionally tried to develop methods to pinpoint the impacts of change (USDA, 1984a), even though such work has been of limited scope and the reliability of findings is often poorly documented. Again, however, it indicates a willingness to change toward a more analytical system of decision making. On an

organizational level, an Office of Policy Analysis has been established, linked through personnel changes to the Technical Services Office that serves as a primary instrument of program change in FSIS. Finally, FSIS has demonstrated its willingness to adopt modern food science techniques--within the limits allowed by its statutes--in the areas of processing inspection (USDA, 1984a). Although the particular implementation of many of these new concepts was commented on elsewhere in this report, FSIS deserves substantial credit for its willingness to make changes and to act on the basis of scientific and technical evidence.

In sum, the current decision-making environment for meat and poultry inspection contains one major plus--the will to change--that outweighs many of the constraints that are bound to make change difficult.

Implementing Program Change

In other parts of this chapter, several specific changes that could improve and expand FSIS capabilities have been considered. More generally, however, the policy and technical infrastructure that could bring the U.S. meat and poultry inspection program closer to the optimal characteristics described earlier is the same as the infrastructure required to implement a risk assessment approach to analysis. Both require a willingness to tolerate a great diversity of professional views in developing policy and the ability to turn outward toward sources of broader expertise. Specifically, FSIS needs to consider developing the following:

- Stronger connections with the research agencies in USDA and elsewhere in the federal government. At a minimum, the Secretary of Agriculture can help develop a more cooperative and productive relationship with both the Agricultural Research Service and the land-grant colleges and universities, through the Cooperative State Research Service.

- A stronger liaison with relevant animal health agencies of USDA and between USDA and other government agencies, so that the meat and poultry inspection program has sufficient and timely knowledge of emerging hazards in the food supply.

- A larger and stronger cadre of professionals who are capable of undertaking the public health and risk assessment roles identified here. USDA will have to bolster significantly its competence in statistics, toxicology, pathology, microbiology, and epidemiology if it is to undertake this task itself.

- Greater use of experts, both internal and external, in practically all the disciplines that affect meat and poultry inspection. Standing committees of experts need to be established to which the agency will submit each nontrivial regulatory proposal in a

preliminary stage, and from which it can receive advice on the research and technology needed.

FSIS faces a challenging future with great opportunity to implement a program, based on quantitative health risk assessment, that will be at least as innovative, timely, and beneficial as the historic advances that followed the 1906 Federal Meat Inspection Act. Such progress has become the tradition of U.S. meat and poultry inspection services. The new tools for rational decision making are now at hand. Use of these tools would be consistent with the traditions of innovation rooted in the origins of FSIS. Implementation of a more rational decision-making process in U.S. meat and poultry inspection is our generation's obligation to the future.

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Appendix A

U.S. Production of Cattle, Swine, Sheep, Chickens, and Turkeys

These tables, drawn from USDA data, provide details on the production, slaughter, and marketing of food-animals in the United States. Information on production by region or state is included whe available. Most tables cover the period from 1958 through 1983.

TABLE A1 U.S. Cattle Population, by Category, 1968-1983[a]

Year	All Cattle and Calves (million)	Number (million) of Cows and Heifers That Have Calved		Number (million) 500 Pounds and Over					Number (million Under 50 Pounds:
				Heifers					
		Beef Cows	Milk Cows	Beef Cow Replace-ments	Milk Cow Replace-ments	Other	Steers	Bulls	Steers, Heifers, and Bulls
1968	109	35	13	6	4	6	15	2	28
1969	110	35	13	6	4	6	15	2	29
1970	112	37	12	6	4	6	15	2	30
1971	115	38	12	7	4	6	16	2	30
1972	118	39	12	7	4	6	16	2	32
1973	122	41	12	7	4	6	17	2	32
1974	128	43	11	8	4	7	17	3	34
1975	132	46	11	9	4	7	16	3	36
1976	128	44	11	7	4	7	17	3	35
1977	123	41	11	7	4	8	17	3	32
1978	116	39	11	6	4	8	17	3	30
1979	111	37	11	6	4	7	16	2	27
1980	111	37	11	6	4	7	16	2	28
1981	114	39	11	6	4	7	16	3	29
1982	116	39	11	7	4	7	16	3	29
1983	115	38	11	6	4	8	16	3	28

a From USDA, 1983.

TABLE A2 U.S. Beef Cow and Stocker Cattle Population, by Region, 1978[a]

Region	Number of States	Beef Cows		Stocker Cattle	
		Number (thousand)	%	Number (thousand)	%
Northeast	11	406	1.0	1,229	3.0
Lake	3	966	2.5	3,017	7.4
Corn Belt	5	5,985	15.5	8,354	20.5
Northern Plains	4	6,136	15.9	7,072	17.3
Southeast	12	9,925	25.7	7,161	17.6
Southwest	4	9,339	24.2	8,280	20.3
Mountain	6	4,017	10.2	3,530	8.7
Pacific	3	1,952	5.0	2,131	5.2
Total	48	38,726	100.0	40,774	100.0

[a] From Boykin et al., 1980. Excludes Alaska and Hawaii.

ABLE A3 U.S. Cow Farms, by Herd Size and Region, 1974[a]

Region	Number of Farms (thousand)	Distribution of Cow Herd Sizes (%)				
		1-19	20-99	100-199	200-499	500 or More
Northeast	18	74.0	24.6	1.1	0.3	0.0
Lake	44	59.1	38.0	2.3	0.5	0.1
Corn Belt	176	44.3	51.3	3.6	0.7	0.1
Northern Plains	122	25.9	59.2	10.6	3.8	0.5
Southeast	189	40.4	51.3	5.8	2.1	0.4
Southwest	108	23.8	58.8	10.6	5.2	1.6
Mountain	43	20.6	47.9	17.0	11.3	3.2
Pacific	24	40.9	39.8	10.0	6.5	2.8
Total	724	37.2	51.7	7.3	3.1	0.7

[a] From Boykin et al., 1980. Excludes Alaska and Hawaii.

TABLE A4 U.S. Beef Cattle Raising Systems, by Region, 1976[a]

Raising system	Share in Region Using System (%)					
	Southeast	Southwest	West	Great Plains	North Central	All
Cow-calf-feeder	87.0	82.1	82.1	77.2	34.2	69.9
Cow-calf-slaughter	6.9	1.5	5.6	7.2	21.3	9.2
Stocker-slaughter[b]	1.4	0.7	1.4	1.6	30.5	8.2
Stocker-feeder	0.9	6.2	2.3	4.2	2.1	3.5
Mixed	3.8	9.5	8.6	9.8	11.9	9.2

[a] From Boykin et al., 1980. Excludes Alaska and Hawaii.
[b] Excluding commercial feedlots.

TABLE A5 U.S. Feedlots and Fed Cattle, by Feedlot Capacity, 1977[a]

Feedlot Capacity	Share of Feedlots (%)	Share of Cattle (%)
Less than 1,000 head	98.5	31.8
1,000 - 1,999	0.6	4.7
2,000 - 3,999	0.3	4.8
4,000 - 7,999	0.2	6.7
8,000 - 15,999	0.2	14.4
16,000 - 31,999	0.1	19.5
More than 32,000	0.1	18.1

[a] From Gee et al., 1979.

TABLE A6 Average Annual Marketings of Fed Cattle from Selected States, 1964-1967 and 1977-1980[a]

State	Fed Cattle Marketed Annually (thousand)		
	1964-1967	1977-1980	Change (%)
Texas	1,283	4,437	246
Nebraska	2,680	3,939	47
Kansas	1,093	3,247	197
Iowa	3,532	2,921	-17
Colorado	1,170	2,226	90
California	2,153	1,410	-35
Illinois	1,323	930	-30
Minnesota	757	743	-2
Oklahoma	338	721	113
Arizona	612	625	2
South Dakota	583	576	-1
Total	15,524	21,775	40

[a] From Van Arsdall and Nelson, 1983.

TABLE A7 U.S. Cattle Slaughtered under Federal Inspection, by Class, 1968-1982[a]

	Number (millions)				Share of Total (%)[b]			
Year	Steers	Cows	Heifers	Bulls and Stags	Steers	Cows	Heifers	Bulls and Stags
1968	15	6	8	0.5	52	20	27	2
1969	16	6	8	0.5	52	20	27	2
1970	17	5	8	0.5	54	17	27	2
1971	17	6	8	0.6	54	18	26	2
1972	18	5	9	0.6	55	17	26	2
1973	17	6	8	0.6	54	18	25	2
1974	18	7	8	0.7	54	20	24	2
1975	16	10	9	1.0	44	28	26	3
1976	17	10	11	0.9	44	25	29	2
1977	18	9	11	0.8	46	24	28	2
1978	17	8	11	0.7	47	21	30	2
1979	16	6	9	0.6	52	18	29	2
1980	16	6	9	0.7	51	19	28	2
1981	16	6	9	0.7	50	19	29	2
1982	16	7	10	0.8	48	20	29	2

[a] From USDA, 1983.
[b] Numbers may not add due to rounding.

TABLE A8 U.S. Cattle and Calves Slaughtered Commercially and on Farms[a]

Year	Cattle Slaughtered (million)				Calves Slaughtered (thousand)			
	Commercial				Commercial			
	Federally Inspected	Other	Farm	Total	Federally Inspected	Other	Farm	Total
1968	30	5	0.4	35	3,876	1,567	170	5,613
1969	31	5	0.3	36	3,637	1,226	146	5,009
1970	31	4	0.3	35	3,024	1,048	131	4,203
1971	31	4	0.3	36	2,806	883	132	3,821
1972	32	4	0.3	36	2,421	632	131	3,184
1973	31	3	0.3	34	1,808	441	127	2,376
1974	33	3	0.5	37	2,355	632	185	3,172
1975	37	4	0.6	41	3,894	1,316	197	5,406
1976	39	4	0.5	43	4,438	912	178	5,528
1977	39	3	0.5	42	4,696	821	175	5,692
1978	37	3	0.4	40	3,620	550	132	4,302
1979	32	2	0.3	34	2,499	325	103	2,927
1980	32	2	0.3	34	2,294	294	91	2,679
1981	33	2	0.3	35	2,478	320	88	2,886
1982	34	2	0.3	36	2,729	292	85	3,106

[a] From USDA, 1983. Numbers may not add up to totals due to rounding.

BLE A9 U. S. Pig, Breeding Hog, and Market Hog Population, 1968-1982[a]

ar	All Hogs and Pigs	Hogs Kept for Breeding	Number of Market Hogs (million) by Weight Groups (pounds)					
			Under 60	60 to 119	120 to 179	180 to 219	220 and Over	Total
68	61	9	26	12	8	4	1	51
69	59	9	24	12	8	4	1	50
70	65	11	27	13	8	4	1	54
71	65	10	26	14	9	5	2	56
72	61	9	25	13	8	5	1	51
73	60	9	24	12	8	5	1	51
74	59	9	24	12	8	5	2	50
75	47	7	18	10	7	4	1	41
76	54	8	22	11	7	4	1	46
77	54	9	22	11	8	5	1	46
78	55	9	21	11	8	5	1	46
79	65	10	25	13	9	7[b]		55
80	65	9	25	14	10	7		56
81	60	8	23	12	9	7		51
82	52	7	19	11	8	7		45

From USDA 1983. Estimates taken on June 1st each year. Numbers may not add up to totals due to rounding.
180 pounds and over.

TABLE A10 U.S. Hog Production, by Region, 1965, 1970, 1975, and 1980[a]

Region	Share of Hog Live Weight Produced (% total production), by Year			
	1965	1970	1975	1980
Corn Belt - Lake States				
Eastern	32	29	29	25
Western	38	37	37	40
Northern Plains	12	14	13	13
Southeast	13	14	15	16
Southwest	2	3	2	2
Other	4	4	4	4

[a] From Van Arsdall and Nelson, 1984.

TABLE A11 U.S. Hog Facilities, by Type, 1980[a]

	Share of Hogs (%), by Region, in Type of Facility			
	Farrow-to-Finish		Feeder-to-Finish	
	North Central	South-east	North Central	South-east
Types of Housing				
None	14	35	5	20
Open front building	24	41	31	42
Fully enclosed				
no outside access	21	18	10	19
outside access	23	2	22	8
Mixed	18	4	32	11
Types of Floors				
Paved	56	46	51	48
Slotted	26	32	15	18
Flush system	2	12	-[b]	10
Scrape system	1	1	0	0
Mixed[c]	10	2	21	7
Dirt	4	6	8	7
Other	1	1	5	10

[a] From Van Arsdall and Nelson, 1984.
[b] Less than 0.5%.
[c] Mixed paved and self-cleaning floors.

TABLE A12 U.S. Farrowing Facilities, by Type and Region, 1980[a]

Enterprise and Region	Share of Pigs (%) in Type of Farrowing Facility						
			Central Facilities with				
	None	Portable Houses	Paved Floor	Slotted Floor	Flush System	Scrape System	Mix Hou
Feeder pigs							
North Central	6	13	18	16	4	17	26
Southeast	8	0	49	24	9	3	7
Farrow-to-finish							
North Central	7	10	38	23	2	1	19
Southeast	16	4	35	27	7	1	10

[a] From Van Arsdall and Nelson, 1984.

TABLE A13 U. S. Hogs Sold, by Relative Size of Farm and Annual Sales, 1964 and 1974[a]

Annual Sales of Hogs (thousand)	Share of Hogs Sold (%)		Share of Farms (%)	
	1964	1974	1964	1974
1 - 99	23	11	67	56
100 - 199	23	13	18	17
200 - 499	33	29	12	18
500 - 999	13	22	2	6
1,000 or more	7	25	1	2

[a] From Van Arsdall, 1978. Numbers have been rounded.

TABLE A14 U.S. Hogs and Pigs Sold, by Size of Enterprise and Region, 1978[a]

Head sold (thousand)	Percent of Annual Sales by Enterprise Size (thousand) (N=Total No. Sold in Region)					
	All Hogs and Pigs			Feeder Pigs		
	North Central (N=71,041)	South-east (N=12,361)	U.S. Total (N=92,140)	North Central (N=14,644)	South-east (N=3,075)	U.S. Total (N=20,020)
1 - 99	7	18	10	8	27	13
100 - 199	10	11	10	10	18	12
200 - 499	26	16	24	26	20	24
500 - 999	24	17	22	22	10	19
1,000 - 1,999	17	12	16			
2,000 - 4,999	10	11	10	34[b]	24[b]	32[b]
5,000 & over	6	15	7			

[a] From Van Arsdall and Nelson, 1984. Numbers have been rounded.
[b] Annual sales of 1,000 or more.

TABLE A15 U.S. Hogs Slaughtered, by Category, and Average Dressed and Live Weights, 1968-1982[a]

Year	At Federally Inspected Facilities-- Number (million) and Weight (pounds)					At All Commercial facilities-- Number (million) and Weight (pounds)		
	Barrows and Gilts	Sows	Stags and Boars	Total	Average Dressed Weight	Total	Average Dressed Weight	Average Live Weight
1968	69	5	0.4	75	151	85	151	239
1969	70	5	0.6	76	153	84	152	239
1970	73	5	0.5	78	155	86	154	240
1971	81	5	0.7	87	156	94	155	239
1972	73	5	0.7	79	160	85	159	239
1973	67	4	0.7	72	164	77	164	241
1974	71	5	0.7	77	167	82	166	244
1975	61	4	0.6	65	166	69	165	240
1976	67	3	0.5	70	167	74	166	238
1977	69	4	0.8	74	170	77	170	237
1978	70	4	0.7	74	171	77	171	240
1979	80	5	0.9	85	172	89	172	242
1980	86	5	1.1	92	172	96	172	242
1981	82	5	1.0	88	173	92	172	243
1982	74	4	1.0	79	173	82	172	243

[a] From USDA, 1983. Numbers may not add up to totals due to rounding.

TABLE A16 U.S. Sheep and Lamb Population, 1968-1983[a]

Year	Number of Sheep and Lambs (thousand)		
	All Sheep and Lambs	Sheep and Lambs on Feed	Stock Sheep
1968	22,223	3,115	19,108
1969	21,350	2,995	18,355
1970	20,423	2,990	17,433
1971	19,731	2,785	16,946
1972	18,739	2,894	15,845
1973	17,641	2,873	14,768
1974	16,310	2,625	13,685
1975	14,515	2,079	12,436
1976	13,311	1,884	11,427
1977	12,722	1,731	10,991
1978	12,421	1,623	10,798
1979	12,365	1,579	10,786
1980	12,687	1,622	11,065
1981	12,936	1,649	11,287
1982	12,966	1,564	11,402
1983	11,904	1,641	10,263

[a] From USDA, 1983.

TABLE A17 The Top Ten Stocker Sheep States, 1982[a]

State	Number of Sheep (thousand)				
	Stock Sheep	Marketings		Shipped into State	Slaughtered
		Sheep	Lambs		
Texas	2,200	412	955	215	903
Wyoming	1,000	226	457	66	2
California	1,010	120	825	300	1,431
South Dakota	700	127	492	47	406
New Mexico	595	78	223	82	118
Montana	600	129	314	21	4
Utah	610	91	343	30	24
Colorado	480	109	725	548	1,348
Idaho	470	77	427	88	1
Oregon	440	84	236	15	26
Other states	3,297	782	2,357	708	2,186
Total	11,402	2,235	7,354	2,120	6,449

[a] From USDA, 1983.

TABLE A18 U.S. Sheep and Lambs Slaughtered at Federally Inspected Commercial Facilities, and Average Dressed and Live Weights, 1968-1982[a]

Year	At Federally Inspected Facilities (thousand)			At All Commercial Facilities--Number (thousand) and Weights (pounds)		
	Lambs and Yearlings	Mature Sheep	Total	Number	Average Dressed Weight	Average Live Weight
1968	10,198	690	10,888	11,884	50	102
1969	9,340	728	10,070	10,691	51	104
1970	9,298	711	10,010	10,552	52	104
1971	9,437	819	10,256	10,729	51	104
1972	9,229	677	9,905	10,301	52	105
1973	8,426	808	9,234	9,597	53	107
1974	7,987	569	8,556	8,847	52	105
1975	6,993	558	7,552	7,835	51	104
1976	6,058	416	6,474	6,714	54	109
1977	5,643	489	6,133	6,356	54	108
1978	4,810	359	5,169	5,369	56	112
1979	4,499	334	4,833	5,017	57	114
1980	4,970	393	5,363	5,579	56	112
1981	5,388	401	5,789	6,008	54	110
1982	5,820	454	6,273	6,449	56	111

[a] From USDA, 1983. Numbers may not add up to totals due to rounding.

ABLE A19 U.S. Broiler and Layer Production, 1968-1982[a]

ear	Total Broilers		Total Layers	
	Number (million)	Weight (million pounds)	Number (million)	Weight (million pounds)
968	2,620	9,326	244	1,109
969	2,789	10,048	252	1,144
970	2,987	10,819	269	1,190
971	2,945	10,818	258	1,212
972	3,075	11,480	233	1,118
973	3,009	11,220	251	1,172
974	2,993	11,320	242	1,186
975	2,950	11,096	233	1,067
976	3,274	12,481	229	1,109
977	3,394	12,962	245	1,172
978	3,614	14,000	242	1,136
979	3,951	15,522	251	1,216
980	3,964	15,544	241	1,180
981	4,150	16,530	242	1,188
982	4,151	16,770	246	1,171

From USDA, 1983.

ABLE A20 U.S. Egg and Broiler Production, by Region, 1980[a]

egion	Eggs		Chickens Produced for Meat	
	Number (billions)	%	Number (millions)	%
ortheast	9.8	14	188	5
orth Central	17.0	24	89	2
outh	30.2	44	3,497	88
est	12.5	18	190	5
otal	69.5	100	3,964	100

From Lasley, 1983.

TABLE A21 U.S. Farms Selling Broilers, by Size of Farm, 1978[a]

Broilers[b] per Farm	Farms[c] Number (thousand)	%	Broilers[b] Number (thousand)	%
1 - 1,999	11,725	34.0	1,544	
2,000 - 3,999	159	0.5	421	0.1[d]
4,000 - 7,999	256	0.7	1,462	
8,000 - 15,999	555	1.6	6,510	0.2
16,000 - 29,999	895	2.6	19,992	0.6
30,000 - 59,999	3,114	9.0	138,926	4.4
60,000 - 99,999	5,432	15.8	409,344	13.1
100,000 or more	12,338	35.8	2,557,421	81.6
Total	34,474	100.0	3,135,619	100.0

[a] From Lasley, 1983.
[b] Includes other chickens produced for meat.
[c] Farms with at least $2,500 sales.
[d] Sales combined for small groups

TABLE A22 Feed Efficiency, Period, and Average Market Weight of U.S. Feeding Broilers 1955, 1965, 1975, and 1980[a]

Year	Feed per Weight Gain (pound for pound)	Feeding Period (days)	Market Weight (pounds)
1955	2.85	73	3.1
1965	2.36	--	3.5
1975	2.10	56	3.8
1980	2.08	52	4.0

[a] From Lasley, 1983.

TABLE A23 U.S. Poultry Slaughtered and Condemned under Federal Inspection, by Category, 1982[a]

Class	Total Slaughtered		Weight Condemned (thousand pounds)	
	Number (thousand)	Weight (million pounds)	Antemortem[b]	Postmortem[c]
Young chickens	4,068,116	16,457	48,130	219,933
Mature chickens	201,843	899	10,889	28,511
Total chickens	4,269,959	17,356	59,019	248,444
Young turkeys	153,331	3,004	7,275	46,392
Old turkeys	1,308	28	176	1,119
Fryer-roaster turkeys	5,737	53	125	488
Total turkeys	160,376	3,085	3,576	47,999
Ducks	19,834	125	152	1,891
Other poultry	d	7	8	56
Total poultry	d	20,574	66,755	298,390

[a] From USDA, 1983. Numbers may not add up to totals due to rounding.
[b] Live weight.
[c] New York dressed weight.
[d] Data not available.

TABLE A24 U.S. Turkey Population and Live Weights, 1968-1982[a]

Year	Number Hatched (million)			Number Raised (million)	Live Weight Produced (million pounds)
	Heavy Breeds[b]	Light Breeds[b]	Total		
1968	100	14	114	107	2,015
1969	103	12	115	107	2,029
1970	116	14	130	116	2,198
1971	115	13	128	120	2,256
1972	126	16	142	129	2,424
1973	129	17	146	132	2,452
1974	126	14	140	132	2,437
1975	121	16	137	124	2,277
1976	131	18	149	140	2,606
1977	136	12	148	136	2,563
1978	149	9	158	139	2,655
1979	166	14	180	156	2,958
1980	172	17	189	165	3,069
1981	177	10	187	170	3,263
1982	177	7	184	165	3,176

[a] From USDA, 1983.
[b] Heavy breeds normal market weight more than 12 pounds; light breeds, less than 12 pounds.

TABLE A25 U.S. Turkey Farms, by Size, 1978[a]

Turkeys per Farm	Farms		Turkeys	
	Number	%	Number	%
1 - 1,999	4,485	61.7	273	0.2
2,000 - 3,999	128	1.8	359	0.3
4,000 - 7,999	305	4.2	1,735	1.2
8,000 - 15,999	421	5.8	4,904	3.5
16,000 - 29,999	538	7.4	11,543	8.2
30,000 - 59,999	701	9.6	29,110	20.6
60,000 - 99,999	389	5.3	28,658	20.3
100,000 or more	304	4.2	64,721	45.8
Total	7,271	100.0	141,303	100.0

[a] From Lasley, 1983. Numbers may not add up to totals due to rounding.

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Appendix B
USDA Quality Control Regulations

On August 12, 1980, the U.S. Department of Agriculture finalized details of the total quality control program, which was approved for use by processing plants on a voluntary basis. The following is a copy of the relevant sections of the Code of Federal Regulations as amended.

Therefore, section 318.4 of the Federal meat inspection regulations (9 CFR 318.4) is amended by changing the section heading and the Table of Contents, by rewording the second and third sentences of paragraph (b), and by adding new paragraphs (c), (d), (e), (f), and (g) to read as follows:

§ 318.4 Preparation of products to be officially supervised; responsibilities of official establishments; plant operated quality control.

* * * * *

(b)***In order to carry out this responsibility effectively, the operator of the establishment shall institute appropriate measures to assure the maintenance of the establishment and the preparation, marking, labeling, packaging and other handling of its products strictly in accordance with the sanitary and other requirements of this subchapter. The effectiveness of such measures will be subject to review by the Department.

(c) Applying for Total Plant Quality Control. Any owner or operator of an official establishment preparing meat food product who has a total plant quality control system or plan for controlling such product, after ante-mortem and post-mortem inspection, through all stages of preparation, may request the Administrator to evaluate it to determine whether or not that system is adequate to result in product being in compliance with the requirements of the Act and therefore qualify as a U.S. Department of Agriculture (USDA) Total Plant Quality Control Establishment. Such a request shall, as a minimum, include:

(1) A letter to the Administrator from the establishment owner or operator stating the company's basis and purpose for seeking an approved quality control system and willingness to adhere to the requirements of the system as approved by the Department; that all the establishment's data, analyses, and information generated by its quality control system will be maintained to enable the Department to monitor compliance and available to Department personnel; that plant quality control personnel will have authority to halt production or shipping of product in cases where the submitted quality control system requires it; and that the owner or operator (or his/her designee) will be available for consultation at any time Department personnel consider it necessary.

(2) In the case of an establishment having one or more full-time persons whose primary duties are related to the quality control system, an organizational chart showing that such people ultimately report to an establishment official whose quality control responsibilities are independent of or not predominantly production responsibilities. In the case of an establishment which does not have full-time quality control personnel, information indicating the nature of the duties and responsibilities of the person who will be responsible for the quality control system.

(3) A list identifying those Parts and sections of the Federal meat inspection regulations which are applicable to the operations of the establishment applying for approval of a quality control system. This list shall also identify which part of the quality control system will serve to maintain compliance with the applicable regulations.

(4) Detailed information concerning the manner in which the system will function. Such information should include, but not necessarily be limited to, questions of raw material control, the critical check or control points, the nature and frequency of tests to be made, the nature of charts and other records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the nature of deficiencies the quality control system is designed to identify and control, the parameters or limits which will be used, and the points at which corrective action will occur and the nature of such corrective action--ranging from least to most severe: Provided, That, subsequent to approval of the total plant quality control system by the Administrator, the official establishment may produce a new product for test marketing provided labeling for the product has been approved by the Administrator, the inspector in charge has determined that the procedures for preparing the product will assure that all Federal requirements are met, and the production for test marketing does not exceed 6 months. Such new product shall not be produced at that establishment after the 6-month period unless approval of the quality control system for that product has been received from the Administrator.

(d) Applying for Partial Quality Control. Any owner or operator of an official establishment preparing meat food products who has a quality control program for a product, operation, or a part of an operation, may submit it to the Administrator and request a determination as to whether or not that program is adequate to result in product being in compliance with the requirements of the Act. Such a request shall, as a minimum, include:

(1) A letter from the establishment official responsible for quality control stating the objective of the program, and that all data and information generated by the program will be maintained to enable the Department to monitor compliance and available to Department personnel.

(2) Detailed information concerning raw material control, the critical check or control points, the nature and frequency of tests to be made, the charts and records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the limits which will be used and the points at which corrective action will occur, and the nature of the corrective action--ranging from the least to the most severe.

(e) Evaluation and Approval of Total Plant Quality Control or Partial Quality Control. (1) The Administrator shall evaluate the material presented in accordance with the provisions of paragraph (c) or

(d) of this section. If it is determined by the Administrator on the basis of the evaluation, that the total quality control system or partial quality control program will result in finished products controlled in this manner being in full compliance with the requirements of the Act and regulations thereunder, the total quality control system or partial quality control program will be approved and plans will be made for implementation under departmental supervision.

(2) In any situation where the system or program is found by the Administrator to be unacceptable, formal notification shall be given to the applicant of the basis for the denial. The applicant will be afforded an opportunity to modify the system or program in accordance with the notification. The applicant shall also be afforded an opportunity to submit a written statement in response to this notification of denial and a right to request a hearing with respect to the merits or validity of the denial. If the applicant requests a hearing and the Administrator, after review of the answer, determines the initial determination to be correct, he shall file with the Hearing Clerk of the Department the notification, answer and the request for hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with Rules of Practice which shall be adopted for this proceeding.

(3) The establishment owner or operator shall be responsible for the effective operation of the approved total plant quality control system or partial quality control program to assure compliance with the requirements of the Act and regulations thereunder. The Secretary shall continue to provide the Federal inspection necessary to carry out his responsibilities under the Act.

(f) Labeling Logo. Owners and operators of official establishments having a total plant quality control system approved under the provisions of paragraph (c) of this section, may only use, as a part of any labeling, the following logo. Any labeling bearing the logo and any wording of explanation with respect to this logo shall be approved as required by Parts 316 and 317 of this subchapter.

(g) Termination of Total Plant Quality Control or Partial Quality Control.

(1) The approval of a total plant quality control system or a partial quality control program may be terminated at any time by the owner or operator of the official establishment upon written notice to the Administrator.

(2) The approval of a total plant quality control system or partial quality control program may be terminated upon the establishment's receipt of a written notice from the Administrator under the following conditions:

(i) If adulterated or misbranded meat food product is found by the Administrator to have been prepared for or distributed in commerce by the subject establishment. In such case, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of terminating the approval. In those instances where there is conflict of facts, a hearing, under applicable Rules of Practice, will be provided to the establishment owner or operator to resolve the conflict. The Administrator's termination of approval shall remain in effect pending the final determination of the proceeding.

(ii) If the establishment fails to comply with the quality control system or program to which it has agreed after being notified by letter from the Administrator or his designee. Prior to such termination, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of the letter. In those instances where there is a conflict of facts, a hearing, under applicable Rules of Practice, will be provided to the establishment owner or operator to resolve the conflict. The Administrator's termination of quality control approval shall remain in effect pending the final determination of the proceeding.

(3) If approval of the total plant quality control system or partial quality control program has been terminated in accordance with the provisions of this section, an application and request for approval of the same or a modified total plant quality control system will not be evaluated by the Administrator for at least 6 months from the termination date, or for at least 2 months from the termination date in the case of a partial quality control program.

(Secs 5, 8, 21, 202, and 407 34 Stat. 1260, as amended, 21 U.S.C. 605, 608, 621, 642, and 677; 42 FR 35625, 35626, 35631)

Further, section 381.145 of the poultry products inspection regulations (9 CFR 381.145) is amended as follows:

1. The paragraph designation "(c)" would be deleted and the present text of that paragraph (c) would be added to the end of paragraph (b) of that section.

2. New paragraphs (c), (d), (e), (f), and (g) would be added to read as follows:

§381.145 Poultry products and other articles entering or at official establishments; examination and other requirements.

* * * * *

(c) Applying for Total Plant Quality Control. Any owner or operator of an official establishment preparing poultry product who has a total plant quality control system or plan for controlling such products, after ante-mortem and post-mortem inspection, through all stages of preparation, may request the Administrator to evaluate it to determine whether or not that system is adequate to result in product being in compliance with the requirements of the Act and therefore qualify as a U.S. Department of Agriculture (USDA) Total Plant Quality Control Establishment. Such a request shall, as a minimum, include:

(1) A letter to the Administrator from the establishment owner or operator stating the company's basis and purpose for seeking an approved quality control system and willingness to adhere to the requirements of the system as approved by the Department; that all the establishment's data, analyses, and information generated by its quality control system will be maintained to enable the Department to monitor compliance and available to Department personnel; that plant quality control personnel will have authority to halt production or shipping of product in cases where the submitted quality control systems require it; and that the owner or operator (or his/her designee) will be available for consultation at any time Department personnel consider it necessary.

(2) In the case of an establishment having one or more full-time persons whose primary duties are related to the quality control system, an organizational chart showing that such people ultimately report to an establishment official whose quality control responsibilities are independent of or not predominantly production responsibilities. In the case of a small establishment which does not have full-time quality control personnel, information indicating the nature of the duties and responsibilities of the person who will also be responsible for the quality control system.

(3) A list identifying those Subparts and sections of the poultry products inspection regulations which are applicable to the operations of the establishment applying for approval of a quality control system. This list shall also identify which part of the system will serve to maintain compliance with the applicable regulations.

(4) Detailed information concerning the manner in which the system will function. Such information should include, but not necessarily be limited to, questions of raw material control, the critical check or control points, the nature and frequency of tests to be made, the nature of charts and other records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the nature of deficiencies the quality control system is

designed to identify and control, the parameters of limits which will be used and the points at which corrective action will occur, and the nature of such corrective action--ranging from the least to most severe. Provided, That, subsequent to approval of the total plant quality control system by the Administrator, the official establishment may produce a new product for test marketing provided labeling for the product has been approved by the Administrator, the inspector in charge has determined that the procedures for preparing the product will assure that all Federal requirements are met, and the production for test marketing does not exceed 6 months. Such new product shall not be produced at that establishment after the 6-month period unless approval of the quality control system for that product has been received from the Administrator.

(d) Applying for Partial Quality Control. Any owner or operator of an official establishment preparing poultry products who has a quality control program for a product, operation, or a part of an operation, may submit it to the Administrator and request a determination as to whether or not that program is adequate to result in product being in compliance with the requirements of the Act. Such a request shall, as a minimum, include:

(1) A letter from the establishment official responsible for quality control stating the objective of the program, and that all data and information generated by the program will be maintained to enable the Department to monitor compliance and available to Department personnel.

(2) Detailed information concerning raw material control, the critical check or control points, the nature and frequency of tests to be made, the charts and records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the limits which will be used and the points at which corrective action will occur, and the nature of the corrective action--ranging from the least to the most severe.

(e) Evaluation and Approval of Total Plant Quality Control or Partial Quality Control. (1) The Administrator shall evaluate the material presented in accordance with the provisions of paragraph (c) or (d) of this section. If it is determined by the Administrator, on the basis of the evaluation, that the total quality control system or partial quality control program will result in finished products controlled in this manner being in full compliance with the requirements of the Act and regulation thereunder, the total quality control system or partial quality control program will be approved and plans will be made for implementation under departmental supervision.

(2) In any situation where the system or program is found by the Administrator to be unacceptable, formal notification shall be given to the applicant of the basis for the denial. The applicant will be afforded an opportunity to modify the system or program in accordance

notification of denial and a right to request a hearing with respect to the merits or validity of the denial. If the applicant requests a hearing and the Administrator, after review of the answer, determines the initial determination to be correct, he shall file with the Hearing Clerk of the Department the notification, answer and the request for hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with Rules of Practice which shall be adopted for this proceeding.

(3) The establishment owner or operator shall be responsible for the effective operation of the approved total plant quality control system or partial quality control program to assure compliance with the requirements of the Act and regulations thereunder. The Secretary shall continue to provide the Federal inspection necessary to carry out the responsibilities of the Act.

(f) Labeling Logo. Owners and operators of official establishments having a total plant quality control system approved under the provisions of paragraph (c) of this section, may only use, as a part of any labeling, the following logo. Any labeling bearing the logo and any wording of explanation with respect to this logo shall be approved as required by Subparts M and N of this Part.

(g) Termination of Total Plant Quality Control or Partial Quality Control.

(1) The approval of a total plant quality control system or a partial quality control program may be terminated at any time by the owner or operator of the official establishment upon written notice to the Administrator.

(2) The approval of a total plant quality control system or partial quality control program may be terminated upon the establishment's receipt of a written notice from the Administrator under the following conditions:

(i) If adulterated or misbranded poultry product is found by the Administrator to have been prepared for or distributed in commerce by the subject establishment. In such case, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of terminating the approval. In those instances where there is a conflict of facts, a hearing, under applicable Rules of Practice, will be afforded to the establishment owner or operator, if requested, to resolve the conflict. The Administrator's termination of approval shall remain in effect pending the final determination of the proceeding.

(ii) If the establishment fails to comply with the quality control system or program to which it has agreed after being notified by letter from the Administrator or his designee. Prior to such termination, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of the letter. In those instances where there is a conflict of facts, a hearing, under applicable Rules of Practice, will be afforded to the

stablishment owner or operator, if requested, to resolve the conflict. he Administrator's termination of quality control approval shall remain n effect pending the final determination of the proceeding.

(3) If approval of the total plant quality control system or artial quality control program has been terminated in accordance with he provisions of this section, an application and request for approval f the same or a modified total plant quality control system will not be valuated by the Administrator for at least 6 months from the ermination date, or for at least 2 months from the termination date in he case of a partial quality control program.

Secs. 7, 11(b), 14, 16 and 22, 71 Stat. 441, as amended, 21 U.S.C. 456, 60(b), 463, 465, and 467d; 42 FR 35625, 35626, and 35631)

Done at Washington, D.C., on: 12 August 1980

s/ Carol Tucker Foreman

arol Tucker Foreman
ssistant Secretary for
ood and Consumer Services

Glossary of Acronyms

CAST	Calf Antibiotic Sulfonamide Test; also, Council for Agricultural Science and Technology
CAT	Computer-Assisted Axial Tomography
CDC	Centers for Disease Control, Public Health Service, U.S. Department of Health and Human Services
CFR	Code of Federal Regulations
CHC	Chlorinated Hydrocarbons
CLS	Commission on Life Sciences
DES	Diethylstilbesterol
DHHS	Department of Health and Human Services (formerly DHEW, Department of Health, Education, and Welfare)
DNA	Deoxyribonucleic Acid
EDB	Ethylene Dibromide
ELISA	Enzyme-Linked Immunosorbent Assay
EPA	Environmental Protection Agency
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration, Public Health Service, U.S. Department of Health and Human Services
FNB	Food and Nutrition Board
FSIS	Food Safety and Inspection Service (formerly FSQS, Food Safet and Quality Service) of U.S. Department of Agriculture
GLC	Gas-Liquid Chromatography
HACCP	Hazard Analysis Critical Control Point
HPLC	High-Performance Liquid Chromatography
LAST	Live Animal Swab Test
MAB	Monoclonal Antibody
MARCIS	Microbiological and Residue Computer Information System
MMWR	Morbidity and Mortality Weekly Report (published by CDC)
MS	Mass Spectrometry
NAS	National Academy of Sciences
NELS	New Line Speed
NMR	Nuclear Magnetic Resonance
NOEL	No-Observed-Effect Level
NRC	National Research Council
NRP	National Residue Program
NTI	New Turkey Inspection
PAH	Polycyclic Aromatic Hydrocarbons
PCB	Polychlorinated Biphenyls
STOP	Swab Test on Premises
TLC	Thin Layer Chromatography
TQC	Total Quality Control (FSIS-initiated program)
USDA	U.S. Department of Agriculture
VMO	Veterinary Medical Officer

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