

Cattle Inspection



Food and Nutrition Board

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Cattle Inspection

Committee on Evaluation of USDA Streamlined Inspection System for Cattle (SIS-C)

Food And Nutrition Board
Institute of Medicine
National Academy of Sciences

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PREFACE

Since the early 1900s, the U.S. Department of Agriculture (USDA) has been responsible for mandatory federal meat inspection programs, which remained essentially unchanged into the 1980s. In 1980, USDA's Food Safety and Inspection Service (FSIS) asked the Food and Nutrition Board of the National Academy of Sciences (NAS) to conduct scientific evaluations of its meat and poultry inspection programs. The Food and Nutrition Board's recommendations were released in two reports published in 1985 and 1987 (NRC, 1985a, 1987a).

Meanwhile, FSIS worked to modernize inspection in high speed slaughter operations through streamlined inspection systems (SIS). These systems were introduced to ensure more efficient use of inspection personnel, to help industry to become more efficient, and to assist the agency's transition to a more public health-oriented inspection. They initiated SIS in pilot plants and published the proposed rule in the *Federal Register* in November 1988 (Fed. Regist., 1988; [Appendix A](#)). In response to questions raised about the proposed rule, FSIS asked the Food and Nutrition Board to evaluate SIS for cattle (SIS-C) for acceptability as an alternative to traditional slaughter inspection.

This six member committee was convened under the auspices of the Institute of Medicine's (IOM) Food and Nutrition Board (FNB) in conjunction with the National Research Council's (NRC) Board on Agriculture. The committee and its three consultants included experts in biostatistics, epidemiology, meat science, meat inspection, public health, veterinary pathology, veterinary microbiology, and veterinary toxicology.

The committee was charged with the following tasks:

- Evaluate SIS-C as compared to the traditional cattle inspection system and its acceptability as an alternative to traditional cattle slaughter inspection.
- Perform on site reviews of two high volume cattle slaughtering plants (establishments) operating under traditional inspection and two plants operating as pilot studies for SIS-C.
- Survey procedures for monitoring chemicals and pathogens in carcasses.
- Examine how this proposed system has integrated recommendations in the 1985 and 1987 reports, which called for FSIS to pursue new scientific directions, address contemporary public expectations for meat and poultry products, and work toward an ideal meat inspection program.
- Evaluate efficacy of SIS-C in protecting the public's health.

The committee received an overview of SIS-C from FSIS management, heard testimony from eight witnesses at a public hearing, and then visited three SIS-C pilot plants and two traditionally inspected plants. Altogether, it met six times. Throughout the study, the committee also requested and received additional data from FSIS ([Appendix B](#)).

During their presentation to the committee, FSIS staff indicated that traditional inspection procedures were serving as the baseline for modernizing inspection and as a springboard for future improvements. *FSIS emphasized that SIS-C is not a system for detecting microbial or chemical contaminants and that it is not a Hazard Analysis Critical Control Point (HACCP) program but, rather, is a single step toward those goals.* FSIS regards SIS-C as an innovative system that identifies control points, increases use of plant personnel in quality control and in presentation of carcasses and parts for inspection, and incorporates statistical samples and tests to monitor products and the slaughter process.

SIS-C differs from traditional inspection in several ways. In traditional inspection programs, FSIS inspectors incise the bile ducts, heart, cheek muscles, and numerous lymph nodes seeking visible lesions. Inspectors are responsible for condemnation and disposition of diseased carcasses. FSIS inspectors also identify and supervise the trimming of carcasses with various dressing defects and nonconformances. Under SIS-C, plant employees incise the heart and cheek muscles, position parts for inspectors, and assume responsibility for dressing nonconformances and designated trimmable conditions (see [Chapter 3](#)). FSIS leadership believes that these conditions can be recognized by personnel with limited experience, are susceptible to market pressures, and are the responsibility of plant management. Under SIS-C, however, inspectors are still responsible for condemnation and disposition of diseased carcasses and still examine every head, viscera, and carcass.

In conjunction with SIS-C, plants killing more than 275 cattle per hour must have a formal written, customized, partial quality control (PQC) program. SIS-C/PQC programs require the plant to identify control points, establish standards, and take actions when FSIS-supervised monitoring reveals that standards are unmet. Plants unable to implement SIS-C/PQC successfully must operate at chain speeds below 275 cattle per hour.

The SIS-C system is currently in effect in five pilot plants conducting high speed, high volume slaughter of fed steers and heifers — a class of animal with low prevalence of conditions detectable by traditional meat inspection procedures. Approximately 80 of more than 1,300 USDA-inspected cattle slaughter plants would be eligible for SIS-C were the proposed rule implemented.

The eight speakers who addressed the committee during the public meeting held on January 23, 1990, represented consumer advocates, the meat industry, food inspectors, former USDA scientists and inspectors, and national associations ([Appendix C](#)). Some of their testimony criticized FSIS for previous deficiencies in inspection programs, for failure to emphasize public health, for unwillingness to listen to the scientific community, for reluctance to improve its technologic capacity, for failure to incorporate recommendations

in previous Food and Nutrition Board reports, and for fundamental flaws in SIS-C. Several speakers criticized SIS-C because responsibility for quality control is given to management of meat plants. This abdication, it was said, compromises the integrity of FSIS and is not feasible because it requires ideal conditions in every plant and requires plant employees to place the public interest above profit considerations. Witnesses also stated that SIS-C is flawed because head, viscera, and carcass inspection are all compromised and there is no assurance that company personnel are properly trimming contaminated areas from carcasses. These problems are compounded by staff reductions and increased paperwork for the inspection force. The opinion was expressed that SIS-C lacks clear rational statements of goals and definitions for its sampling plans and that solid scientific data supporting those plans are absent.

Meat industry representatives questioned USDA-FSIS's ability to regulate plant quality control programs. They suggested that clear guidelines and appeal procedures are needed if the government assumes this role.

Most witnesses emphasized concern about microbial and chemical contaminants. The committee had to deal early with the real distinction between safety and quality because FSIS contends SIS-C is not designed to detect and remove these contaminants. The FSIS chemical residue monitoring program whether in traditional or SIS-C plants is designed to provide incidence information — not to prevent public exposure to residues.

The committee visited three SIS pilot plants (in Texas, Colorado, and Nebraska) and two traditionally inspected plants (in Texas and Kansas). Its findings from these site visits are summarized in [Appendix D](#). The committee interviewed 24 lay food inspectors, 6 inspectors in charge, 5 veterinarians, 5 supervising veterinarians (including one area supervisor), 7 representatives of plant management, and 9 plant quality control personnel.

From the outset, it was apparent that people were concerned about food safety, meat and poultry inspection, and SIS-C. The committee received sworn affidavits and letters from inspectors and veterinarians who were disillusioned with SIS-C (see [Appendix E](#)) and many letters from one veterinarian who was formerly an FSIS employee. The committee was also bombarded with testimony, many other letters, information, undocumented anecdotes, newspaper clippings, and dogmatic statements assailing SIS and blaming it for imperfections in meat and poultry inspection programs. Much of this input implied that the public expects the government to ensure zero risk of meat-borne disease through inspection. The committee heard little evidence that the public is aware that some bacterial contamination of raw meat is inevitable and no mention of the crucial role of food handling, preparation, and serving methods in limiting foodborne diseases.

The committee was chosen for its diversity and scientific credibility. Because of its charge, it considered only commentary relevant to SIS-C. It was a challenge to sort through the emotions, political motivations, hidden agendas, and vested interests of people presenting opinions and recommendations. Because of the lack of hard quantitative data,

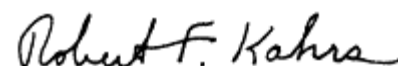
it was difficult to separate perception from fact. This complex controversial issue abounds with unsubstantiated accusations, subjective opinions, and deep emotional involvements. The committee did its best to listen carefully, to be critically analytical, and to address the specific charge. Although the report deals only with beef cattle slaughter and SIS-C, the committee addressed some recommendations dealing with poultry in one of the earlier reports (NRC, 1987a) when it believed they had application to beef slaughter and the FSIS mission. The committee hopes the report is fair and will serve the best interests of the American people.

[Chapter 1](#) (the Executive Summary) summarizes the committee's charge, findings, conclusions, and recommendations. [Chapter 2](#) provides an introduction and a historic overview of meat inspection and public concerns about food safety. In [Chapter 3](#), the committee examines the proposed SIS-C ruling, its rationale, and its potential impact on consumers. The statistical procedures used in SIS-C are discussed in [Chapter 4](#). [Chapter 5](#) contains a discussion of microbiological and toxicological data. An example of how to collect and analyze microbiological samples is presented in [Appendix F](#). [Chapter 6](#) discusses how the proposed SIS rule could have incorporated recommendations in the earlier Food and Nutrition Board reports. A Glossary of terms and acronyms can be found in [Appendix G](#). The affiliations and major research interests of committee members and staff are presented in [Appendix H](#).

The committee commends the assistance, hard work, and support of the FNB staff: Dr. Farid E. Ahmed, for the organizational and administrative support of the committee's work, Frances Peter for editing the report, and Barbara Matos for typing the document.

The committee expresses its appreciation to FSIS personnel for expediting facility visits and providing data, to all the plant personnel who extended hospitality, and to all the witnesses who testified at the public hearing. The committee is also grateful to the anonymous USDA inspectors and veterinarians and many plant employees who volunteered time and shared their concerns.

As chairman, I also thank the committee members and consultants and their employers; they volunteered countless hours and effort to produce an objective and timely report on a controversial subject that is a small part of a major national issue — the safety of the food supply.



ROBERT F. KAHRS, CHAIRMAN

COMMITTEE ON EVALUATION OF USDA STREAMLINED INSPECTION SYSTEM FOR CATTLE

CONTENTS

1	Executive summary	1
	Committee charge, its response, and its conclusions	3
	Recommendations	6
2	Introduction and Historical Review of Meat Inspection	8
	Abstract	8
	Historic food safety concerns and early meat inspection legislation	8
	Developments after the Meat Inspection Act of 1906	9
	Emergence of HACCP as a model inspection system	13
	Contemporary public concerns about meat inspection	14
	Conclusions	15
3	The Proposed SIS Rule	16
	Abstract	16
	Rationale and assumptions of the ruling	16
	An overview and commentary on SIS-C and the slaughter PQC program	17
	SIS-C postmortem inspection	19
	Streamlined inspection procedures	19
	Cervical/head inspection	19
	Viscera and carcass inspection	22
	Uniform presentation standards	23
	Specific equipment and facilities	23
	Carcass dressing requirements	23
	Assessing the wholesomeness of the carcass and product	24
	FSIS data in support of the proposed ruling	26
	Impact of SIS-C on consumers, inspectors and plants	27
	Consumers	27
	Inspectors	28
	Plant managers and employees	29
	Conclusions and recommendations	29
4	Statistical Considerations	34
	Abstract	34
	Rationale supporting the change from AQL to SIS	34
	Use of CUSUM for process control	35
	The sampling basis for CUSUM	36
	Discussion	38

Discussion	38
Recommendations	40
5 Microbiologic and Toxicologic Assessment	42
Abstract	42
Assessment	42
Recommendations	46
6 The Extent to Which Previous FNB Recommendations Have Been Integrated into the SIS Proposed Rule	48
Abstract	48
Recommendations in Meat and Poultry Inspection: The Scientific Basis for the Nation's Program	49
Recommendations	49
Detection and elimination of pathogenic microorganisms	49
Preventing and detecting chemical residues	50
Monitoring hazardous agents during livestock production and traceback mechanisms	50
Integration of risk assessment procedures into the inspection process	51
Research and advisory programs to develop high technology-based inspection	51
Characteristics of an optimal meat and poultry inspection program	51
A system of traceback to producers	52
Use of plant personnel to monitor critical control points	52
Use of contemporary technologic expertise in inspection management	52
Multitiered levels of inspection	53
Analysis of the utility of each inspection procedure	53
Develop a data base on specific causes of condemnations	54
Rapid screening for residues	54
Protection of consumers from residues	55
Hazard Analysis Critical Control Point (HACCP) Programs	55
Documentation and compliance enforcement	55
Enhanced enforcement capability	56
Improve technologic base of FSIS	56
Mandatory continuing education	57
Involvement of scientists in policy development	57
Expert advisory panels	57
Interagency liaison	58
Data and information analysis	58
Implementation timetable	59
Recommendations in Poultry Inspection: The Basis for a Risk-Assessment Approach	59

General recommendations	59
Specific Recommendations	60
Conclusions	63
References	65
Appendices:	67
A Proposed Rule. Streamlined Inspection System-Cattle and Staffing Standards	68
B Information Provided by USDA-FSIS to Committee	82
C Public Meeting Agenda	84
D Reports on Site Visits	86
E Summary of Verbal and Written Testimony by FSIS Inspectors	88
F Bacteriological Study of Beef Carcasses in Quebec	90
Annex 1 Data Sheet for Establishment	94
Annex 2 Needle Point Stamp for Marking Samples to be Taken	97
Annex 3 Areas From Which Samples are to be Taken and Location of Points at Which to Take Temperature and Relative Humidity Readings	98
G Glossary of Terms and Acronyms	99
H Affiliations and Major Research Interests of Committee and Staff	103
Tables:	
2-1 Analyses Performed by FSIS in 1989	12
3-1 An Overview of the SIS-C/PQC Program	18
3-2 SIS-C and Traditional Postmortem Inspection Procedures	21
3-3 Size and Frequency of Sampling by Plant QC Personnel and FSIS Inspectors	25
5-1 Classification of Worldwide Meatborne and Poultryborne Microbial Pathogens According to Modes of Transmission	43
Figures:	
3-1 Interactions Between Plant Process Control Operations and Plant Quality Control and Federal Meat Inspection Staff	20
4-1 Probability of Observing No Defects in Various Lot Sizes and Line Speeds When the Average Number of Defects/Sample Unit (Carcass Side) is 0.1	37
4-2 Evaluation of CUSUM for SIS-C, Assuming $n=3$, $c=0$	39

1

EXECUTIVE SUMMARY

According to the U.S. Department of Agriculture (USDA), the role of its Food Safety and Inspection Service (FSIS) is "to set policies and regulations, based on the best possible science to protect public health and to foster public confidence in the safety of our food" (Smith, 1990, p. 7). "In the next decade, FSIS intends to complete the transition from an inspection service to a public health agency capable of controlling risks from the producer to the consumer with the aim of reducing foodborne illness acquired through consumption of meat products" (Crawford, 1990, p. 12).

FSIS has proposed the Streamlined Inspection System for cattle (SIS-C) as the first step in modernizing slaughter inspection of fed cattle.¹ The Committee on Evaluation of USDA's SIS-C, established within the Food and Nutrition Board of the Institute of Medicine, National Academy of Sciences, studied fed-cattle inspection procedures with the FSIS goals in mind. Its analysis was also influenced by the following factors:

- Meat quality and meat safety are not synonymous. Although there is overlap, meat *quality* largely depends on palatability factors, aesthetically pleasing appearance, freedom from visible lesions and foreign materials, and good keeping characteristics. Meat *safety* deals with the presence of microbial pathogens and levels of chemical residues.
- Contemporary foodborne illnesses are associated with pathogenic microbial contamination and possibly chemical residues. Neither are detectable by traditional inspection methods. Traditional meat

¹ *Fed cattle* comprise young castrated males (steers) and young females that have never calved (heifers); both are fed special finishing rations in feedlots immediately prior to slaughter. This class of cattle is usually slaughtered in large packing plants with fast line speeds. They are usually uniform in age, size, and weight and have fewer condemnable conditions than do nonfed cattle or cull cattle that are sent to slaughter because it is no longer economically feasible to maintain them. SIS-C as evaluated by the committee is intended for use in high speed operations slaughtering largely fed cattle. It is currently not FSIS's intention to extend SIS-C to operations slaughtering classes of cattle (e.g., veal calves and dairy cattle) that tend to have higher incidences of chemical residues and condemnable defects that are detectable at inspection.

- inspection² emphasizes visible abnormalities more relevant to quality than to food safety.
- The public is not adequately familiar with the limitations of meat inspection systems in detecting and removing pathogens and chemical residues that present risks to public health. It is unrealistic to believe every carcass can be tested for all microorganisms that are pathogenic in humans and all potentially toxic chemical residues.
 - A well-designed and comprehensive program based on principles of the Hazard Analysis Critical Control Point (HACCP) system³ can reduce or even eliminate many risks. But the public should understand clearly that meat products may contain pathogens that can cause disease in humans if not handled properly through production, processing, distribution, retailing, storage, and preparation.
 - Effective detection and control of residues (and possibly pathogens) will require the development of a practical cost-effective animal identification system to permit traceback to possible sources of residues or contamination. This technology is under development but needs considerable perfecting before it can be applied routinely.
 - The quantitative data base in the peer-reviewed scientific literature is not sufficient to support a rational public debate about meat safety or the advantages and disadvantages of existing and proposed inspection systems.
 - For more than 80 years, FSIS has developed in its inspectorate a strong culture of determination and responsibility for final decisions

² *Traditional inspection* requires USDA inspectors to examine organoleptically each carcass and viscera as they move separately through plants. In traditional inspection, inspectors seek visible disease lesions, defects, and nonconformances (see [Chapter 3](#)), conduct a final inspection before carcasses enter the washer or cooler, and have authority for final disposition by declaring each carcass as passed, or condemned, or by requiring rework (trimming) under supervision of an inspector.

³ *Hazard Analysis Critical Control Point (HACCP)* system consists of (1) an assessment of hazards associated with growing, harvesting, processing/manufacturing, distribution/marketing, preparation, and/or use of a given raw material or food product; (2) determination of critical control points required to control any identified hazard(s); and (3) establishment of procedures to monitor critical control points. Basically the HACCP system provides a more specific and central approach to the control of microbiological hazards than that achievable by traditional inspection and quality control procedures (WHO, 1980) (see [Chapter 2](#)).

on carcass disposition and dressing standards. Under SIS-C,⁴ inspectors learned that some of those decisions had become the responsibility of plant employees who were untrained in meat inspection.

- FSIS has not persuaded all its inspectors that SIS-C is an improvement over traditional inspection. Objectors are concerned about possible declines in meat safety and an increase in the incidence of foodborne diseases due to reduction of inspector authority and control and the introduction of statistical sampling.
- Statistical sampling methods can be used to estimate the occurrence of detectable defects. If the point in the process at which these defects are likely to occur is known, then statistically based monitoring can trigger corrective actions. Cumulative Sum (CUSUM), the statistical basis for SIS-C, is a means of checking the process to ensure that processing modifications, inadvertent mistakes, and poor training do not cause an upward trend in defects over time. However, CUSUM, or other statistical sampling procedures, have limitations when they are used to assess processes applied to products that are not uniform, i.e., that are made from heterogeneous raw materials that contain many defects. They do not ensure that the product is free from defects and are inadequate to ensure that no contaminated or defective meat reaches the consumer. This distinction seems to be the source of considerable misunderstanding.

COMMITTEE CHARGE, ITS RESPONSE, AND ITS CONCLUSIONS

The committee was charged with examining five major issues. These are listed below along with the committee's response and conclusions, where applicable.

⁴ In *Streamlined Inspection System for Cattle (SIS-C)*, some cuts and organ positioning formerly done by FSIS inspectors are carried out by plant employees, the viscera and carcass inspection stations are combined, and inspection is completed at the viscera inspection belt. In SIS-C, every carcass, viscera, and head receives individual FSIS inspection. However, some specific inspection procedures are omitted and establishment employees remove designated trimmable conditions and dressing nonconformances (see [Chapter 3](#)) without FSIS supervision. In SIS-C, inspectors monitor finished products by examining results of the establishment's statistical analysis of a small random sample of carcasses and by-products and by conducting additional testing of their own.

1. Evaluate SIS-C as it compares to the traditional cattle inspection system and its acceptability as an alternative to traditional cattle slaughter inspection.

After completing its evaluation, the committee drew the following conclusions:

- Traditional inspection, SIS-C, or SIS-C with a partial quality control (PQC)⁵ program (SIS-C/PQC)⁶ are not designed to detect or eliminate microbial or chemical hazards presented by meat products. No data have been published to allow a determination of the relative merits of each system in improving meat safety.
- When quality control programs are effectively implemented, SIS-C/PQC is acceptable as an alternative to traditional cattle slaughter inspection.
- FSIS should adopt with modifications the proposed rule that appeared in the *Federal Register* on November 30, 1988 (see [Appendix A](#)). SIS-C/PQC should be implemented in plants with demonstrated ability to conduct effective quality control programs.
- SIS-C without PQC should be permitted only for periods of less than 1 year in plants undergoing transition from traditional inspection to SIS-C/POC. There is no logical basis for making PQC optional for plants with lower speeds.
- From a food safety viewpoint, SIS-C alone is probably no better, and in some situations can be less effective, than traditional inspection because the reduced oversight by government inspectors is not compensated by a total commitment to product quality on the part of industry.
- SIS-C/PQC is the most important change in bovine meat inspection

⁵ *Partial Quality Control (PQC)* programs involve identifying points in the process (critical control points) that are critical to finished product standards, setting operational standards at each critical control point, defining and documenting checks on critical control points, and stating required action where standards are unmet. The PQC is designed by plant management, customized for each establishment and monitored by FSIS. PQC programs are required of SIS-C plants slaughtering more than 275 cattle per hour.

⁶ *Streamlined Inspection System for Cattle/Partial Quality Control (SIS-C/PQC)* is an SIS-C program in conjunction with PQC. In the proposed rule, this combination is optional for establishments with slaughter rates of 275 or less cattle per hour.

since 1906. For this system to work in practice, both FSIS and industry must fully endorse the philosophy of shifting responsibility for meat quality from FSIS to industry so that the government can concentrate its resources on safety.

2. Perform on site review of two cattle slaughtering establishments operating under traditional inspection and two operating as pilot plants for SIS-C.

The committee visited two traditional and three SIS-C plants, two of which were operating under SIS-C/PQC. Since it was not possible to conduct surprise inspections, the committee assumed that the plants were operating under optimal conditions at the time of the visits. Sufficient observations were made by the committee to give it a full understanding of the theory and practice of traditional and SIS-C inspection.

3. Survey procedures for monitoring pathogens and chemicals in carcasses.

Under most systems of cattle inspection, FSIS monitoring of pathogens and chemical residues in carcasses produces archival and trend data. It is not designed to prevent public exposure or eliminate these risks to public health. Protecting consumers from exposure to foodborne health hazards is a complex and almost overwhelming challenge requiring comprehensive HACCP programs (see [Chapter 2](#)) and earnest interagency coordination⁷ (NRC 1985b, 1987a). Thus far, however, FSIS efforts to improve interagency relations have not had an impact on SIS-C. Some segments of industry are ahead of FSIS in reducing microbial and chemical risks through HACCP-like approaches (see [Chapter 5](#)).

FSIS must support the research needed to determine how inspection techniques can be improved to reduce levels of microbial and chemical contaminants and must develop monitoring technology that protects consumers from potentially harmful exposures.

4. Examine how previous Food and Nutrition Board recommendations have been integrated into SIS-C.

In light of the focus and goals declared for the FSIS in the 1990s (Crawford, 1990; Smith, 1990), it is unfortunate that FSIS has not integrated more of the recommendations in previous Food and Nutrition Board reports (NRC, 1985a, 1987a) into SIS-C (see [Chapter 6](#)).

⁷ *Coordination* among state and federal agencies and institutions that conduct educational Or regulatory programs affecting production, processing, distribution, preparation, and serving of foods of animal origin. These include the Food and Drug Administration (FDA), the Animal and Plant Health Inspection Service (APHIS), the Centers for Disease Control (CDC), the Extension Service, state departments of agriculture, universities, and others.

5. Evaluate the efficacy of SIS-C in protecting public health.

Traditional inspection, SIS-C, and SIS-C/PQC focus on quality; they are not designed to address major current public health concerns (i.e., safety). Preventing carcass contamination through increased attention to critical control points, as outlined in company PQC programs for slaughter and dressing processes, probably benefits public health. However, there are no published data on which to base any conclusions.

In its study, the committee found that public expectations surpass the capability of current meat inspection laws and procedures and possibly the Congressional mandate to FSIS. A comprehensive reevaluation of inspection programs and health risks from the producer to the consumer is essential to protect the public from health risks prevalent in modern production, marketing, and food preparation systems. To this end, the committee offers the following observations on meat inspection systems:

- Traditional meat inspection, relying on organoleptic examinations, can ensure satisfactory meat product quality but is not fully effective in protecting the public against foodborne health hazards not detectable with these techniques. Therefore, this type of meat inspection should not be regarded as the gold standard against which other proposed inspection systems or new technologies for food safety are judged.
- The desired characteristics of the final product should determine the ideal standards for inspection systems. Desired attributes of meat and meat products include both safety and quality issues, which are not exclusive (see [Chapter 3](#)).

RECOMMENDATIONS

If the role of FSIS is to establish policies and regulations based on the best possible science to protect public health and to foster public confidence in the safety of meat and meat products, the committee recommends that the following steps be taken:

- The Secretary of Agriculture should enlist the assistance of the Agricultural Research Service (ARS), the Cooperative State Research Service (CSRS), universities, other research institutions, and private industry in FSIS's efforts to develop and implement scientifically and statistically based methods of evaluating the public health aspects of existing and proposed inspection programs. Additional resources are needed for epidemiologic and food safety research to support well-designed HACCP-based food safety programs.
- The federal government should design its inspection programs to focus on contemporary public health issues. It should insist that industry comply with policies and procedures required to protect

- public health and foster public confidence in the safety of the food supply.
- SIS-C/PQC should be implemented in slaughter operations that demonstrate management and employee commitment to effective PQC programs.
 - FSIS should establish mandatory finished product standards and enhance its procedures under traditional systems to extend the benefits of PQC to all cattle, including veal calves and cull dairy cows, that pose the greatest risks from microbial/chemical contamination.
 - FSIS should improve communications with its field inspectors to ensure that they share and concur with agency goals and philosophies of food safety in the twenty-first century.
 - The strength and sincerity of inspector concerns must send a clear signal to FSIS. If the agency is to achieve its ambitious goals for the next decade, it must learn from the SIS-C experience that it is imperative to involve its field employees in development and implementation of new procedures.
 - USDA, other agencies, and industry should foster and promote food safety education for the public. The public must understand the potential for contamination of meat and meat products by human pathogens and should learn safe food handling practices.

2

INTRODUCTION AND HISTORICAL REVIEW OF MEAT INSPECTION

ABSTRACT

Throughout history, meat inspection legislation, regulations, and procedures have been altered to keep pace with changing methods of beef production, slaughter, processing, and consumption. Today, rapidly changing technologies and increasing public expectations dictate a major reevaluation of inspection systems and philosophies.

The Federal Meat Inspection Act of 1906 (P.L. 59-242) and the Wholesome Meat Act of 1967 (P.L. 90-201) were designed and implemented to provide the public with a safe, wholesome meat supply. Today's consumer relies on the Food Safety and Inspection Service (FSIS) inspectors to ensure this.

No raw food product is totally sterile. Furthermore, contamination and recontamination may occur. Therefore, consumers must be aware of and implement proper handling, storage, and preparation practices for meat.

Beef production and processing are highly competitive, rapidly changing industries. Today, most finished beef cattle production is concentrated in feedlots in the midwestern and southwestern regions of the United States, where more than 15 million steers and heifers are slaughtered annually (FSIS, 1990b). In some plants, more than 400 cattle are processed each hour. These numbers and speeds present challenges to those responsible for the inspection of all cattle and assurance of a safe and wholesome edible product for the consumer.

Over the years, the U.S. Department of Agriculture (USDA) has made adjustments, changes, and modifications in an effort to keep abreast of the dynamic livestock industry. As the FSIS moves into the twenty-first century, it must make radical changes in its system and its ability to respond to the food safety needs of 250 million Americans.

HISTORIC FOOD SAFETY CONCERNS AND EARLY MEAT INSPECTION LEGISLATION

The public has always been concerned about the cleanliness, safety, and wholesomeness of its food supply. In early agrarian societies, people personally observed food from harvest to consumption. Today, consumers rely on unseen third parties to scrutinize the safety and wholesomeness of perishable foods and to protect them against natural and man-made hazards that can enter the food chain.

Since antiquity, people have associated "unclean" meat with disease and have placed religious or government restrictions on slaughter, processing, distribution, and consumption of meat products. Religious restrictions against eating certain meat products originated in biblical times and still exist today. In ancient times, hogs probably were infected with the trichinosis organism, an intramuscular parasite, and

people who consumed inadequately cooked pork became ill. Religious prohibition on pork consumption probably prevented serious public health problems long before the actual causes of trichinosis and other diseases were known. Today, rabbis and their representatives still determine if kosher meat meets ritualistic requirements.

Laws enacted in Italy in the thirteenth and fourteenth centuries to correct unsanitary and fraudulent practices required butchers to renew their licenses annually, prohibited misrepresentations, substitutions, and unsanitary practices, and provided for inspections. And so the science of meat hygiene was born.

The health of slaughter animals has long been associated with meat safety. The first meat inspection law in North America was enacted in New France (Canada) in 1706 (Brandly, et al., 1966). It required butchers to notify authorities when animals were to be slaughtered so that meat could be inspected. Farmers were also required to certify that animals destined for slaughter had not been sick, down, or poisoned. At that time, the close relationship between butchers and consumers helped prevent grossly unsanitary butchering practices, because buyers could voice complaints directly.

In the 1880s, the quality of dressed beef, salted pork, and bacon was important to export markets. Rumors in foreign countries suggested that diseases in U.S. livestock rendered meat unfit for food. A bill passed on August 30, 1890 (stat. 2594, 51st Congress) as a result of these pressures provided for final product inspection before export upon request of a buyer, seller, or exporter.

A meat inspection act passed on March 3, 1891 (26 stat. 1089) and a meat inspection amendment of March 2, 1895 (28 stat. 727, 731) strengthened meat inspection laws but did not provide for a national meat inspection system. In the early 1900s, when Theodore Roosevelt was president, there was public outcry over unsanitary conditions and inadequate inspection. This public indignation was increased by Upton Sinclair's novel *The Jungle* (Sinclair, 1906), in which he described the horrendous working conditions and poor sanitation in Chicago slaughterhouses. This led to the enactment on June 30, 1906 of the comprehensive Meat Inspection Act of 1906 (P.L. 59-242), which strengthened requirements for sanitary conditions in packing houses and required inspection of meat for interstate commerce.

DEVELOPMENTS AFTER THE MEAT INSPECTION ACT OF 1906

Since the Meat Inspection Act of 1906, there have been periodic changes in meat inspection regulations. The early legislation included, as it does now, inspection before (antemortem), during, and after (postmortem) slaughter; inspection during all processing steps; approval of labels for processed meat products; and strong controls over the sanitation, facilities, and equipment used in meat packing plants operating under federal inspection.

Following enactment of the 1906 Meat Inspection Act, USDA provided

inspection that helped control some zoonotic diseases, such as tuberculosis and cysticercosis, the lesions of which can be detected visually. Traditional meat inspection is based on organoleptic examinations in which inspectors make professional judgments based on what they see, feel, and smell. These procedures have provided reasonably acceptable products to consumers since 1906, even though the vast majority of foodborne diseases occurring today are caused by microorganisms that cannot be detected visually.

Dr. Robert K. Somers, a former Deputy Administrator of USDA's Meat Inspection program, reviewed the changes that occurred from 1906 to 1966 (Somers, 1966). Other historic accounts of meat inspection appeared in a previous Food and Nutrition Board report (NRC, 1985c) and other sources (Brandly et al., 1966). Implementation of the National Humane Slaughter Act of August 27, 1958 (P.L. 85-765, 85th Congress) improved the way animals were rendered insensible at slaughter. Frequent changes have been made in the "regulations governing the meat inspection of the USDA" (Somers, 1966), which cover the entire gamut of facilities, sanitation, antemortem inspection, postmortem inspection, labeling, reinspection and preparation, transportation, imported products, standards of identity, and relevant details. Some of these changes were the result of legislation in such Acts as the Horse Meat Act of June 24, 1919 (41 Stat. 241, 66th Congress); Imported Meat Act of June 17, 1930 (P.L. 361, 71st Congress); Agricultural Marketing Act of August 14, 1955 (P.L. 272, 84th Congress); and Wholesome Meat Act of December 15, 1967 (P.L. 90-201, 90th Congress). Other changes were instituted by directives from the Secretary of Agriculture, or the Administrator responsible for meat inspection, as new knowledge and research dictated greater protection of the consumer.

Meat inspection was first administered by the Bureau of Animal Industry, which later became part of the USDA's Agricultural Research Service (ARS). Later, it was administered by three divisions in USDA's Consumer and Marketing Service (CMS), Livestock Slaughter Inspection Division, and Processed Meat Inspection and Technical Services Division. These changes were made to keep pace with the rapidly changing industry and to strengthen protection to consumers.

With continued industrial development and improved transportation, the meat industry became national, the personal touch was lost, and consumers could no longer influence the butcher/packer regarding sanitation, product wholesomeness, and freedom from adulteration. Up to World War II, the meat packing industry was centralized in cities, and livestock were shipped for long distances. When feedlots developed, slaughter plants left cities and moved to areas where finished cattle were concentrated.

By the 1960s, it was apparent that the 1906 act did not provide adequate consumer protection because some conditions were not covered in the law and because all animals slaughtered for intrastate commerce were not adequately inspected. Inspection was a state responsibility, but because state funds for inspection were limited, extensive abuses occurred. The 1906 law also permitted interstate shipment of

products from whole carcasses slaughtered for intrastate commerce and the import of uninspected meat products, and did not control rendering plants. The Wholesome Meat Act of 1967 (P.L. 90-201) gave the USDA authority to regulate transporters, renderers, cold storage warehouses, and animal-food manufacturers. Requirements on imported meat became more stringent, and inspection of all animals prior to slaughter (antemortem inspection) became mandatory.

The meat industry has grown, and the jurisdiction of federal meat inspection has increased. This growth has presented challenges requiring greater sophistication and efficiency of USDA monitoring of this vast industry. Reorganization of this arm of the USDA under the title of the Food Safety and Inspection Service (FSIS) evolved to better address the safety and wholesomeness of all food products, especially those of animal origin, which are highly perishable. In accomplishing its mission, FSIS today employs a field force of approximately 8,000 people (1,500 veterinarians and 6,500 food inspectors) and spends about \$400 million annually.

Modern beef production involves the finishing of steers and heifers in feedlots, which supply more than 15 million cattle per year to large U.S. slaughter plants. Today, large meat plants slaughter from 200 to 400 cattle per hour (3,000 to 5,000 per plant per day). Approximately 10% of U.S. cattle slaughtering plants handle 90% of commercial cattle (FSIS, 1990b), and 58.1% of U.S. cattle slaughtering occurs in four states: Kansas (18.0%), Texas (17.0%), Nebraska (16.7%), and Colorado (6.4%). The concentrated industry and speed of processing present major challenges to the nation's meat inspection system.

The high concentration of cattle in feedlots provides opportunity for spread of microorganisms such as *Salmonella* and *Campylobacter* that cause diseases. On the other hand, feedlot cattle are more uniform in size and age and less likely to be diseased, down, dying, or loaded with drugs than are cull dairy cattle, mixed groups of slaughter cattle, or veal calves. This uniformity, large numbers, high speeds of slaughter (exceeding 400 carcasses per hour in some modern facilities), and low levels of organoleptically detectable defects in large fed-cattle slaughter operations make them candidates for innovative inspection techniques. USDA has attempted to alter traditional meat inspection methods to make use of modern technology to better monitor levels of microorganisms and residues of therapeutic drugs, agricultural chemicals, and environmental pollutants that cannot be detected organoleptically. However, today's inspection is still essentially organoleptic. The sheer volume of carcasses needing inspection requires ever-increasing numbers of trained and physically able inspectors; however, resource limitations have prevented the expansion of the inspection workforce. A current strategy is to give more quality control responsibility to management of slaughter facilities, as was recommended in previous Food and Nutrition Board reports (NRC, 1985b, 1987a). This strategy was based on the premise that the wholesomeness of the final product is the joint responsibility of industry (management) and the FSIS. This concept as applied to beef is called Streamlined Inspection System for Cattle (SIS-C).

Throughout the twentieth century, advances in microbiology and toxicology led to the identification and description of specific causes of many foodborne diseases. Scientists developed new tests and epidemiologic techniques for investigating foodborne disease outbreaks. Toxicological tests have become increasingly sensitive, permitting detection of infinitesimal amounts of natural or man-made substances. However, these technologies are usually applied to disease investigations only when a potential agent is suspected. It is not economically or logistically possible to monitor all food products for every possible harmful agent, but random testing revealing traces of potentially harmful materials has caused public alarm. The hype of the biotechnologic revolution and the advent of convenience packaging, preparation, and serving methods have helped the public forget age-old precautions. Thorough cooking is still necessary to reduce microbial loads, and strict hygiene is necessary to prevent recontamination. Current generations need to know that care is needed in the kitchen as well as the slaughterhouse.

Laboratories have been established across the nation to provide supplemental scientific analysis of meat and meat products and for approval of additives incorporated into meat products.

In 1955, 29,000 samples were tested by USDA laboratories; in 1965, more than 174,000 samples were tested; and in 1989, 564,000 analyses were conducted in the various species of animals slaughtered under U.S. federal inspections as shown in [Table 2-1](#).

Table 2-1 Analyses Performed by FSIS in 1989

Type of Analysis	Number of Analyses Performed on: All Species ^a Steers and Heifers ^b	
Food chemistry	62,435	
Food microbiology	36,908	
Chemical residues	185,163	3,022
Antibiotic residues	255,851	844
Pathology	11,017	
Serology	1,630	
Food additives	10,907	
Radiation	139	
TOTAL	564,050	3,866

^a Source: FSIS, 1990b.
^b Unpublished data from FSIS.

These data demonstrate the contemporary challenges faced by FSIS. FSIS has also had to address the European Economic Community (EEC) hormone ban and the *Listeria* and *Salmonella* scares (FSIS, 1990b). It has also responded to residue episodes by intensifying its surveillance of heptachlor, aflatoxin, and sulfamethazine since 1989 (FSIS, 1990b). These activities testify to the changing face of FSIS as it progresses from an inspection agency to a public health agency. In a brochure entitled *Inspection Horizons, Food Safety and Inspection Service Strategy for the 1990s* (FSIS, 1990a), FSIS addresses its future plans to provide the U.S. consumer with a safe meat supply.

EMERGENCE OF HACCP AS A MODEL INSPECTION SYSTEM

As advancing microbiologic, toxicologic, and epidemiologic technology indicated the enormity and complexity of the food safety issue, segments of the food industry and of the regulatory and scientific communities embraced an apparently exemplary model for controlling microbiologic contamination of foods. The hazard analysis critical control point (HACCP) concept had been evolving through the 1970s and 1980s. It provided new vocabulary and complicated standards to which existing and proposed inspection systems could be compared.

The HACCP system consists of (1) an assessment of hazards associated with growing, harvesting, processing/manufacturing, distribution/marketing, preparation and/or use of a given raw material or food product; (2) determination of critical control points required to control any identified hazard(s); and (3) establishment of procedures to monitor critical control points. Basically, the HACCP system provides a more specific and central approach to the control of microbiological hazards than that achievable by traditional inspection and quality control procedures (WHO, 1980).

"The HACCP system for meat 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" (NRC, 1985b). In order to minimize microbial contamination of beef using HACCP concepts, HACCP systems must be designed uniquely for the various types of cattle production systems and slaughter operations and customized for every individual processing plant and product.

This complex approach has broad applications to all points in the food chain from production through consumption. It has been expanded beyond microbial contamination to include potential chemical hazards (FSIS, 1989a). Critics fear FSIS will extend it beyond contamination considerations into regulation of labeling, economic adulteration, and other nonsafety issues. FSIS has been urged to identify critical control points solely on the basis of public health considerations (FCN, 1990).

The HACCP concept was first applied in the 1960s to ensure risk-free foods for U.S. astronauts. In the 1980s, it was recommended by a committee of the Food and Nutrition Board (NRC, 1985b) and the National Advisory Committee on Micro

biological Criteria for Foods. In 1989, FSIS made a commitment to this highly specialized and scientific system without any clear evidence that all of its personnel fully understand it.

HACCP has been specifically recommended as a basis for meat and poultry inspection (NRC, 1985a, 1987a), and it has been modified through many years of operation and fine-tuning. It is designed to prevent problems from occurring rather than to identify contaminated products at the end of the production line. According to FSIS, "it should benefit consumers, the industry and the agency by focusing inspection activities on critical areas of product safety, wholesomeness, and preventing adulteration; focusing industry responsibilities and actions to produce safe and wholesome food; and increasing the scientific basis for inspection operations" (FSIS 1989a).

CONTEMPORARY PUBLIC CONCERNS ABOUT MEAT INSPECTION

The safety of foods of animal origin, particularly meat, is a contemporary public concern involving science, politics, regulatory programs, and the economics of meat production and processing. It has worldwide implications as the United States struggles to remain competitive in a dynamic global economy.

In the United States, foodborne diseases appear to be steadily increasing: an estimated 5 million cases of foodborne disease and approximately 5,000 related deaths occur annually. This apparent increase is variously attributed to automated food processing, increased reliance on fast foods, greater use of prepackaged foods and microwave ovens, urbanization, public naivete about food production and slaughter methods, and lack of knowledge about the hygienic precautions required at all stages of food handling, including preparation and serving. Other contributing factors may include better surveillance, improved reporting, more sensitive diagnostic tests, and improved methods of detecting contaminating microorganisms and chemical residues.

The current revival of interest in food safety has been fueled by reports of massive foodborne disease outbreaks. The hype of the biotechnologic revolution has convinced the public that government can assure them of zero risk of foodborne diseases. Unwillingness to accept any level of any unwanted materials (no matter how trivial) in meat has given rise to the concept of zero tolerance. However, both zero risk and zero tolerance are unachievable. Nevertheless, they are worthy targets.

It is not economically and logistically feasible to achieve total freedom from all microbial and chemical contamination in meat through slaughter inspection. However, the public deserves effective national policies that provide:

- a degree of assurance of minimal food-related exposure to microbial pathogens that cause illness in humans;

- a degree of assurance that production, slaughter, processing, packaging, distribution, preparation, and serving of meat will be conducted so as to limit contamination and growth of pathogenic microorganisms;
- a degree of assurance of minimal exposure to levels of chemicals, antibiotics, or other residues that may be allogenic, acutely toxic, cumulatively toxic, or carcinogenic;
- recognition that varying susceptibilities exist and that different populations have unique food safety needs; and
- believable scientific information to underpin regulatory guidelines for production and processing of meat products.

Mounting pressures for these assurances are coming from the scientific community, consumer groups, public interest groups, and public officials. Previous Food and Nutrition Board reports (NRC, 1985a, 1985b) have outlined legitimate reasons for public concern about foodborne diseases transmitted by beef or beef products.

CONCLUSIONS

The USDA has made many changes as it has strived to fulfill its mandate during 84 years of meat inspection. However, advancing technology, new methods of food processing and serving, and increasing public expectations dictate frequent reassessment of meat inspection programs and new approaches. The future will require new ways of preventing public exposure to contaminants, scientifically valid and believable methods of evaluating inspection technology, and implementation of appropriate portions of HACCP programs.

3

THE PROPOSED SIS RULE

ABSTRACT

The proposed SIS-C rule applies to plants in which only heifers and steers are slaughtered. Thus, it is applicable to approximately 80 of about 1,300 cattle slaughtering plants inspected by USDA. SIS-C involves an important change in philosophy whereby industry assumes full responsibility for meat quality, permitting FSIS to concentrate on safety. By assuming the full costs and responsibility for quality, industry will have an economic incentive to enforce quality controls and correct manufacturing processes causing defects.

The proposed rule describes new and streamlined postmortem procedures; uniform presentation standards for viscera and body parts; specific equipment, facilities, and inspection space requirements; and carcass and edible by-product finished product standards.

To verify that product standards are being met by plant processing personnel, SIS-C plants with chain speeds exceeding 275 head per hour must employ quality control personnel to implement an ISIS-approved and monitored partial quality control (PQC) program (SIS-C/PQC) in which a statistical procedure known as cumulative sum (CUSUM) is used to evaluate wholesomeness and acceptability of products throughout a work shift and over longer periods.

The committee examined various FSIS documents ([Appendix B](#)) supporting the proposed rule ([Appendix A](#)) and assessed the impact of SIS-C on consumers, inspectors, and packers.

The committee recommends that desired final product characteristics, not meat inspection as traditionally being done, should be the standard against which inspection systems or new technologies are judged. The scientific basis for traditional, SIS-C, and SIS-C/PQC meat inspection was found to be inadequate. The committee concluded that when quality control programs are effectively implemented, SIS-C/PQC is acceptable as an alternative to traditional inspection. The committee recommends that SIS-C without a PQC program should be an interim process lasting no more than 1 year. Strong concerns about SIS-C held by a number of FSIS inspectors led the committee to recommend that FSIS pay more attention to employee communication and education.

RATIONALE AND ASSUMPTIONS OF THE RULING

The proposed rule defining the Streamlined Inspection System-Cattle and Staffing Standards (Fed. Regist., 1988; [Appendix A](#)) details procedures, definitions, and numerical standards that could bewilder those not experienced with the meat packing industry. They include topics such as the candlepower of lighting, the size of mirrors, the diameter of stains, and whether organs should be observed and palpated, or merely observed. These details obscure the most important issue—the shift of responsibility for quality from FSIS to industry. *For SIS-C to work in practice, both FSIS and industry must fully subscribe to this new philosophy, which is the most important change in bovine*

meat inspection since 1906.

Traditional meat inspection has placed FSIS and industry in an unsatisfactory relationship in which packers without total commitment to quality control throughout the slaughter and dressing processes expect FSIS inspectors to detect and deal with quality problems before the carcass leaves the slaughter floor. Traditionally, FSIS inspectors, who must ensure that only wholesome products enter commerce, spend 70 to 90% of their time identifying and dealing with dressing nonconformances¹ and designated trimmable conditions² that are obvious and easily identified. Some have little or no implication for public health. These defects can be corrected by packing plant employees. If industry had to assume the full costs and responsibility for dressing operations, it would have economic incentive to adopt effective quality controls and to correct manufacturing procedures that permit defects.

SIS-C creates a new relationship between FSIS and industry. This partnership, with shared responsibility, permits FSIS inspectors to concentrate on Pathologic lesions. It makes industry take active steps to prevent problems by identifying and resolving those points in the slaughter and dressing processes at which carcass contamination or dressing defects occur.

Slaughter and dressing must be performed in a sanitary manner but can never be sterile operations. The procedures, machinery, and technology involved are intricate and must be seen to be understood. The carcass can be contaminated by contact with ingesta, feces, mud balls, equipment, and people. *It would be safer for public health if contamination could be prevented rather than detected and trimmed away afterward.* Carcasses that are cleaner during and after dressing are less likely to have extensive (and invisible) surface bacterial contamination that can worsen during processing before the product reaches the consumer. SIS-C seeks to involve every plant worker, not just the federal inspectors, in prevention programs.

AN OVERVIEW AND COMMENTARY ON SIS-C AND THE SLAUGHTER PQC PROGRAM

Antemortem inspection and slaughter are identical in SIS-C and traditional systems. Postmortem inspection under SIS-C has three elements that differ from traditional systems: diminished postmortem inspection, uniform presentation of carcass and parts, and additional specific equipment and facility requirements (Table 3-1). After postmortem inspection by FSIS inspectors, the carcass and edible by-products are

¹ *Dressing nonconformances* are defects on the carcass that result from errors in the handling, slaughtering, or dressing operations performed by establishment employees. These include bruises, hair, dirt, ingesta, feces, organ remnants, and machine grease.

² *Designated trimmable conditions* are abnormal conditions that are not caused by improper procedures, that are readily identifiable, and that do not affect the disposition of the carcass. These include fractures, arthritis, localized abscesses, and pigmentation.

Table 3-1 An Overview of the SIS-C/PQC Program Plant Quality Control Staff

Plant Quality Control Staff	Plant Production Staff and FSIS Inspectorate		
PQC Program Requirements:	Fed steers and heifers only (healthiest segment of population) ↓ Antemortem inspection (FSIS) ↓ Slaughter ↓ SIS-C Postmortem Inspection (FSIS)—(Every carcass, every head, and every set of viscera).		
<ul style="list-style-type: none">• Approved by FSIS• Compulsory if slaughtering > 275 head/hr• Voluntary if ≤ 275 head/hr			
Principal Components of PQC Program:	Streamlined postmortem procedures:	Uniform presentation standards: head, tongue, viscera, carcass (scored under PQC in SIS-C/PQC plants)	Specific equipment, facilities, and inspection space
<ul style="list-style-type: none">• Identification of critical control points (CCPs) in slaughter and dressing• Development of standards at each CCP• Specification of actions to be taken if CCP standards are not met	<ul style="list-style-type: none">• head• viscera• carcass		
	↓ Dressing nonconformances and designated trimmable conditions removed by establishment employees		
Responsibilities of Plant Employees in PQC Program:	Carcass produced to specific 'finished product standards'	Edible by-products produced to specific 'edible by-product standards'	
<ul style="list-style-type: none">• Randomly sample head, tongue, carcass, and edible by-products; measure compliance with product standards			
	↓ Reinspection of carcasses at random by FSIS inspector, who also monitors establishment QC tests of compliance with product standards		
<ul style="list-style-type: none">• Inform production supervisor of any process trends	Process in control: Plant producing product that meets standards over time	Process out of control: plant producing product that does not meet standards. Establishment takes corrective action under inspector	

examined by plant employees and all dressing nonconformances and designated trimmable conditions are removed. The goal of these procedures is to produce wholesome carcasses and edible by-products, according to specific product standards.

To verify that product standards are being met, some SIS-C plants employ quality control personnel to implement a PQC program. These people randomly sample heads, tongues, carcasses, and edible by-products from the slaughter line and measure compliance with product standards by a statistical procedure known as CUSUM (see [Chapter 4](#)), which is monitored by the inspector. The goal is to evaluate the wholesomeness and acceptability of the products using these standards.

Final oversight of product standards is provided by FSIS inspectors, who independently sample heads, tongues, and carcasses; measure their compliance with product standards; and compare their results with the plant's records. The frequency and nature of sampling, tests performed, standards, means of comparison, and definitions of terms are described in detail in the proposed rule (Fed. Regist., 1988). The FSIS inspector must determine if slaughter and packing processes are "in control" (i.e., that the products meet or exceed standards). If it is "out of control," the establishment must take immediate corrective action under supervision of the inspector.

Under SIS-C, packing plants slaughtering more than 275 cattle per hour must have an approved PQC program. For those with slower line speeds, the PQC program is optional. In plants without PQC, the FSIS inspector oversees product standard compliance by using the same procedures included in operations with a quality control program ([Figure 3-1](#)).

SIS-C POSTMORTEM INSPECTION

Under SIS-C, as in traditional inspection, FSIS inspectors inspect every carcass, every head, and every set of viscera. FSIS insists that this will not change, since the law mandates 100% inspection.

Streamlined Inspection Procedures

SIS-C differs from traditional inspection in the following details (see also [Table 3-2](#)).

Cervical/Head Inspection

Under SIS-C, the lateral retropharyngeal lymph nodes are not incised; the inspector observes but does not cut the masticatory muscles, which have been incised by a plant employee; and a plant employee, not the inspector, palpates the tongue. The inspector takes action when a palpable tongue abnormality is identified by the plant employee. Heads must be presented by the plant employees in a specified uniform manner to ensure timely and consistent inspection.

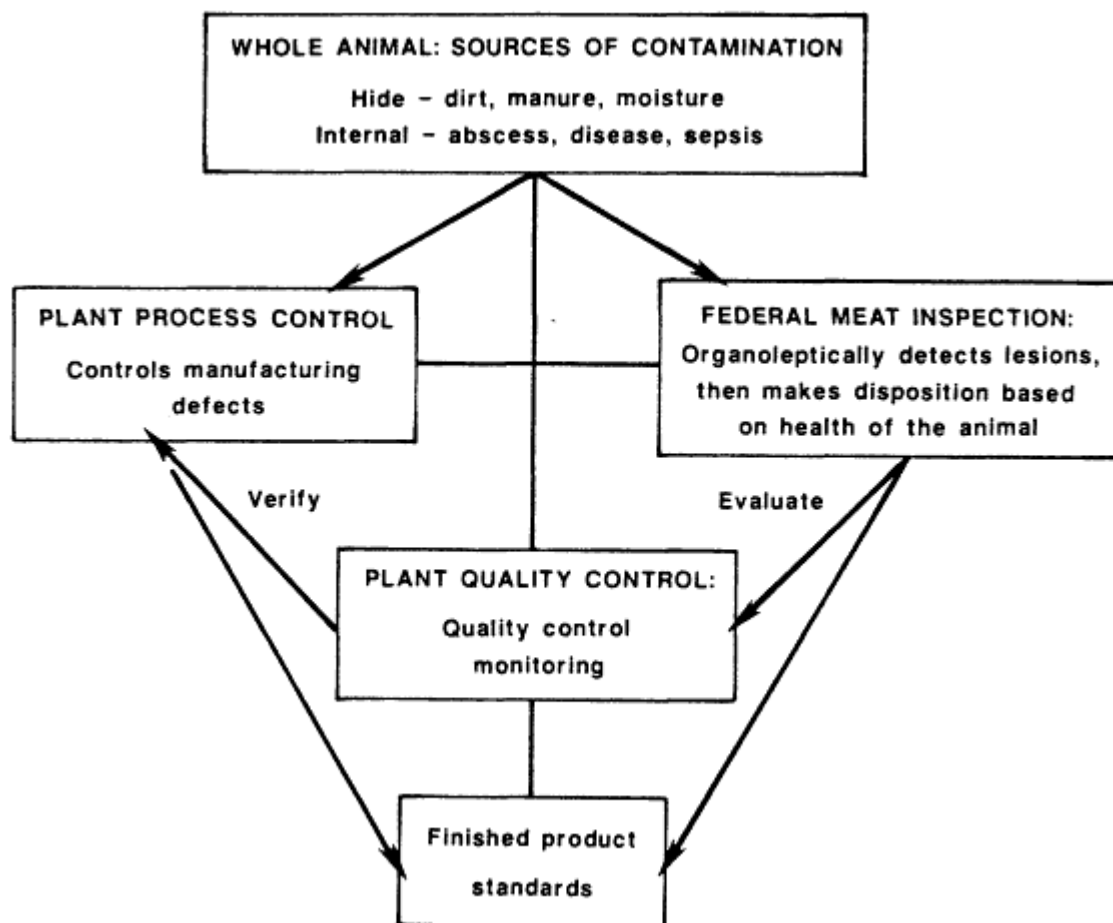


Figure 3-1

Interactions Between Plant Process Control Operations and Plant Quality Control and Federal Meat Inspection Staff

FSIS presented data to the committee to support its view that these changes in cervical/head inspection do not permit lesions of diseases to pass undetected or alter carcass disposition (Wesson, 1983). Some inspectors who spoke to members of the committee on site visits disagreed (see [Appendix E](#)).

Table 3-2 SIS-C and Traditional Postmortem Inspection Procedures^a

SIS-C	Traditional
<u>Head Inspection</u>	<u>Head Inspection</u>
Observe leading side and surfaces of head, eye, and incised leading lateral and medial muscles of mastication.	Incise lymph nodes attached to the tongue—medial retropharyngeal (suprapharyngeal), lateral retropharyngeal (atlantal), and mandibular.
Incise and observe leading parotid lymph node.	Observe and palpate tongue.
Observe trailing incised medial and lateral muscles of mastication.	Observe surfaces of head and the eyes.
Incise and observe trailing parotid lymph node.	Incise and observe parotid lymph nodes and lateral and medial muscles of mastication.
Incise and observe lymph nodes attached to the tongue—medial retropharyngeal (suprapharyngeal) and mandibular.	<u>Viscera Inspection</u>
Observe tongue and lateral retropharyngeal (atlantal) lymph nodes.	Observe eviscerated carcass.
<u>Viscera/Carcass Inspection</u>	Observe mesenteric lymph nodes and abdominal viscera.
Observe outer surfaces of eviscerated carcass (including dorsal surface) with the use of the mirror and observe the superficial inguinal (supramammary) and internal iliac lymph nodes.	Observe and palpate ruminoreticular junction.
Observe pelvic and peritoneal cavities, kidneys, and the diaphragm.	Observe esophagus and surface of spleen.
Observe pleural cavity and cut surfaces of muscles and bone.	Incise and observe lymph nodes of the lungs—mediastinal (posterior, middle, anterior) and bronchial (right and left).
Observe mesenteric lymph nodes and abdominal viscera.	Observe and palpate costal (curved) surfaces of lungs.
Observe ruminoreticular junction.	Incise heart, from base to apex or vice versa, through interventricular septum, and observe cut and inner surfaces.
Observe esophagus and spleen.	Turn lung over; observe ventral (flat) surfaces and outer surface of heart.
Incise and observe lung's lymph nodes— mediastinal (posterior, middle, anterior) and left tracheobronchial.	Incise and observe hepatic (portal) lymph nodes.
Observe and palpate costal surfaces of lungs.	Open bile duct (both directions) and observe its contents.
Observe inner, cut, and outer surfaces of heart.	Observe and palpate ventral surface of liver.
Observe hepatic (portal) lymph nodes.	Turn liver over, palpate renal impression, and observe and palpate parietal (dorsal) surface.
Open bile duct (both directions), and observe its contents.	<u>Carcass Inspection</u>
Observe and palpate ventral surface of liver.	Palpate and observe superficial inguinal (supramammary) and internal iliac lymph nodes.
Turn liver over, palpate renal impression; observe and palpate parietal (dorsal) surface.	Observe lumbar region.
	Observe and palpate kidneys.
	Observe pillars of diaphragm and peritoneum.
	Observe pleura, cut surfaces of muscles, and bones, neck, and carcass exterior.

^a Source: FSIS, 1989b

Viscera and Carcass Inspection

Under SIS-C, unlike traditional inspection, inspection of viscera and carcasses takes place simultaneously, facilitating identification of corresponding parts and organs. Because of time constraints, it is important that plant personnel present the viscera in a specified manner (see section on [Uniform Presentation Standards](#), below).

As shown in [Table 3-2](#), SIS-C differs from traditional inspection of viscera and carcasses in several ways. In SIS-C, the ruminoreticular junction (common site for abscesses) is not palpated; plant employees cut the heart muscle (inspector observes); various organs/lymph nodes are no longer palpated or incised; and the inspectors do not observe the split vertebral column and surrounding tissues, since the carcass is split further along the rail (beyond the viscera-carcass inspection station). These differences are a major source of discontent among inspectors. Under traditional inspection, FSIS inspectors viewed the interior and exterior of both sides of the eviscerated and split carcass and had an unobstructed view of the kidneys and diaphragm. Under SIS-C, the last FSIS inspectors in the line are posted at the carcass-viscera station, where they examine viscera presented on a moving belt on one side, observe the inside of the corresponding whole (i.e., unsplit) eviscerated carcass as it passes by on a chain on the other side, and examine the back of the carcass for dirt or blemishes through a mirror. Except for randomly sampled split carcasses, this is the last time the inspectors view the carcass before it is washed and sent into the cooler. Under SIS-C, in plants slaughtering fewer than 234 head per hour, a plant employee removes the kidneys for presentation with the viscera at the viscera/carcass station. At higher slaughter rates, kidneys are examined in the unsplit carcass.

After carcasses pass the viscera-carcass station, plant employees trim dirt, stains, hair, and other blemishes from them. Under SIS-C, there are no inspectors to ensure that trimming has been done correctly before the carcass is split and washed. This is the responsibility of the plant's certified trimmers. Their work is checked by plant quality control staff. Federal inspectors monitor the final products according to finished product standards and check that quality control is being performed as specified in [Figure 3-1](#).

Critics of SIS-C contend that inspectors should view the split vertebral column to detect discolorations, spinal abscesses, and other blemishes: this would require an additional inspector to be situated on the line after the carcass is split. FSIS management disagrees with the need for an inspector and believes that company trimmers can recognize and deal with any dressing nonconformances and designated trimmable conditions discovered on splitting.

FSIS presented data to support its view that these procedural changes in viscera/carcass inspection do not permit lesions of diseases to pass undetected or alter carcass disposition (Wesson, 1983). However, most inspectors interviewed by the committee and those who testified at the public hearing disagreed with the FSIS

position.

Uniform Presentation Standards

Work-measurement studies were conducted by FSIS to determine the times needed for organoleptic SIS-C procedures. More inspectors are added when chain speeds are increased. Careful, consistent, and uniform presentation of heads, tongues, and viscera is important so that inspectors can spend their time examining for disease rather than sorting through haphazardly distributed organs on a moving belt. The consistency with which organs are presented for inspection is monitored under the SIS-C program.

Certain procedures previously performed by FSIS inspectors are the responsibility of establishment personnel under SIS-C, and the time formerly spent in performing these steps is used to inspect for lesions. The important aspects of presentation standards are:

- palpating the tongue
- incising masticatory muscles
- opening heart chambers and incising the interventricular septum
- positioning organs for ease and consistency of inspection

Some inspectors claim their ability to detect eosinophilic myositis and cysts (the larval stage of the beef tapeworm) is compromised when cutting of heart and cheek muscles is delegated to plant employees. This opinion is based on the premise that the feel of the inspector's knife passing through these lesions helps them recognize their presence and provides an opportunity to view the cut surfaces immediately before they are covered by seeping blood.

Specific Equipments and Facilities

FSIS specifies facility and equipment requirements for SIS-C. These include a special mirror positioned so that inspectors can view the back of the carcass as it passes while looking into the opened front of the carcass at kidneys and serosal surfaces. Lighting standards for each inspection station are also specified.

The committee heard testimony that mirrors become covered with condensed moisture and do not always present an unobstructed view of disease conditions or dirt on the back of the carcass. Other testimony refuted this contention. The committee found the mirrors to be satisfactory for observing the backs of the carcasses in the SIS-C plants it visited; however, one inspector observed did not appear to be watching the mirror consistently.

CARCASS DRESSING REQUIREMENTS

Plant production employees (as distinct from quality control employees) are

responsible for removing dressing nonconformances and other designated trimmable conditions. They must adhere to finished product standards for carcasses and edible by-product standards. In SIS-C plants, FSIS inspectors monitor compliance with the standards and take corrective action if the establishment has failed to apply the standards. There is, therefore, a two-tier system for quality control—production staff and FSIS inspectors. This approach was suggested in a previous Food and Nutrition Board report (NRC, 1985a).

In SIS-C/PQC plants, there is a third tier—a plant quality control (QC) group—that reports through a supervisor to the plant manager in a chain of command independent from that of the production staff. The actual independence of PQC staff has been questioned by critics of SIS-C/PQC, especially FSIS inspectors who allege that some plant QC employees are urged by management to neglect details that may slow the process. This QC group monitors the production process continually, performs random sampling to at least the minimal frequency stipulated in the proposed rule published in the *Federal Register* ([Appendix A](#)), and uses the finished product standards and CUSUM to measure process control. FSIS inspectors evaluate the ability of the company's production personnel to control the process by:

- checking timeliness and accuracy of records
- performing sample tests to correlate with plant QC's findings
- checking presentation standards
- applying product standards to the carcass, head, and edible by-products
- performing CUSUM calculations

Under both SIS-C and SIS-C/PQC, FSIS veterinarians and inspectors are responsible for determining if the carcass and parts are wholesome before entering commerce. However, concern was expressed that FSIS can lose control of the final product once it has passed the final inspection (carcass-viscera) station.

ASSESSING THE WHOLESOMENESS OF THE CARCASS AND PRODUCT

A beef carcass reinspection program known as Acceptable Quality Level (AQL) has been used in traditionally inspected plants for many years. In this program, carcasses are examined for wholesomeness, cleanliness, and acceptability, but the level of process control is not evaluated (see [Chapter 4](#)).

FSIS has developed a system in which CUSUM is used to continually monitor the entire slaughter and dressing process. Through it, FSIS and plant employees can learn whether the process is in control, out of control, improving, or deteriorating. The method for calculation of CUSUM, the definitions of all terms, and the details of all standards are set out in the *Federal Register* ([Appendix A](#)) and are discussed in [Chapter 4](#).

Sample size and sampling frequency as given in the *Federal Register* are shown in

Table 3-3.

Table 3-3 Size and Frequency of Sampling by Plant QC Personnel and FSIS Inspectors^a

Size of Sample	Sampling Frequency	
	By Plant QC Personnel	By FSIS Inspectors
Three half carcasses	Once an hour	Twice every 8 hours
Five tongues	Once an hour	Twice every 8 hours
Five heads	Once an hour	Twice every 8 hours
Ten units of each edible by-product	Once every 2 hours ^a	At least once every 8 hours

^a Variable by inspector.

FSIS developed finished product standards to measure wholesomeness and acceptability, e.g., cleanliness. These standards define limits of conformance that products must meet to avoid the risk of having to rework³ the product. They are applied after the carcass has been inspected for disease. They are not aimed at detecting public health problems or diseases missed during inspection. The limits represent the national average of products qualifying for designation as "U.S. Inspected and Passed" in all plants slaughtering all classes of cattle.

Plant QC personnel and FSIS inspectors independently determine the total number of nonconformances for each subgroup, reduce this number to a CUSUM value, and measure this against predetermined standards (see [Appendix A](#)).

When plants maintain process control at or below tolerance⁴, final products should be within the limits of acceptability. Products that do not meet the acceptable standard indicate that there is a deficiency somewhere in the slaughter or dressing process. CUSUM calculations and finished product standards should alert the plant

³ *Rework* is reprocessing the product to correct the condition or conditions causing the nonconformances. For carcasses, this usually means trimming to remove dressing nonconformances and designated trimmable conditions.

⁴ *Tolerance* identifies a limit above which the product is deemed to be unacceptable.

and FSIS inspectors to problem areas in the system. Because finished product standards are used to monitor the process, potential or emerging problems can be identified promptly provided the standards are appropriate. Test results over time can be used to define trends.

If the production is not in control, certain specific actions are required. For example:

- The line must slow by 10% to correct presentation problems (plant takes action).
- Product/carcasses and by-products are held for rework if finished product standards are not met. The plant takes action.
- FSIS inspectors have authority to increase sampling rates in trouble areas and to require that the operation temporarily slow or stop until problems are corrected.

FSIS data comparing AQL scores under traditional inspection with SIS-C CUSUM scores in the same plant over time show that improvement in product cleanliness correlated with introduction of SIS-C (FSIS, 1989b; see also [Appendix B](#)). However, correlation does not prove that SIS-C caused the improvement (see [Chapter 4](#)).

FSIS DATA IN SUPPORT OF THE PROPOSED RULING

FSIS presented the following documents to the committee in support of the proposed rule:

- "A Study on the New Cattle Post-Mortem Inspection Procedure for Steers and Heifers" (Wesson, 1983). In this study it was concluded that the new cattle postmortem inspection procedure was as effective as the traditional procedure in all areas except liver inspection. The new procedure proved more effective in identifying visible liver defects under the conditions of the test. Work-measurement studies showed that the new procedure will result in increased inspection productivity.

The Wesson study involved a comparison of traditional and new inspection procedures at four steer/heifer slaughter plants with line speeds of 320, 225, 185, and 95 cattle per hour. Data from two other plants, in which cows and bulls were slaughtered, were omitted from the report. This omission was criticized by a witness at the public hearing. FSIS justified this omission because SIS-C is intended only for plants that slaughter steers and heifers.

- "Development of Finished Product Standards for the SIS-C Inspection Procedure" (FSIS, 1989).

This manuscript described how FSIS develops finished product standards.

- "Results of Finished Product Standards Test for SIS-C Pilot Plants" (see [Appendix B](#)). This report charted the results of finished product standards test results for the SIS-C pilot plants. Data for the earliest month were compared with the corresponding month 1 year later and were graphed in comparison to the national average of carcass acceptability (tolerance). Four plants produced products well below tolerance. In one plant, the process was not controlled and corrective action was required.

- "Comparison of Carcass Cleanliness Using Traditional and Streamlined Inspection Procedures" (see [Appendix B](#)). Carcass cleanliness was compared in a plant that switched from traditional inspection with AQL to SIS-Cattle with finished product standards. Carcasses were scored with AQL under both systems of inspection. Product cleanliness improved after SIS-C was introduced (see [Chapter 4](#)).

- "Slaughter and Condemnation Data for Steers and Heifers" (see [Appendix B](#)). Analysis of 1985-1989 data from the FSIS Animal Disease Reporting System (ADRS) indicated no discernible difference in condemnation rates or causes of condemnation between SIS-C procedures and traditional inspection, nor were there differences in the rates of carcasses passed with restrictions. However, the rate of condemnation in the five pilot plants increased after conversion to SIS-C.

The primary goal of inspection is to make decisions on the disposition of carcasses—not specific etiologic or morphologic diagnoses. Thus, condemnation data provided by FSIS reveal little about the public health merits of inspection. Diseases of public health importance that can be detected organoleptically at slaughter, such as cysticercosis and tuberculosis, are very rare (e.g., approximately three diagnosed cases of tuberculosis on average are found within each million animals slaughtered) and are detected with equal frequency under SIS-C and traditional systems (data provided by FSIS, see [Appendix B](#)).

IMPACT OF SIS-C ON CONSUMERS, INSPECTORS, AND PLANTS

Consumers

Although SIS-C is not directed primarily toward human health risks, it should have no adverse effect on the health of consumers of meat and edible by-products. Conditions of public health importance that are missed under SIS-C inspection are likely to be missed under traditional inspection as well.

A consumer dissatisfied with a purchased product can seek redress from the supplier or not buy the product again. It is impossible, however, given the structure of the meat industry, for a customer unhappy about cleanliness of meat purchased from a supermarket to influence the practices of the packing plant from which that product came. The only purchasers potentially able to influence plants are the large fast-food and supermarket chains. Many of these have their own quality control procedures to assess the cleanliness and microbial burden of products. The committee asked FSIS if it had any evidence that the major chains used their own quality control data to choose suppliers; however, FSIS did not have this information.

Inspectors

FSIS inspectors and veterinarians have the frontline positions in safeguarding the acceptability of the nation's meat supply. If unwholesome or contaminated meat passes by them, the bacterial load could increase and contaminate other products as it passes into the chain of transport, storage, handling, and preparation to the ultimate consumer. FSIS staff in the field take their responsibilities very seriously; the committee was impressed by their sincerity and conscientiousness.

The introduction and evaluation of SIS-C were complicated by unrelated and controversial issues, such as increased chain speeds, union-employer relations in the packing industry, working conditions, occupational safety (especially repetitive motion injuries), job security, and job stature. These issues obscured the essence of SIS-C— that advancing technology and increasing public expectation necessitate a major overhaul of the philosophy, concepts, and details of the meat inspection system. This change (SIS-C) has caused conflict within FSIS that could have been avoided by better communication, training, and appreciation of the concerns of field inspectors about basic concepts of SIS-C.

For 80 years, FSIS has done an excellent job of training inspectors and developing a culture of responsibility for decisions on carcass disposition and standards of dressing and fabricating final product. Suddenly, with the introduction of SIS-C, inspectors were told that decisions they once controlled had been assigned to plant employees who are not trained in meat inspection. Under SIS, inspectors lost the opportunity to check the work of plant employees in the reinspection process. Whatever the statistical merits may be, FSIS inspectors do not accept the agency position that reinspecting only 6 of between 4,000 and 6,000 sides of beef from an 8-hour shift is adequate. Moreover, inspectors do not support the agency view that most microbial and chemical residue samples are generally taken to provide data for proactive intervention to prevent disease rather than for retrospective analysis.

There are no substitutes for good data and solid scientific facts in developing and testing new rules and regulations. FSIS has compiled some data to persuade its own management of the merits of SIS-C and has presented arguments to convince them that change is appropriate. However, enthusiasm for SIS-C was not successfully

communicated to many long-term field employees of the agency. It is clear that fewer FSIS inspectors are being used to staff plants under SIS-C and SIS-C/PQC. FSIS could have used surplus inspectors to validate finished product standards, to study the frequency and numbers of reinspections needed, and to improve surveillance for microbial and chemical contaminants in SIS-C plants. These steps might have alleviated anxieties among rank-and-file meat inspectors worried about product quality. More inspectors could have been trained in SIS-C. Instead of aiming for a new inspection procedure on a par with the traditional, FSIS could have implemented an SIS-C program that incorporated the underlying philosophy of the earlier Food and Nutrition Board studies (NRC 1985a, 1987a) and made clear technological advances. The committee believes the planning of such a program should begin with the decision that traditional inspection should no longer be the standard by which other systems are judged and that it is more rational to evaluate systems based on the desired characteristics of the final product.

Plant Managers and Employees

Managers and workers in SIS-C plants have an important new role to play in ensuring product quality. This must be understood by all workers and inspectors—not just managers, quality control personnel, and certified trimmers. SIS-C plants are food processing plants—not meat packers or slaughterhouses.

The committee heard much testimony about the characteristics of jobs in packing plants. These jobs are not viewed as being very attractive, and turnover is high. Many workers are recent immigrants with poor English language skills and come from countries with low standards of hygiene and food handling. Thus, FSIS and industry must establish training standards and a certification program for all plant employees involved in the slaughter, dressing, and handling of meat products.

FSIS must also establish better employee training and retraining programs in SIS-C/PQC concepts and other planned innovations so that all workers and managers are committed to the goals, concepts, and standards of new inspection programs.

CONCLUSIONS AND RECOMMENDATIONS

- Traditional meat inspection, relying on organoleptic detection methods, can ensure satisfactory meat product quality but is not fully effective in protecting the public against contemporary foodborne health hazards, such as microorganisms, hormones, and residues of toxic chemicals and heavy metals. Therefore, traditional meat inspection should not be used as the gold standard against which inspection systems or new technologies are judged.

- The desired characteristics of the final product should be the starting point for design and evaluation of inspection systems. For meat, desirable final product characteristics include, but are not limited to, the following:

Aesthetically pleasing⁵ (free from dirt, hair, bruises, grease, mud, ingesta, feces).

Free from visible lesions⁵ (tumors, cysts, hemorrhages, inflammation, or other evidence of disease or injury).

Have good keeping quality⁵ (low population of spoilage microorganisms).

Low levels of bacterial pathogens and other infectious agents that can cause disease in humans.

Hormones, antibiotics, toxins, pesticides, heavy metals, and other toxic substances, at or below established safe levels for humans.

These desired characteristics of meat products relate to both safety and quality, which are not mutually exclusive because quality procedures can affect microbial burdens and thus indirectly influence safety. However, total emphasis on quality only obliquely addresses the crucial safety issues of preventing microbial and chemical contamination. The distinction between quality and safety is as follows: *safety* relates to the presence of pathogenic microorganisms or levels of chemical residues; *quality* concerns aesthetically pleasing appearance, absence of visible lesions, and good keeping characteristics through low levels of spoilage-causing microorganisms.

- All possible efforts should be made to minimize contamination of meats and to remove contaminated products from the food chain. Now, and for the foreseeable future, it is not possible to ensure that all raw meat products are totally free of microbial pathogens that can cause disease in humans. Inevitably, some portion of the meat supply will be contaminated with some detectable level of one or more pathogens. Ideally, it is hoped that contamination can be kept below established safe thresholds. However, as outlined in previous Food and Nutrition Board reports (NRC, 1985a, 1987a), such thresholds are difficult to estimate because microbial populations can multiply rapidly and because human susceptibility to different diseases is highly variable. The best that can be done is to assess how closely inspection systems approach the ideal, if unattainable, goal of total freedom from microbial pathogens.

Both traditional meat inspection and SIS-C focus largely on visible lesions. Both systems partly address the microbial loads that determine keeping characteristics and

⁵ These characteristics constitute quality. They are desirable but have no primary effect on human health. Meat quality also includes color, texture, tenderness, juiciness, marbling, and other desirable characteristics not considered in the report (see [Appendix G](#)).

levels of pathogenic microorganisms by monitoring plant hygiene and refrigeration and by trimming carcasses visibly contaminated with feces, dirt, or hair. Except for occasional sampling, sporadic tracebacks, and voluntary residue avoidance programs, neither system addresses chemical residues. The major difference between the systems is that FSIS inspectors enforce efforts to control visible contamination under traditional systems, whereas in SIS-C, much of this responsibility is delegated to plant employees.

In SIS-C/PQC, both aesthetic appearance and freedom from visible lesions are addressed. Through increased hygiene and emphasis on an effective PQC program, SIS-C/PQC may reduce contamination with spoilage or pathogenic microorganisms. Thus, SIS-C/PQC is potentially superior to SIS-C and traditional inspection. In the absence of total quality commitment from industry, SIS-C alone (i.e., without PQC) is probably no better than traditional inspection and in some situations, can be less effective than traditional inspection because the reduced oversight by government inspectors is not compensated by a total commitment to product quality on the part of industry.

- The beef packing industry should aggressively adopt improved quality control measures. In SIS-C, FSIS expects industry quality control personnel to prevent problems by identifying and correcting slaughter and dressing procedures during which carcass contamination or dressing defects occur. The committee found that some members of the meat packing industry had indeed taken such steps, for example, by improving employee hygiene (through training and increased use of rubber gloves, hair nets, aprons, and washing stations) and by wrapping hindquarters to prevent fecal smearing of carcasses during hide removal. These procedures, and others identified by frequent product and process evaluation during slaughter and dressing, help reduce microbial contamination. The committee found that some plants have exceeded FSIS expectations for SIS-C/PQC by implementing a comprehensive HACCP system (see [Chapter 2](#)) covering the desirable characteristics of meat products, including chemical residue analyses of feedstuffs and water, controls on the use of microbials and pharmaceuticals in feedlots, and rapid microbiological testing of a representative number of carcasses every day. Unfortunately, industry quality and safety data are not in the public record, nor has FSIS conducted independent studies to verify and quantify reported reductions in chemical and microbial contamination.

- Inspection programs have the following limitations: By definition, traditional meat inspection can only ensure aesthetically pleasing appearance and freedom from visible lesions.

SIS-C also includes only aesthetically pleasing appearance and freedom from visible lesions. The difference between traditional meat inspection and SIS-C lies only in the persons responsible for the quality of the product.

SIS-C/PQC is targeted to aesthetically pleasing appearance and freedom from visible lesions and, by enhanced attention to basic principles of hygiene, also can improve keeping quality and minimize contamination by microbial pathogens. Although not ideal, SIS-C/PQC appears better able than SIS-C or traditional inspection to meet the characteristics of an effective inspection program. Moreover, it is the only system of the three that can be readily extended (and has been extended by industry) to detect and reduce contamination or to become part of a full-fledged HACCP program that addresses all the desirable characteristics of products in a comprehensive prevention program rather than as a result of after-the-fact detection efforts. Although in plant HACCP programs cannot decrease intestinal colonization of live cattle by microorganisms, such as *Salmonella*, which are pathogenic in humans, they can minimize public risk by decreasing the degree to which carcasses are contaminated with intestinal contents and exogenous fecal debris.

- SIS-C alone, i.e., without PQC, should be used only as a temporary transition phase no longer than 1 year as the plants move from traditional inspection to SIS-C/PQC, because there is no logical basis for making PQC optional for plants operating at slow speeds, as suggested by FSIS. In this 1-year SIS-C transition period, the following must be achieved:

Management and employees of both FSIS and the plant must learn to understand and share the goals of the plant PQC program.

Plant personnel must be monitored closely by FSIS to ensure that the PQC program is strictly implemented as designed.

Objective, easily understandable, and statistically analyzable data on finished product standards in the plant must be presented to inspectors to assure them that the system works and that plant employees are capable of implementing it.

- SIS-C alone, i.e., without PQC, should not be used beyond the transition period because it includes less government oversight.
- The scientific bases of traditional meat inspection, SIS-C, and SIS-C/PQC are inadequate or nonexistent. However, FSIS now has access to data from its own studies and the experiences of the five pilot SIS-C plants, including chemical and heavy metal analysis, to design an improved system of inspection based on the proposed rule.

- FSIS should regularly publish data in the scientific literature so that its work and conclusions can be scrutinized by peers and other experts outside the agency. The Wesson Study, for example, could have been submitted for publication in

peer-reviewed scientific literature instead of being published as an agency monograph without extramural review.

- SIS-C and SIS-C/PQC are restricted to fed steers and heifers—the healthiest portion of the cattle population. Traditional inspection will continue to be used for cull dairy cows and veal calves, which present the greatest risks from microbial and chemical contamination, even though this system is not able to protect consumers from these factors. FSIS should enhance its inspection procedures and microbial/chemical analyses in the traditional system and establish compulsory finished product standards to ensure that animals other than steers and heifers will yield products with characteristics as close as possible to those described above.

- FSIS should tailor its inspection and analysis in a multitiered system based on the degree of risk to the public's health presented by any one plant. For example: Plants with traditional inspection would be given increased FSIS monitoring of contamination by spoilage and pathogenic microorganisms and chemicals.

Plants with a HACCP system covering all desirable product attributes would be given minimal inspection.

Plants with SIS-C/PQC would have greater FSIS monitoring of contamination by spoilage and pathogenic microorganisms and chemicals, but decreased monitoring for visual defects.

Plants with SIS-C (in a 1-year transition period) would receive increased FSIS monitoring of all desirable product attributes.

In the 1-year period of transition from SIS-C to SIS-C/PQC, the purpose of increased monitoring of ideal product attributes would be twofold:

- to increase the level of confidence of inspectors in the competence of plant employees by providing objective, statistically analyzable data and

- to monitor plant employees more closely in the intensive training/transitional phase.

- FSIS should seek advice from an expert consultant group on ways to improve communications with and understanding by its field inspectors, especially in the philosophy of food safety. Verbal and written testimony indicates that a major communication problem exists between FSIS management and field staff (see [Appendix E](#)).

4

STATISTICAL CONSIDERATIONS

ABSTRACT

The Cumulative Sum (CUSUM), a widely accepted method for maintaining process control In manufacturing, is a feasible approach to statistical evaluation of the slaughter process. it can help ensure that procedural or policy changes, personnel turnovers, inadvertent mistakes, poor training, or mechanical deficiencies do not establish an upward trend in defects that are detectable by inspection. CUSUM is a good choice to help control the process and ensure uniformity of processing. however, many people erroneously believe CUSUM as used in SIS-C is intended to ensure that no contaminated or otherwise defective meat reaches The consumer. That is not its purpose, and it is inadequate to provide that assurance in cattle slaughtering operations.

Therefore, CUSUM In SIS-C will not directly ensure a pleasing, clean, wholesome, and toxin-or pathogen-free product. As one part of the processing and inspection effort, it monitors system performance by checking that the process is consistent in its ability to detect and remove visible defects and that processing modifications do not establish an upward trend in these defects.

The limitations of CUSUM as an inspection tool for assessing a nonuniform product must be clearly recognized. Because of these limitations, greater flexibility must be built into the sampling scheme along with an emphasis on optimizing the quality of the final product rather than simply obtaining acceptable CUSUM scores.

CUSUM is appropriate for maintaining process control provided appropriate tolerance limits are set and provided all lots are adequately sampled. however, CUSUM cannot eliminate the need for adequate inspection and for microbiologic and toxicologic testing.

The primary statistical considerations related to SIS-C involve three points: (1) the rationale supporting a change from Acceptable Quality level (AQL) scores to CUSUM for SIS-C; (2) the use of CUSUM for process control; and (3) the method of sampling for CUSUM Determinations.

RATIONALE SUPPORTING THE CHANGE FROM AQL TO SIS

The rationale for favoring SIS-C over traditional inspection came from AQL scores (see definitions in [Appendix G](#)), based on both traditional and SIS-C procedures. These data showed that one of the five plants sampled (plant #5) had lower AQL scores when SIS-C was in effect (FSIS, 1989; Wesson, 1983). These data are consistent with the hypothesis that SIS-C might produce lower AQL scores in that specific plant (plant #5), but are an inadequate basis for accepting this hypothesis or inferring that SIS-C produces lower AQL scores in other plants. Furthermore, these conclusions should not be drawn from data on this one plant, because there was a downward trend in AQL scores in that plant when traditional inspection was still in place. Other

variables, such as management changes, that are unrelated to inspection procedures could have affected the results. After the initial improvements, little consistent further improvement was observed.

USE OF CUSUM FOR PROCESS CONTROL

CUSUM is a widely accepted method for maintaining process control in manufacturing products that must be kept within certain tolerances. At appropriate stages of production, product samples are examined for deviations from specified limits in composition, dimensions, or other features. CUSUM is a good method for monitoring manufacturing processes to detect changes that cause failure of products to meet required specifications. CUSUM is an acceptable method of monitoring the process to discover problems introduced by factors such as personnel turnover, inadequately trained personnel, mechanical deficiencies, plant policy, and changes in procedures. This is the purpose for which FSIS uses CUSUM. However, many people believe erroneously that CUSUM as used in SIS-C is intended to ensure that no contaminated or otherwise defective meat reaches the consumer. CUSUM sampling and calculations are not designed to detect defects that are missed by inspectors or trimmers.

In SIS-C, CUSUM is used to monitor slaughtering of cattle; this is similar to process control in manufacturing facilities. However, unlike manufacturing processes that merge raw materials into some product, in SIS-C the incoming material is modified by separating or removing certain parts and by detecting and removing defects. In SIS-C, a nonuniform product, i.e., cattle with various defects and from different sources, enters the processing plant. In addition, certain defects can be introduced by the processing. CUSUM attempts to monitor the system's performance in detecting and removing both types of defects and producing a uniform (with respect to defects) final product.

According to "FSIS Data Presentation to the Committee," CUSUM involves use of a tolerance level "set at the national average for the total of the weighted nonconformances for all of the plants tested" (FSIS, 1989b). Data from a randomly selected sample of plants were used to determine the average quality cleanliness and processing defects) of products produced in the United States. This average is applied to SIS-C plants whose initial performance should have been much better than the national average because of the uniform age, size, and weight of the cattle they slaughter. In CUSUM, as in SIS-C, the tolerance limits might more appropriately be based on what is acceptable for every plant rather than on an average reflecting what plants were doing at any particular time. It would be surprising if these measures were identical. The issue is not whether CUSUM is appropriate; it can be a valuable part of SIS-C. Rather, the important factors are (1) the tolerance limits within which plants can operate and be labeled "in control" or "out of control", (2) the appropriate actions that require more conservative processing practices such as slower line speeds and reprocessing, and (3) the way in which CUSUM is utilized and interpreted within the

entire framework of SIS-C.

Cattle arrive at the processing plant with various defects. Defects may be clustered in herds or lots. They may be related to traumas during transport, to diseases, or to nutritional influences at the feedlot. In addition, defects are also introduced by processing. Therefore, defects measured in SIS-C can come from two sources: the cattle entering the plant and the process itself. If cattle entering the plant had standard defects, then monitoring the defects would monitor the process. A goal of SIS-C monitoring is to remove defects from both sources without distinguishing between them. One question to be answered is whether the effectiveness of CUSUM monitoring is influenced by the condition of the lot entering the plant. Is process control affected by the number of defects, the number of cattle with defects, the clustering of defects, and the kinds and locations of defects? Is it possible for some lots with high numbers of defects to enter the plant and not be included in the sampling for CUSUM?

If the processing of cattle is the same for all lots, the nature and location of defects do not influence the ability of inspectors to discover them, and if all lots are adequately represented in CUSUM, then the clustering of defects within lots might be less important. However, if defects of particular kinds or in certain locations are more difficult to observe, then clustering of defects in lots is important, and the monitoring method needs to ensure that there is adequate sampling within lots (possibly representing all herds). The feasibility of representing all sources in the sampling is at best questionable. On the other hand, sampling from all lots may be feasible and could be incorporated into the plan for CUSUM in the same way that sampling during certain time intervals is planned.

Finally, CUSUM in SIS-C plays an indirect, not a direct, role in ensuring pleasing, clean, wholesome, and toxin-or pathogen-free products as part of the entire processing and inspection effort. It is a check on the process to ensure that processing modifications, inadvertent mistakes, and poor training do not establish an upward trend in the number of defects undetected by the inspection. It does not guarantee that the product is free from defects, but should ensure that the process is consistent in its ability to detect and remove defects.

THE SAMPLING BASIS FOR CUSUM

If there is substantial variation in the average number of defects among lots, then the sampling for CUSUM needs to include an adequate number of subgroups from each lot. The plan for CUSUM monitoring of carcass and viscera includes the plant's sampling subgroups of three consecutive carcass sides with a frequency of one subgroup sample per hour and FSIS sampling subgroups of three consecutive sides every 8 hours; other products are sampled with different criteria. If carcasses from a lot composed of several herds are distributed randomly along the production line, the probabilities of detecting defects in a particular lot should be determined to understand

how well sampling will represent the lot.

The probability that defects in a given lot will be detected can be studied by examining the converse probability that the sampled units will not include any defects in a lot, when in fact they exist. [Figure 4-1](#) depicts these probabilities based on the following assumptions:

- 1. The distribution of defects in lots is Poisson.
- 2. The average number of defects per carcass side is 0.1.
- 3. Three carcass sides are observed each hour.
- 4. Carcass sides are independent. (This is, of course, an oversimplification.)

The probabilities have been calculated and plotted for line speeds from 200 to 400 per hour in increments of 50, and for lot sizes of 250 to 3,000 in increments of 250.

The probabilities of observing no defects among sampled units from single lots having an average of 0.1 defects per carcass are very high for the smaller lot sizes and decrease as the lot sizes increase. This is to be expected, since more carcass sides would be sampled from the larger lots for any given line speed. The probabilities are consistently higher for faster line speeds, because a smaller proportion of carcass sides is sampled for faster line speeds, regardless of the lot size. By looking at the points where the lines intersect with a particular probability on the graph, it can be seen that the lot size must increase for each increment in line speed to achieve that probability.

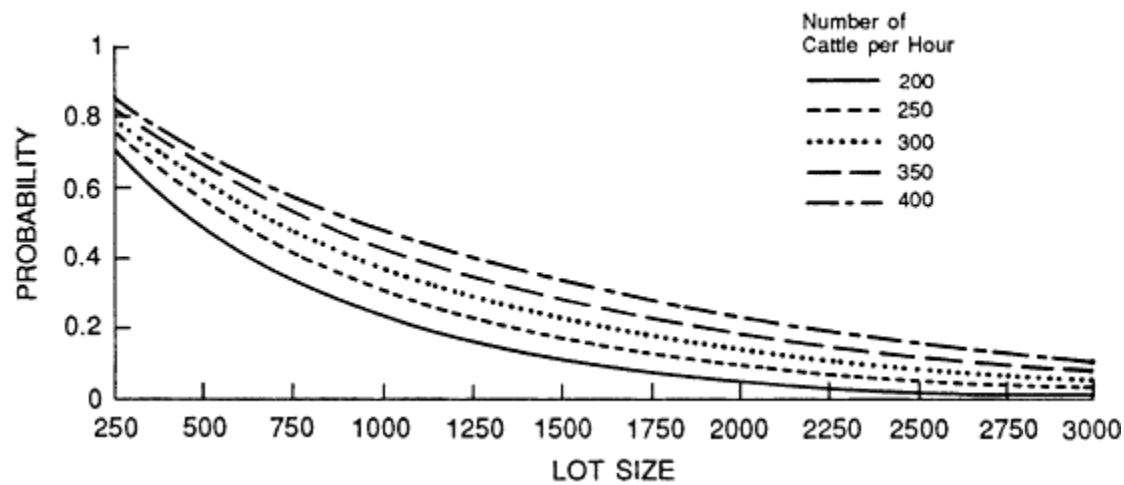


Figure 4-1
Probability of Observing No Defects in Various Lot Sizes and Line Speeds
Sample Unit (Carcass Side) is 0.1

When the Average Number of Defects/
Sample Unit (Carcass Side) is 0.1

For example, the following line speeds and lot sizes were all associated with the same probability (0.223) of observing no defects in the lot (line speed/lot size): 200/1,000, 250/1,250, 300/1,500, 350/1,750, and 400/2,000. Higher line speeds can be used with larger lots to achieve probabilities comparable with those of lower line speeds and smaller lots. However, these probabilities relate only to the discovery of at least one defect in a lot (1.0 minus the probability of not detecting a defect) and do not address adequate numbers to assess the level of defects in a lot. Of course, when faster line speeds are used with small lots, there is a chance that some small lots will not be represented in the sample.

In summary, a simple Poisson model was used to compute probabilities that some defective product will be accepted using CUSUM. These computations showed that defects among cattle in small lots are more likely to be missed than those in large lots and that faster line speeds are associated with higher probabilities of accepting defective meat. This demonstrated that a CUSUM-based inspection scheme will allow—with disturbingly high probability—some defective meat to pass undetected in small lots and in plants with high line speeds, and reinforced the position that its use should be limited to process control.

A second approach to studying the potential for defective cattle to pass the CUSUM monitoring process is presented in [Figure 4-2](#). This figure presents the operation characteristic curve for CUSUM. When the fraction nonconforming is 0.1 or lower, the probability of accepting the lot is 0.73 or higher. Disturbingly high probabilities of acceptance (0.51, 0.34, 0.21) remain even when the fraction of nonconforming products is high (e.g., probabilities of 0.51, 0.34, and 0.21 are associated with nonconforming fractions of 0.2, 0.3, and 0.4, respectively).

These probability computations demonstrate the need to clearly define the objectives of the inspection program. If the objective is to control the process and ensure uniformity of processing, CUSUM is a good choice. However, if the objective is to ensure that no contaminated or otherwise defective meat reaches the consumer, CUSUM is inadequate. This distinction is crucial.

DISCUSSION

In a broad sense, the question of the usefulness of the CUSUM is not a statistical one but relates more to the objectives of inspection and quality control in plants. The materials upon which this document is based suggest that the purpose of quality control and the role of meat inspectors in processing plants are viewed differently, depending on whose interests are being served. At least four different interests are involved in the processing of cattle:

1. Industry wants to produce an appealing finished product as efficiently, inexpensively, and quickly as possible.

2. USDA wants to fulfill its mandate to ensure wholesomeness, protect public health, prevent adulteration, and protect against economic fraud.
3. Consumer groups want a safe final product that has a good appearance.
4. Health organizations want to ensure that the product is not contaminated with disease-causing organisms, toxins, or chemicals.

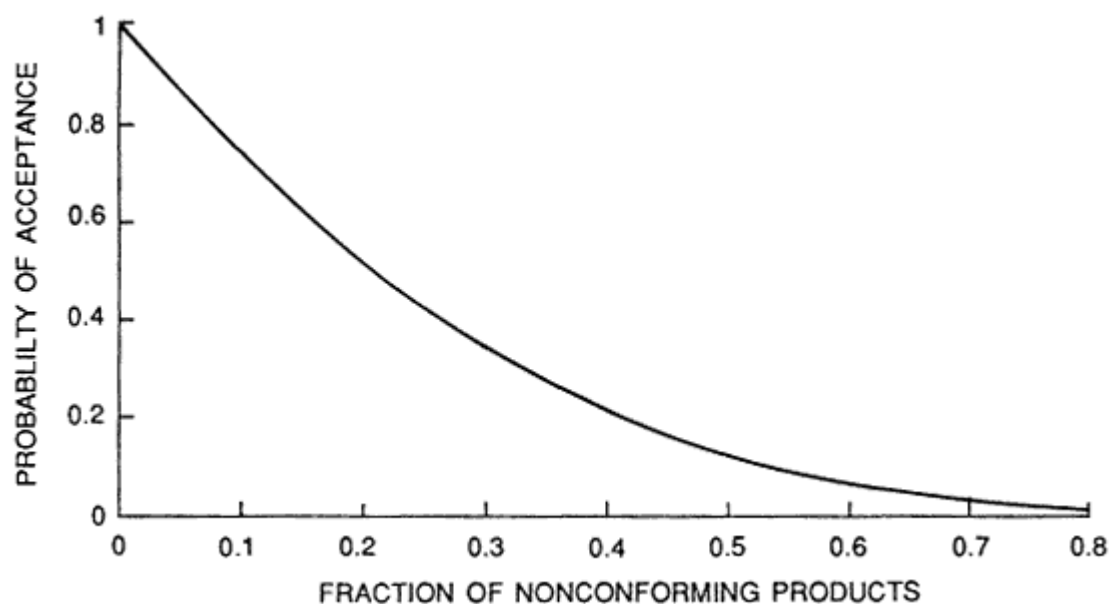


Figure 4-2
Evaluation of CUSUM for SIS-C, Assuming $n=3$, $c=0$

These goals may be an oversimplification of the issues, but they are important in evaluating inspection procedures and designing sampling schemes.

There are probably no economically feasible sampling schemes that could satisfy all these concerns. An attempt to sample adequately is built into SIS-C (see [Chapter 3](#)) by having plants institute their own quality control programs that are monitored by USDA. According to this plan, USDA samples only for finished product standards and continues 100% inspection of head, carcass, and viscera. After this inspection, the head and viscera are separated from the carcass and company personnel cut and trim

for the cooler. At another company station, the cuts are again viewed and three carcass sides are sampled once or twice each shift and the products are examined for processing defects only. The inspectors maintain their CUSUM, which should be similar to the plant's score.

This plan could be expected to accomplish the following in the best of circumstances:

1. The company quality control program (QC) could be designed to detect visual defects exceeding acceptable limits among the cattle being processed and remove the defects or condemn the defective meat. This would require a sampling scheme that could take into account cattle lots from different sources and other potentially important factors.
2. The 100% inspection of heads, viscera, and carcasses would accomplish exactly what traditional inspection has accomplished, assuming that the inspection is performed with the same thoroughness as in the traditional program.
3. Documentation and monitoring of plant QC would help ensure that deviations from the plant norm would be followed by appropriate actions.
4. CUSUM would allow inspectors to monitor the plant process so that the defects introduced and missed during processing could be monitored, and trends toward increasing numbers of defects could be detected and corrected. However, the method alone could not be expected to ensure that carcasses leaving the plant meet the expectations mentioned above.

CUSUM is appropriate for maintaining process control, provided the tolerance levels are set for maintaining an acceptable process for all plants and are not at the level observed in a sampling of plants, and provided all lots are adequately sampled. However, CUSUM cannot eliminate the need for the other parts of SIS-C, including inspection and other testing (e.g., microbiological and toxicologic).

It is important to distinguish between two objectives that might be part of the SIS-C in order to realize the impact of the probabilities presented in this chapter. One objective might be process control (i.e., ensuring that the process remains consistent in its detection of defects). CUSUM will be helpful in attaining this objective. The other, and primary, objective should be preventing contaminated or defective meat from being accepted. CUSUM will not ensure that the final product is free from defects or from microbial and chemical contamination.

RECOMMENDATIONS

The theoretical and statistical considerations underlying CUSUM should be

reevaluated with the following points in mind:

- The limitations of CUSUM as an inspection tool for assessing a nonuniform product must be clearly recognized. Because of these limitations, greater flexibility must be built into the sampling process along with an emphasis on optimizing the quality of the final product rather than simply obtaining acceptable CUSUM scores.
- For CUSUM, or any comparable sampling system, the statistical basis for setting initial sample sizes and tolerance levels must be validated in a series of ongoing controlled studies.
- USDA should evaluate CUSUM's performance with respect to accepting defective lots of meat. This should be done in two ways: (1) Operating characteristic curves should be developed for various schemes by using CUSUM. These can be used to evaluate performance under various conditions and assumptions by providing probabilities of accepting defective meat. Ideally, the probability of accepting defective meat should be zero or very close to zero. (2) CUSUM should be tested in plants to determine how often it actually accepts defective meat. This evaluation should also include observations on microbial or chemical contamination and should be designed with adequate sample numbers to facilitate valid interpretations of the results.

5

MICROBIOLOGIC AND TOXICOLOGIC ASSESSMENT

ABSTRACT

Microbiologic and toxicologic (chemical) hazards that are vitally important to public health are not addressed in SIS-C. Continuous assessment of such hazards based on scientifically valid sampling and the use of more effective methods must be a part of any meat inspection system. Moreover, research must be conducted on slaughtered cattle to provide statistically valid data to test hypotheses relating to microbiologic and toxicologic hazards in order to enhance and preserve public health and restore public confidence in the current inspection system.

ASSESSMENT

As emphasized in previous Food and Nutrition Board (FNB) reports (NRC, 1985a, 1987a), microbiologic and toxicologic hazards represent the greatest risk to human health associated with meat. A full assessment of possible microbiologic and toxicologic risks associated with red meat goes well beyond the charge of this committee. These risks have been reviewed in detail in previous Food and Nutrition Board reports (NRC, 1985a, 1987a). [Table 5-1](#) is taken from the 1985 report *Meat and Poultry Inspection*. Although it includes information on both red meat and poultry, it illustrates the diversity of microbial agents that may be present in or on meat and meat products.

Salmonella and *Campylobacter jejuni* are generally regarded as posing the major microbiologic risks associated with meat and poultry. However, we currently lack the epidemiologic data necessary to calculate the proportion of human infections due to these organisms that are attributable specifically to red meat (i.e., attributable risk data). In unpublished data from the USDA National Surveillance Survey made available to the committee (see [Appendix B](#)), *Salmonella* were isolated from 1.8% of 5,319 frozen red meat samples tested; the significance of these results is unclear, since complete details on study methodology were not available. Recent concern has also focused on contamination of meat by enterohemorrhagic strain of *Escherichia coli*, a newly described human pathogen that can cause hemorrhagic colitis and, in severe cases, the hemolytic-uremic syndrome.

Risks associated with toxicologic hazards appear to be smaller. However, they have been less well defined and often do not have the immediately obvious health consequences of bacterial or viral infections.

These observations led successive FNB committees to recommend that the Food Safety and Inspection Service (FSIS) intensify its efforts to control and eliminate contamination by microorganisms that cause disease in humans and optimize its

Table 5-1 Classification of Worldwide Meatborne and Poultryborne Microbial Pathogens According to Modes of Transmission^a

Pathogenic microorganisms transmissible to humans by <u>ingestion of raw or undercooked</u> meat and poultry:	
<i>Bacillus anthracis</i>	<i>Sarcocystis</i> spp.
<i>Balantidium coli</i>	<i>Taenia saginata</i>
<i>Campylobacter coli</i>	<i>Taenia solium</i>
<i>Campylobacter fetus</i> subsp. <i>fetus</i>	<i>Toxoplasma gondii</i>
<i>Campylobacter jejuni</i>	<i>Trichinella spiralis</i>
<i>Escherichia coli</i>	<i>Yersinia enterocolitica</i>
<i>Francisella tularensis</i>	<i>Yersinia pseudotuberculosis</i>
<i>Salmonella</i> spp.	
Pathogenic microorganisms transmissible to humans by <u>ingestion of cooked or otherwise heat-processed</u> meat or poultry that became contaminated after the heat processing or that was improperly stored after initial heat processing:	
	<i>Shigella</i> spp.
Any of the above	<i>Staphylococcus aureus</i>
<i>Bacillus cereus</i>	<i>Streptococcus pyogenes</i>
<i>Clostridium botulinum</i>	
<i>Clostridium perfringens</i>	
Pathogenic microorganisms transmissible <u>by contact with animal tissue</u> or <u>by inhalation of aerosols or dust</u> from animals:	
<i>Bacillus anthracis</i>	<i>Leptospira</i> spp.
<i>Brucella</i> spp.	<i>Listeria monocytogenes</i>
<i>Chlamydia psittaci</i>	Newcastle disease virus
<i>Cowpox virus</i>	<i>Pseudomonas mallei</i>
<i>Coxiella burnetii</i>	<i>Streptococcus pyogenes</i> ^{>}
<i>Erysipelothrix rhusiopathiae</i>	<i>Toxoplasma gondii</i>
<i>Francisella tularensis</i>	
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:	
<i>Aeromonas</i> spp.	<i>Plesiomonas shigelloides</i>
<i>Bacillus licheniformis</i>	<i>Proteus</i> spp.
<i>Citrobacter</i> spp.	<i>Providencia</i> spp.
<i>Klebsiella</i> spp.	<i>Streptococcus faecalis</i>
	<i>Streptococcus faecium</i>

^a Source: NRC, 1985a.

National Residue Program (NRP) for dealing with toxicologic risks (NRC 1985a, 1987a). When the SIS-C program is considered in this context, several questions arise. Some of these issues are dealt with elsewhere in this report, but the committee believes that they are important enough to warrant repeating in this chapter.

Have previous FNB recommendations concerning microbiologic and toxicologic hazards been integrated into SIS-C?

According to FSIS, the microbiologic or toxicologic issues discussed in previous FNB reports are not directly addressed in SIS-C.

Might SIS-C have an indirect effect on microbiologic or toxicologic hazards in red meat?

Modifications in inspection procedures could result in reduced microbial contamination of carcasses only if they lead to improved handling of carcasses or plant sanitation. Thus, evaluation of inspection systems should consider possible effects on total microbial counts, and on detection and counts of such pathogens as *Salmonella*, *Campylobacter*, and enterohemorrhagic *Escherichia coli*.

It is unlikely that improved inspection procedures could lead to reduced levels of toxicologic or chemical hazards. However, any changes in carcass rinses or equipment sanitizing chemicals should be evaluated for possible effects of these contaminants on human health.

Are there data documenting the effects of SIS-C on microbiologic or toxicologic hazards?

FSIS data on microbiologic and toxicologic hazards are available for some individual plants. Unfortunately, existent data sets are construed inconsistently and appear to be too small to permit meaningful statistical comparisons between SIS-C and traditional systems. Such confounding variables as differences in source and type of cattle also complicate the analysis. The committee received USDA data on only 35 SIS-C samples from five SIS-C plants (see [Appendix B](#)). No conclusions about inspection systems could be drawn due to the small sample size, low frequency of contamination, and the freezing of specimens for shipment. Comparable problems arise in trying to draw conclusions from available toxicologic data.

Some processing plants (such as the Monfort plant in Greeley, Colorado) have developed data bases on microbial contamination of products. These data are of interest, and their generation should be encouraged. However, industry-derived data can not be substituted for substantive, statistically valid FSIS data that are subject to the scrutiny of scientific peer review processes.

If there is a need for such data, how could they be obtained?

There is need for data on microbiologic and toxicologic hazards in meat to address the committee's concerns and those of the public. These data would permit comparisons among various inspection systems and continuing assessment of inspection strategies in any one plant.

Relatively simple studies could be designed to provide these basic data and to test appropriate hypotheses. For example:

- Hypothesis 1: The bacterial contamination (i.e., total plate counts, *Salmonella* counts, etc.) of carcasses in SIS plants is no different—neither greater nor less—than that of traditionally inspected carcasses of similar source and type slaughtered under similar conditions.
- Hypothesis 2: Bacterial contamination does (or does not) correlate with carcass error rates, as determined by organoleptic techniques.
- Hypothesis 3: Bacterial contamination rates are (or are not) more dependent on-line speed than on inspection strategy.

To evaluate these hypotheses statistically, it would be desirable to determine the sample sizes required to provide acceptable alpha (α)¹ and beta(β)² risk levels and also to consider possible confounding effects such as type of cattle being slaughtered. A preliminary study, such as one performed by Agriculture Canada ([Appendix F](#)), could provide data for sample size determinations.

After methods have been established, a continuing program of data collection should be developed and hypotheses retested to provide ongoing assessment of quality control programs and inspection processes. Sudden occurrence of high aerobic bacterial counts (e.g., standard plate counts, coliform counts, or *Salmonella* counts) in a plant might indicate a breakdown in the control of bacterial contamination that is detectable by quality control procedures and inspection processes. Sudden increases in the incidence of enteric bacterial pathogens might indicate an increase in fecal contamination of carcasses by carrier animals. Similarly, a sudden increase in chemical contamination or residues would indicate the need for traceback to sources of contamination. To accomplish these goals, FSIS should identify the most effective methods and should use rapid diagnostic tests, such as enzyme-linked immunosorbant assays (ELISA) and DNA probes for pathogenic microorganisms, as previously recommended by FNB committees. Programs of this type could also be incorporated

¹ α (or type I)—refers to the error made if a true hypothesis is rejected.

² β (or Type II)—refers to the error made if a false hypothesis is accepted.

into ongoing studies of the relationship of antimicrobial use to drug resistance in pathogens isolated from foodborne disease outbreaks in humans (IOM, 1989).

Realistic and appropriate standards to protect public health are complex but very important. Under favorable conditions, pathogenic bacteria multiply rapidly to levels adequate to cause human disease both in the plant and after the carcass enters the market. Therefore, microbiologic standards must be considered carefully. The zero risk concept may be appropriate to consider as an idealistic goal for pathogenic bacteria (which grow and multiply). Thus, the detection of low levels of microorganisms can be important, because such organisms can multiply rapidly to levels adequate to cause illness in humans.

On the other hand, the negligible risk standard can be an appropriate goal for levels of toxins or chemicals (NRC, 1987b), because their concentrations do not increase. In fact, levels of chemicals in food are usually substantially reduced by food processing and food preparation. Further research is needed on establishing negligible risk levels for chemicals in food to ensure that sensitive population subgroups, such as infants, children, or immunocompromised people, are not susceptible to risks from chemical levels that would be safe for most people. Specific issues related to the effects of pesticides on infants and children are currently under study by a National Research Council committee in the Board on Agriculture. This report will be released in 1991 (NRC, in press).

FSIS is not authorized to conduct basic research. Therefore, the necessary studies must be done by researchers outside FSIS. However, USDA must realize that a modern, scientifically based inspection service must conduct or fund research to evaluate practical problems. Modernization of inspection requires sophisticated computer systems, computer modeling, rapid diagnostics, and the ability to integrate this technology into on-line inspection strategies.

In summary, ongoing assessment of microbiologic and toxicologic hazards through well-designed and scientifically valid studies is essential to meat inspection. Results of these assessments must be considered in any comparison of inspection strategies.

RECOMMENDATIONS

- Microbiologic, toxicologic, and chemical data must be considered by FSIS in designing and evaluating any inspection systems designed to protect public health.
- If FSIS is to develop sound, believable, scientifically based inspection strategies, a research group must be established with the appropriate statistical, epidemiologic, microbiologic, and toxicologic expertise to frame and test hypotheses relating food inspection to microbiologic and chemical hazards. This

group should be based in USDA. It must have the flexibility to coordinate with other government agencies (e.g., the Food and Drug Administration and the Centers for Disease Control) involved in maintaining the safety of the food supply. It must also have adequate funds to draw on expertise from outside the government (i.e., universities and private industry).

6

THE EXTENT TO WHICH PREVIOUS FNB RECOMMENDATIONS HAVE BEEN INTEGRATED INTO THE SIS PROPOSED RULE

ABSTRACT

Four of the modifications made in traditional cattle inspection to produce SIS-C are in accord with previous Food and Nutrition Board recommendations (NRC, 1985a, 1987a). These are:

- FSIS inspection resources have been shifted to emphasize detection of lesions rather than dressing defects.
- Partial Quality Control (PQC) programs have been designed and implemented by management of some pilot plants.
- Concepts of sampling and process control have been introduced.
- Quantifiable data on macroscopic defects are generated, and inspection can be intensified in accordance with those data.

A start has been made to address some earlier Food and Nutrition Board recommendations. For example, technical expertise is being acquired by the FSIS in pathology, microbiology, toxicology, and epidemiology, from within the agency and outside. However, progress in implementing these recommendations is difficult because of limited funding. Liaisons with other agencies and advisory bodies have not yet had an impact on plants under traditional inspection or under SIS-C. Development and utilization of rapid tests to detect microbiologic contaminants and chemical residues have been very slow.

There is no visible progress in responding to many of the other Food and Nutrition Board recommendations in earlier reports. SIS-C was not intended to provide greater public health protection. Thus, improvement in eliminating unseen hazards is incidental. No steps have been taken to improve the identification and traceback of fed cattle, and few efforts have been made to improve the analysis of specific diagnoses and to relate them to animal husbandry practices.

The committee was charged with examining how SIS-C integrated previous Food and Nutrition Board (FNB) recommendations, specifically those in *Meat and Poultry Inspection: The Scientific Basis for the Nation's Program* (NRC, 1985a) and *Poultry Inspection: The Basis for a Risk-Assessment Approach* (NRC, 1987a). Although SIS-C was designed and implemented in pilot projects before the release of those reports, it partially addresses some of their recommendations. It should be made clear that SIS-C was not intended to be an FSIS response to the previous FNB reports. However, the committee was charged with examining the degree to which SIS-C integrated

previous recommendations into the proposed rule.

During the course of its study, the committee studied the previous FNB reports, observed what portions of them had evidently been adopted in the plants visited, read FSIS printed responses to the FNB reports (FSIS 1986, 1990c), queried USDA officials verbally, and studied FSIS written responses to a request for an accounting of the relationship of SIS-C to each recommendation in the 1985 report (see [Appendix B](#)).

The committee did not undertake a reexamination of all the issues and recommendations raised in the earlier reports. It chose to comment briefly rather than present a detailed chronicle identifying every minor action of FSIS in response to earlier recommendations, and to address only those issues that we included in SIS-C and only those covered in the references provided to the committee by FSIS (FSIS, 1986, 1990c).

In the following paragraphs, each recommendation of the previous committees is paraphrased and followed by the comments of the present committee on the degree of integration.

RECOMMENDATIONS IN MEAT AND POULTRY INSPECTION: THE SCIENTIFIC BASIS OF THE NATION'S PROGRAM (NRC, 1985A)

RECOMMENDATIONS

Detection and Elimination of Pathogenic Microorganisms

The committee recommended that FSIS intensify its efforts to control and eliminate contamination with microorganisms 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 recommended 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 prevalence is low, these infections present important and avoidable occupational hazards. Better epidemiological surveillance and coordination of efforts to eradicate these diseases are also needed.

Comment of the Present Committee: This recommendation has not been integrated into SIS-C, which is not designed to provide inspection procedures for the detection of invisible contamination by pathogenic microorganisms. There is no conclusive evidence that product contamination with invisible pathogenic microorganisms is either better or worse under SIS-C.

Preventing and Detecting Chemical Residues

The committee recognized that the National Residue Program (NRP) is constrained in many ways by its legislative mandates. It recommended, however, that the NRP strive to make substantial progress in several categories to meet the requirements of an optimal program identified by the committee. In particular, the NRP should incorporate strategies that would protect consumers from exposure to potential health hazards. One of the ways this could be accomplished is to introduce a system to identify and trace animals back 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 suggested 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.

Comment of the Present Committee: Comments on this recommendation will be found below among those in the section on "Characteristics of an Optimal Meat and Poultry Inspection Program."

Monitoring Hazardous Agents During Livestock Production and Traceback Mechanisms

The committee recommended that means be found for FSIS to coordinate the control and monitoring of hazardous agents during production, when those agents enter the food supply. Furthermore, it recommended 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 recommended 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.

Comment of the Present Committee: The design of the SIS-C inspection program does not incorporate this recommendation in whole or in part.

Integration of Risk Assessment Procedures into the Inspection Process

Overall, the committee recommended 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 resulting from any modifications to the inspection process.

Comment of the Present Committee: The design of SIS-C did not include the principle of risk assessment in whole or in part. There is no evidence that SIS-C confers greater benefit to public health than traditional inspection.

Research and Advisory Programs to Develop High Technology-Based Inspection.

In the judgment of the 1985 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 recommended 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 and other government agencies as well as private groups is essential. Thus, the committee also recommended the establishment of a scientific advisory body composed of representatives from government, industry, universities, and research organizations to facilitate such interaction.

Comment of the Present Committee: In the data reviewed, the committee found no evidence that SIS-C incorporates this recommendation in whole or part. However, FSIS has proceeded slowly to pursue some of these recommendations by using some new tests in the inspection of swine and nonfed cattle. Also, FSIS has developed a National Advisory Committee on Microbiological Evaluation of Foods.

Characteristics of an Optimal Meat and Poultry Inspection Program

The 1985 committee identified the following components (not in any order of priority) of an optimal meat and poultry inspection system. It recognized that many of these components were part of the FSIS system at the time of its review in 1985. The present committee summarized FSIS's May 1990 responses to these components (FSIS, 1990c) and added its comments:

A System of Traceback to Producers

1985 Report:

A trace-back and recall system from final sale to producer for all animals and products destined to enter the human food supply was recommended by the committee as an essential step for the generation of data that are important to the prevention of disease in humans and that will enable processors and the government to recognize potential hazards in the food chain (NRC, 1985b).

Summary of FSIS's May 1990 Response: A regulation has been promulgated regarding

identification of swine moved interstate prior to slaughter (FSIS, 1990c).

Comments of the Present Committee: This 1985 recommendation has not been integrated into SIS-C.

Use of Plant Personnel to Monitor Critical Control Points

1985 Report:

The committee recommended maximum use of plant personnel in process-by-process and day-to-day monitoring of critical control points and FSIS oversight to ensure compliance.

Summary of FSIS's May 1990 Response: This recommendation has been implemented.

Comments of the Present Committee: The recommendation has been integrated into SIS-C.

Use of Contemporary Technologic Expertise in Inspection Management

1985 Report:

The 1985 committee recommended that all phases of inspection be performed by 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, plant 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.

Summary of FSIS's May 1990 Response: To increase its access to technical expertise, FSIS decided to recruit already trained food technologists, to educate agency personnel in inspection procedures, and to enlist the help of other specialists through contracts. To date, it has hired and trained more than 219 food technologists, has embarked on a program of training FSIS personnel as pathologists, is planning in 1990-1991 to send two employees to a university to receive training in biotechnology, and has added a basic introduction to biotechnology to the curriculum in the FSIS inspection training program at Texas A&M University. It has also convened the National Advisory Committee on Microbiological Criteria for Foods.

Comments of the Present Committee: The committee recognizes that FSIS has begun to acquire needed technical expertise. However, there are very few FSIS employees with contemporary training in fields such as microbiology, toxicology, and epidemiology,

and few consultants are used.

Multitiered Levels of Inspection

1985 Report:

The 1985 report recommended 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).

Summary of FSIS's May 1990 Response: The frequency and intensity of inspection are influenced by the documented history of the plant's performance.

Comments of the Present Committee: The recommendation is implemented in part under SIS-C, since the sampling scheme varies in intensity, depending on compliance, and since corrective action is possible when levels of visible contamination increase. But lowering visible contamination does not equate with lowering public health risk. The committee found no evidence that attention is paid to the special needs of the intended consumer.

Analysis of the Utility of Each Inspection Procedure

1985 Report:

Another 1985 recommendation was the 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 and for detecting aesthetically objectionable conditions and whether they are necessary to protect consumers against fraud or are able to provide other identifiable benefits.

Summary of FSIS's May 1990 Response: FSIS has been working on the list of diseases identified by each step of the procedure. It has been collecting data on swine to correlate condemnations with specific diseases. There are plans to correlate these data with farm disease data collected by the National Animal Health Monitoring System (NAHMS) of the Animal and Plant Health Inspection Service (APHIS), to replicate the model for other species, and to upgrade and enhance the Animal Disease Reporting System.

Comments of the Present Committee: The list recommended by the 1985 committee could be interpreted in two ways: (1) a list of specific diseases detected during the meat inspection process or (2) a list relating specific detectable diseases to each anatomic site examined in each inspection maneuver.

FSIS appears to have responded to the first interpretation. Except for a few diseases such as tuberculosis, actinobacillosis, and cysticercosis, data available at present give only broad general categories of the diseases of cattle that may be the reason for condemnation. This lack of information is the same under both traditional and SIS-C inspections. Progress is being made at an extremely slow rate.

The present committee believes that SIS-C might have suffered less resistance from FSIS employees had the basis for such changes from the traditional system (e.g., deleting incision of the atlantal lymph nodes and medial masticatory muscles) been explained to them. The original set of procedures was formulated with specific diseases in mind, and it is acceptable to change procedures to reflect changes in disease prevalence over time.

Develop a Data Base on Specific Causes of Condemnations

1985 Report:

Random sampling of retained or condemned carcasses and parts of carcasses is needed 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.

Summary of FSIS's May 1990 Response: An Extension Service study (pilot program) is under way to determine if definitive diagnoses are effective in disease prevention. The success of this pilot program will determine future funding. Agency pathologists are working to improve specific disease diagnosis and are developing procedures to gather and use this information.

Comments of the Present Committee: There appears to be no change under SIS-C in the establishment or use of specific disease diagnoses as a basis for upgrading inspection efficiency or for continuing education of inspectors.

Rapid Screening for Residues

1985 Report:

Rapid, inexpensive screening tests are needed to detect a broad array of chemical and biological contaminants that may be hazardous to the consumer.

Summary of FSIS's May 1990 Response: Four tests have been developed or used by FSIS (for sulfa drugs, antibiotics). Eleven additional tests are being developed; some are undergoing field trials. A chromatography system that is durable under field conditions and a computer-assisted residue testing system are being evaluated.

Comments of the Present Committee: The developed tests mentioned by FSIS are used mostly on swine, veal calves, or cull cows and are not routinely implemented under SIS-C. FSIS has begun to move in the right direction by developing rapid diagnostic tests, but much more effort is needed to incorporate the latest knowledge into diagnostic capabilities and rapid residue identification.

Protection of Consumers from Residues

1985 Report:

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

Summary of FSIS's May 1990 Response: The development of a data base has begun. Information will be provided on incidence of residues. It would be unrealistically expensive to change the focus from monitoring of incidence to prevention of consumer exposure.

Comments of the Present Committee: Development and planning activities have not yet yielded results. The public and inspectors still hold the opinion that residue monitoring is intended to reduce public exposure and are dissatisfied because of their perception that this has not happened.

Hazard Analysis Critical Control Point (HACCP) Programs

1985 Report:

Emphasis should be placed on HACCP. Inspection should be limited where the historic yield of violations is low and where public health risks are negligible.

Summary of FSIS's May 1990 Response: FSIS began pilot testing the HACCP principle at a poultry processing plant in Puerto Rico in conjunction with a bacterial control project. FSIS intends to issue a report.

Comments of the Present Committee: There has been some change under SIS-C, especially where PQC programs are mandated. The changes relate only to the historic yield of violations and quality issues. They do not provide proactive intervention to protect the public.

Documentation and Compliance Enforcement

1985 Report:

FSIS should provide documented assurance, backed by substantial compliance

enforcement, of the sanitary wholesomeness of all meat and poultry products.

Summary of FSIS's May 1990 Response: Data have been generated on plant deficiencies, and corrective and preventive actions have been taken to improve sanitation. Audits of inspection effectiveness are conducted. FSIS has initiated a project to have industry take responsibility for sanitation of its plants, so that inspectors become regulators rather than quality control supervisors.

Comments of the Present Committee: The committee has observed that under SIS-C, quantifiable data are being generated on the level of macroscopic defects found on the product.

Enhanced Enforcement Capability

1985 Report:

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

Summary of FSIS's May 1990 Response: FSIS initiated three programs in the last decade to enhance its enforcement capabilities. These programs are now being integrated. Under the integrated system, noncomplying plants will be subject to a series of enforcement actions that can culminate in withdrawal of inspection. At present, enforcement plan is used successfully in meat processing operations; there is a plan to harmonize slaughter operations with processing operations.

Comments of the Present Committee: The committee did not look into penalties for violators under either traditional inspection or SIS-C.

Improve Technologic Base of FSIS

1985 Report:

Adequate resources are needed 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.

Summary of FSIS's May 1990 Response: FSIS requested and was granted funds to support methods development. Work is being done through the Agricultural Research Service. The methods embrace modern biotechnology.

Comments of the Present Committee: Development and planning activities have not yet yielded results that are used routinely under SIS-C.

Mandatory Continuing Education

1985 Report:

A mandatory system of initial and continuing education is needed to train inspection personnel in food science, food technology, pathology, and public health in combination with a recertification program.

Summary of FSIS's May 1990 Response: FSIS had in place a mandatory system of initial and continuing education for inspection personnel at the time of the 1985 report. It trains veterinarians, food inspectors, industry personnel, and supervisors. There is a Career Development Program, which provides refresher courses. Also, it has supported training at universities in pathology and epidemiology.

Comments of the Present Committee: In view of the importance of the fundamental changes in meat inspection philosophy implicit in SIS-C, FSIS could have done more to promote training of its inspectors at SIS pilot plants (see [Chapter 3](#)).

Involvement of Scientists in Policy Development

1985 Report:

A large scientific and technical FSIS staff of respected scientists is needed to participate in the development of policy.

Summary of FSIS's May 1990 Response: Through a newly created position at the Assistant Deputy Administrator for Science level, FSIS laboratories have become part of the decisionmaking team. The creation of the National Advisory Committee on Microbiological Criteria for Foods, which gives the agency access to scientific and technical advice, was a response to the 1985 Food and Nutrition Board recommendation.

Comments of the Present Committee: The administrative changes do not seem yet to have made major differences in SIS-C plants (see [Chapter 3](#)).

Expert Advisory Panels

1985 Report:

Standing advisory panels composed primarily of outside experts should be established to provide consultation on both policy and practice related to meat and poultry safety. Disciplines represented on these panels should include food science and technology, computer applications, microbiology, biostatistics, epidemiology, veterinary medicine, toxicology, systems analysis, animal health, economics, marketing, nutrition,

and risk analysis. Again, no one discipline should dominate any panel. All major regulatory proposals should be reviewed by these standing advisory panels prior to finalization.

Summary of FSIS's May 1990 Response: The Meat and Poultry Inspection Advisory Committee had already been convened at the time of the Food and Nutrition Board report. The Secretary of Agriculture must consult with that committee before issuing product standards and labeling requirements and on matters affecting the operation of federal and state inspection programs. The agency contracted with a panel of outside experts in connection with the bacterial project being conducted in Puerto Rico on poultry to assess the critical control points for contamination with aerobic bacteria, including *Enterobacteriaceae* and *Salmonellae*. A Residue Advisory Committee is envisioned.

Comments of the Present Committee: As discussed in earlier chapters, these various advisory panels do not seem to be integrated into SIS-C (see [Chapter 5](#)).

Interagency Liaison

1985 Report:

Strong liaison between FSIS, CDC, the Food and Drug Administration, and relevant animal health agencies is needed at the federal, state, and local levels to ensure that no hazards are overlooked.

Summary of FSIS's May 1990 Response: FSIS agreed with the FNB recommendations. A complex mosaic of interrelationships has been set up.

Comments of the Present Committee: These liaisons do not seem to have made a difference yet at the level of the plant under either traditional or SIS-C procedures.

Data and Information Analysis

1985 Report:

A rapid, timely, and flexible system (probably computerbased) should be used extensively to acquire, transfer, analyze, and widely disseminate data related to inspection and to meatborne hazards.

Summary of FSIS's May 1990 Response: Funds have been obtained, and data bases and networks are being established.

Comments of the Present Committee: Data being collected seem to relate to housekeeping activities of a large regulatory organization rather than to tracking of

meatborne hazards.

Implementation Timetable

1985 Report:

The committee encouraged FSIS to compare its program with all the above criteria for an optimal meat inspection program and to establish a schedule for incorporating missing components as soon as feasible.

Comments of the Present Committee: Some of these criteria for an optimal meat inspection program are included in SIS-C and SIS-C/PQC, but this inclusion was not in direct response to the 1985 report (NRC, 1985a). In fact, as mentioned earlier, SIS-C was designed before that report was issued.

RECOMMENDATIONS IN POULTRY INSPECTION: THE BASIS FOR A RISK-ASSESSMENT APPROACH (NRC, 1987A)

RECOMMENDATIONS

Although the recommendations in the 1987 report address poultry inspection, some are relevant to red meat inspection. As in the preceding section, the present committee provides comments as to whether the SIS-C inspection proposal integrates recommendations deemed relevant to red meat inspection.

General Recommendations

1987 Report:

FSIS should adopt the well-established precepts of risk assessment as an integral part of its strategy to identify and manage public health risks associated with poultry. The risk model presented in the 1987 report was recommended as a prototype that FSIS could refine by applying its extensive knowledge of the poultry system (NRC, 1987a).

Comment of the Present Committee: There was no evidence to indicate that the risk model proposed in the 1987 report (NRC, 1987a) was used for SIS-C, which was designed in the early 1980s.

1987 Report:

FSIS should evaluate the current inspection system by using the risk-assessment model proposed by the committee and on the basis of its findings, modify the system so that it more directly addresses public health concerns.

Comment of the Present Committee: There was no evidence to indicate that this was considered in the proposed SIS-C rule.

1987 Report:

Rather than focusing on one procedure, such as bird-by-bird inspection, as the primary component of an inspection process, FSIS should direct its efforts toward the establishment of a comprehensive quality assurance program. Such a program would consist of several components, one of which might be organoleptic inspection.

Comment of the Present Committee: SIS-C is an organoleptic inspection procedure, and the products are examined on a carcass-by-carcass basis. The FSIS concept of finished-product sampling and mandatory PQC programs has considerable merit and is a step toward meeting this recommendation.

1987 Report:

Emphasis should be shifted from detection to prevention of problems at the earliest feasible stage in production to increase the effectiveness of poultry risk-management activities.

Comment of the Present Committee: Not covered by SIS-C, although SIS-PQC has the potential to do this.

Specific Recommendations

1987 Report:

FSIS should attempt to ensure that all aspects of the poultry production system are included in any risk model used, even if certain areas fall within the purview of other agencies.

Qualitative risk assessments should form the initial bases for planning and selecting inspection and quality assurance programs. Quantitative assessments should be used when qualitative assessments prove inadequate and when sufficient data are available.

Comment of the Present Committee: Some quantitative assessments were done in establishing finished product standards for SIS-C based on visible defects found in traditional inspection when carcasses were approved for human consumption, but there were no risk assessments.

1987 Report:

The association between microorganisms in and on poultry at slaughter and the occurrence of disease in humans is complex. Several potential sources of contamination exist throughout the poultry system. The committee recognized, therefore, that attempts to resolve this problem will be correspondingly difficult and may require collaboration with other agencies. On the basis of its review of the literature and established principles of microbiology, however, the committee recommended that certain actions—such as the following—be taken to reduce the potential for disease to be caused by poultryborne microorganisms:

- The ongoing search for data on microbial risks should continue and be complemented by new research. Emphasis should be placed on the prevention of disease in humans rather than on simple control of microbial counts during slaughter and processing.
- Potentially pathogenic microorganisms on poultry should be identified, the potential for exposure to an infectious dose of each pathogen should be determined, and the potential impact on public health that would result from the failure to control exposures should be evaluated.

Comment of the Present Committee: These concepts were not included in criteria established for SIS-C.

1987 Report:

The critical control points at which known pathogenic microorganisms such as *Salmonella* and *Campylobacter* may be introduced into the poultry system should be identified and monitored, preferably as a part of a HACCP program.

Comment of the Present Committee: Efforts to address critical control points are a part of the PQC portion of SIS-C/PQC. However, there is confusion between control points critical to compliance with regulations and those critical to public health.

1987 Report:

A population-based surveillance program should be established so that disease occurrence can be correlated with inspection strategies. This will require measuring the level of pathogenic microorganisms on market-ready poultry as well as establishing a system for surveillance of disease within a well-defined population.

A range of educational programs for people who raise poultry and for those who handle raw broilers in slaughterhouses, at retail, and during food preparation in the home and commercial establishments should be developed or intensified. As part

of this effort, poultry products should be labelled at retail to inform consumers how to handle the poultry to prevent diseases originating from microbial contaminants.

The committee's major recommendations regarding chemical residues were based on its observation that important sources of residues had not been considered in the FSIS monitoring program and that priorities for risk management had not been set according to the relative magnitude of risk for known residues. If adopted by FSIS, the following recommendations should result in distinct improvements in the residue program:

- Using degree of risk as a basis, FSIS should establish priorities for monitoring residues and associated activities.
- Potentially hazardous chemical residues in poultry and their points of origin should be identified.
- The risks associated with identified hazardous residues should be determined.
- Using known risks as a basis, FSIS in collaboration with the U.S. Environmental Protection Agency (EPA) and Food and Drug Administration (FDA) should ensure that tolerance levels are set for known hazardous residues.
- Control programs to monitor the entry of residues into poultry should be developed.
- FSIS should determine how chemically contaminated poultry might be removed from the marketplace or production line.
- FSIS should begin to lay the groundwork for shifting resources from the organoleptic inspection of each broiler chicken to a more comprehensive program with statistically based sampling as one of its primary features. This should be undertaken as a first step in modifying the traditional bird-by-bird inspection system.

Comment of the Present Committee: The present committee concluded that the portions of the 1987 report dealing with poultry (NRC, 1987a) have application to beef slaughter and the FSIS mission. Thus, they must be considered within the present committee's charge to evaluate how SIS-C integrates recommendations in previous Food and Nutrition Board reports. The present committee knows FSIS is aware of the basic concepts implicit in these recommendations and their application to beef slaughter operations. Although FSIS officials discuss these concepts frequently and they appear in several agency publications (FSIS 1986, 1990a, b, c), there is little evidence of substantive progress toward integrating them into SIS-C.

1987 Report:

FSIS should shift the focus of its residue program from the detection of contaminants in market-ready products to the prevention of their introduction at points as early as possible in the production process. Such a shift would necessarily extend the agency's interests to areas that are now the responsibility of other government (including state and local) agencies. FSIS should attempt to persuade such agencies that closer communication regarding poultry-associated health hazards is a matter of primary importance and that their effective control will require a concerted effort among responsible authorities.

Federal government support of broiler chicken inspection and related activities should be allocated primarily according to the degree that it can contribute to reductions in public health risk. The current postmortem poultry inspection system does not address or meet this objective.

Traditional poultry inspection techniques originated from the need to control diseases of poultry and to ensure a sanitary environment during slaughter. Over the past few decades, however, it has become apparent that the methods needed to detect and control poultry-associated public health threats are more complex than organoleptic inspection techniques alone can provide. Thus, the present committee agreed with the earlier Committee on the Scientific Basis of the Nation's Meat and Poultry Inspection Program that FSIS should consider using risk-assessment techniques to manage and control poultry-associated hazards. The committee hopes that its risk assessment model and its discussion of some potential applications will assist FSIS in controlling poultry-related health risks and developing a quality assurance program that will lead to nutritious and increasingly safe products.

Comment of the Present Committee: These recommendations have not been incorporated into SIS-C.

CONCLUSIONS

As a result of its analysis of the recommendations in previous Food and Nutrition Board reports and assessment of the degree of their incorporation into SIS-C, the present committee drew the following conclusions:

1. SIS-C inspection does not integrate very many of previous Food and Nutrition Board recommendations either in whole or in part. Its design predated these reports, and there is no evidence that it was redesigned to incorporate aspects of these recommendations that would have improved the public health focus of meat inspection.
2. The modifications to traditional cattle inspection that have been made to

produce SIS-C do introduce a number of concepts that are in line with previous recommendations. These are:

- The concentration of resources for organoleptic inspection has been shifted to detection of lesions rather than to detection of dressing defects. There are, however, very little data to show that this move has either increased or decreased public health protection.
 - Sampling and process control concepts have been introduced together with quantifiable finished product standards. This should permit ongoing accumulation of data on carcass defects. These data could be used to evaluate current procedures as a basis for decisions about changes in inspection systems.
 - The requirement, under certain circumstances, for Partial Quality Control (PQC) programs designed and implemented by plant management is a positive step in keeping with Food and Nutrition Board recommendations. If managers in industry take initiatives to develop these programs and show commitment to safety of the product, these programs can improve public health, regardless of inspection activities.
3. The introduction of SIS-C has been accompanied by a reduction in the number of inspection personnel assigned to these plants when compared to similar plants using traditional inspection. This presented an opportunity for FSIS to reassign the surplus inspectors within the plant to implement additional procedures in microbiological and chemical residue monitoring that had been identified as a component of an optimal inspection system, but this was not done. Had this occurred, FSIS might have found greater acceptance of SIS-C by its field staff and produced a better-program.

REFERENCES

- Brandly, P.J., G. Migaki, and K.E. Taylor. 1966. Meat Hygiene. Third edition. Lea & Febiger, Philadelphia. 1966.
- Crawford, L. 1990. FSIS will come of age in the 90's. Pp. 12-14, 24 in National Provisioner. April 23, 1990, Chicago, Ill.
- FCN (Food Chemical News). Industry Groups Wary of FSIS Plans for HACCP-Based Inspection. Food Chemical News. July 30, 1990. Pp 50-54.
- Federal Register. 1988. Proposed Rule. Streamlined Inspection System—Cattle and Staffing Standards. Fed. Regist. 53: 48262-48275.
- FSIS (Food Safety and Inspection Service). 1986. FSIS Future Agenda Response to the NAS Recommendations. June 1986. Policy and Planning Staff, FSIS/USDA, Washington, D.C. 145 pp.
- FSIS (Food Safety and Inspection Service). 1989a. The Hazard Analysis Critical Control Point (HACCP) System and the Food Safety Inspection Service; Concept Paper. October 1989. FSIS/USDA, Washington, D.C. 4 pp.
- FSIS (Food Safety and Inspection Service). 1989b. Streamlined Inspection System Guidelines. December 1989. FSIS/USDA, Washington, D.C. 85 pp.
- FSIS (Food Safety Inspection Service). 1990a. Inspection Horizons, Food Safety and Inspection Service Strategy for the 1990s. February 1990. FSIS/USDA, Washington, D.C. 13 pp.
- FSIS (Food Safety and Inspection Service). 1990b. Meat and Poultry Inspection, 1989. Report of the Secretary of Agriculture to the U.S. Congress. March 1990. FSIS/USDA, Washington, D.C. 40 pp.
- FSIS (Food Safety and Inspection Service). 1990c. Response to the National Academy of Sciences Report. Elements of an Optimal Inspection Program. Policy Evaluation and Planning Staff. May 1990. FSIS/USDA, Washington, D.C., 26 pp.
- IOM (Institute of Medicine). 1989. Human Health Risks with the Subtherapeutic Use of Penicillin or Tetracyclines in Animal Feed . A report of the Committee on Human Health Risk Assessment of Using Subtherapeutic Antibiotics in Animal Feeds. Division of Health Promotion and Disease Prevention. National Academy Press, Washington, D.C. 216 pp.
- NRC (National Research Council). 1985a. Meat and Poultry Inspection: The

- Scientific Basis of the Nation's Program. A report of the Food and Nutrition Board. National Academy Press, Washington, D.C. 209 pp.
- NRC (National Research Council). 1985b. An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients. A report of the Subcommittee on Microbiological Criteria, Committee on Food Protection, Food and Nutrition Board. National Academy Press, Washington, D.C. 436 pp.
- NRC (National Research Council). 1985c. Chapter 2: The History of the Inspection Programs and the Debate on Current Procedures. Pp. 13-20 in Meat and Poultry Inspection: The Scientific Basis of the Nation's Program. A report of the Food and Nutrition Board. National Academy Press, Washington, D.C.
- NRC (National Research Council). 1987a. Poultry Inspection. The Basis for a Risk Assessment Approach. A report of the Food and Nutrition Board. National Academy Press, Washington, D.C. 167 pp.
- NRC (National Research Council). 1987b. Regulation of Pesticides in Food. The Delaney Paradox. A report of the Committee on Scientific and Regulatory Issues Underlying Pesticide Use Patterns and Agricultural Innovation, Board on Agriculture. National Academy Press, Washington, D.C. 272 pp.
- NRC (National Research Council). In press. The Scientific and Regulatory Issues Surrounding Pesticides in the Diets of Infants and Children. A report of the Board on Agriculture and Commission on Life Sciences. National Academy Press, Washington, D.C.
- Sinclair, Upton. 1906. The Jungle. Reprinted in 1960 as a Signet Classic, The New American Library, New York, N.Y. 350 pp.
- Smith, J. A. 1990. Government shares safety responsibility. Pp. 7, 8 and 15 in National Provisioner. April 23, 1990, Chicago, Ill.
- Somers, R.K. 1966. 60 Years of Federal Meat Inspection. Agricultural Marketing. Consumer and Marketing Service, June 1966. U.S. Department of Agriculture. Washington, D.C. 2 pp.
- Wesson, K.M. 1983. A Study on the New Cattle Post-Mortem Inspection Procedures for Steers and Heifers. October 1983. USDA/FSIS, Slaughter Inspection Standards and Procedures Division, Washington, D.C. 52 pp.
- WHO (World Health Organization). 1980. Report of the WHO/ICMSF (International Commission on Microbiological Specifications for Foods) Meeting on Hazard Analysis Critical Control Point System in Food Hygiene held in Geneva, Switzerland, June 9-10, 1980. WHO, Geneva, Switzerland. 16 pp.

APPENDICIES

Appendix A

Proposed Rules

Federal Register

Vol. 53, No. 230

Wednesday, November 30, 1988

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

Department of Agriculture

Food Safety and Inspection Service

9 CFR Parts 307 and 310

[Docket No. 83-008P]

Streamlined Inspection System-Cattle and Staffing Standards

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to amend the Federal meat inspection regulations to establish a new system of post-mortem inspection for cattle. This method would be known as the "Streamlined Inspection System-Cattle" (SIS-Cattle) when the system is operated without a slaughter partial quality control (PQC) program or as the "Streamlined Inspection System/Partial Quality Control-Cattle" (SIS/PQC-Cattle) when the system is operated in conjunction with a slaughter PQC program. An approved slaughter PQC program would be required for establishments operating at slaughter rates greater than 275 head per hour. The PQC program would be optional for establishments that operate at slaughter rates of 275 head per hour or less. This SIS inspection system would be implemented in all establishments that slaughter cattle (steers and heifers only) and have an on-line staffing requirement of three inspectors or more.

SIS-Cattle would incorporate modifications of the present cattle post-mortem inspection procedure and combine viscera and carcass inspection stations so that that inspection is completed at the viscera table. The proposed rule would also establish Finished Product Standards (FPS) for carcasses, heads and tongues and standards for other edible byproducts. The FPS program uses the cumulative sum (CUSUM) which is a statistical concept used by the establishment and monitored by the inspector. Compliance is determined based on sample results collected over a period of time. These standards would be used to evaluate the wholesomeness and acceptability of products.

This proposed rule would also establish staffing standards for the inspection of steers and heifers based on work measurement data and facility requirements.

All establishments under the SIS system would be responsible for proper head, tongue, viscera, and carcass presentation. The operation of a PQC program for the presentation standards would be an option for SIS-Cattle establishments. Establishments operating under SIS/PQC-Cattle would include presentation standards in their PQC program.

The SIS-Cattle system would also require establishment employees to palpate and present the tongue, incise the cheek muscles, and open the heart for inspection personnel.

Additionally, the establishment would be responsible for the removal from carcasses of defects that are the result of the handling, slaughtering, or dressing operations and the removal of designated trimmable defects as listed in the beef carcass finished product standards program.

This system would provide an increase in slaughter method and personnel efficiency, as well as provide an increase in product yield, while still providing consumers with wholesome and otherwise unadulterated products. These gains have been demonstrated and documented in four pilot cattle establishments.

DATE: Comments must be received on or before: January 30, 1989.

ADDRESS: Written comments should be sent in duplicate to the Policy Office, Attn: Linda Carey, FSIS Hearing Clerk, Room 3175, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250 (see also "Comments" under **SUPPLEMENTARY INFORMATION**).

FOR FURTHER INFORMATION CONTACT: Dr. Douglas L. Berndt, Director, Slaughter Inspection Standards and Procedures Division, Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 447-3219.

SUPPLEMENTARY INFORMATION: Executive Order 12291

The Agency has determined that this proposal is not a major rule under Executive Order 12291. It will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The principal effect of this proposed rule is to improve post-mortem inspection procedures for cattle which will result in maximum inspection efficiency and increased productivity. Certain new requirements should be placed upon the establishment; however, these requirements would be counterbalanced by the dollar gain resulting from the increased productivity.

It is estimated that the cost of complying with these new requirements would not exceed \$40,000 per establishment. There are currently 55 operations which slaughter steers and heifers and require three or more inspectors. However, 24 of these operate in two shifts from a single facility. Therefore, the total number of facilities to be modified would be 43. As such, the estimated initial cost to industry for implementing the SIS-Cattle system would not exceed \$2 million.

Net productivity gains would offset the one-time cost of facility changes. It is estimated that an approximate 40 percent gain in productivity would result because of an establishment's ability to increase its production rate without requiring additional inspectors or inspection space. Four pilot cattle establishments under this system have been able to show, by documented evidence, an increase in yield, an increase in control of production, and better supervisory control of employees. Under SIS/PQC-Cattle, establishments should also realize further gains due to decreased product contamination, decreased trimming, increased shelf life of products, and other considerations. Actual monetary gain would depend upon the management practices at each individual establishment.

Effect on Small Entities

The Administrator has determined that this proposed rule would not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. Pub. L. 96-354 (5 U.S.C. 601). SIS-Cattle is designed for slaughter establishments having three or more inspectors. Specifically, this proposal would affect the approximately 43 establishments which slaughter steers and heifers and require three or more inspectors. Those establishments are not small entities. Establishments having less than three inspectors would not be affected by this system.

Paperwork Requirements

This proposed rule would require establishments to perform finished product and edible byproduct testing. All establishments would be required to maintain certain records to verify that the finished product standards and the edible byproduct standards have been met. This proposed rule would also require establishments operating under SIS/PQC-Cattle to develop and submit to the Administrator for approval a PQC program designed to ensure that the dressed cattle carcasses are wholesome and properly prepared. Such establishments would be required to maintain certain records to fulfill their obligation under the approved PQC programs. These requirements will be submitted to the Office of Management and Budget (OMB) under control number 0583-0015 for approval (44 U.S.C. 3504(h)).

Comments

Interested persons are invited to submit written comments concerning this proposed rule. Written comments should be sent, in duplicate, to the Policy Office and should refer to the docket number appearing in the heading of this document. All comments submitted pursuant to this notice will be made available for public inspection in the Policy Office between 9:00 and 4:00 p.m., Monday through Friday.

Background

The United States has had mandatory meat inspection for products prepared for commerce since 1906. The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) requires, among other provisions, that the Secretary of Agriculture, through appointed inspectors, carry out a post-mortem examination of the carcasses and parts of certain domesticated food animals, including cattle, which are capable of use as human food when these animals are slaughtered in an official establishment that is subject to inspection under the Act. Post-mortem inspection involves an examination by one or more trained food inspectors, under veterinary supervision, of the head, viscera, and other parts of the carcass of each animal slaughtered, for the purpose of detecting disease or other conditions that could cause the carcass or any part to become unfit for human food or otherwise adulterated.

I. Traditional Inspection

Routine cattle post-mortem inspection has traditionally been performed at three points in the slaughter operation. Cervical (head) inspection is conducted at an early point in the dressing operation; viscera inspection is conducted after the carcass has been eviscerated; and carcass inspection is conducted towards the end of the dressing operation. At each point, an inspector observes and palpates the carcass and its parts. For head and viscera inspection, an inspector also incises certain muscles, lymph nodes, and organs. The inspector examines the carcasses and directs and verifies establishment employees' performance of trimming operations. These traditional procedures, which are outlined in the Meat and Poultry Inspection Manual,¹ have proven to be an effective method of inspection and have changed little since the inception of Federal meat inspection in 1906. Since that time, however, there have been many significant changes in the way cattle are raised and moved to slaughter, in the types and frequency of cattle diseases, and in the technology used to slaughter the animals and dress their carcasses.

The improved health of cattle today is largely the result of modern production methods. A large number of cattle are now bred and raised under controlled environments designed to promote growth and prevent disease. The controlled use of various chemicals, antibiotics, and vaccines has improved the health of cattle and decreased the number of these animals rejected as human food.

Competitive pressures have produced many industry changes. Slaughter operations are now located close to where the animals are grown, thus eliminating arduous and costly shipment to slaughter. Also, the packing industry continues to become more concentrated with less than 10 percent of the cattle abattoirs slaughtering more than 75 percent of the cattle. Furthermore, automation and technology have increased industry productivity and product uniformity.

The inspection procedures for cattle carcasses have not kept pace with changes in the livestock and meat industry. By "modernizing" cattle inspection procedures, PSIS would increase its inspection productivity while maintaining the assurance of wholesomeness of cattle carcasses entering the Nation's food supply.

In certain situations, the traditional cattle inspection procedures may limit the rate at which an establishment slaughters animals and dresses carcasses. A redesigned system of cattle inspection would improve inspection productivity and allow faster line speeds for cattle slaughterers, thus providing a means for increased efficiency.

In 1982, FSIS implemented new swine post-mortem inspection procedures and staffing standards which allowed higher production rates for swine operations (August 4, 1982, 47 FR 33673). The postmortem inspection staffing standards for traditional cattle inspection were also revised at that time. During that rulemaking procedure, PSIS announced that a new method for cattle post-mortem inspection was being developed. FSIS has completed its development of the new method, called the Streamlined Inspection System-Cattle.

II. The Streamlined Inspection System-Cattle

As discussed earlier, under the traditional method of cattle inspection, inspectors are closely involved with the slaughter establishment's operations. In addition to examining each carcass for signs of disease, the inspectors identify and point out carcass dressing nonconformances and designated trimmable conditions to establishment workers, and direct them to ensure that the defects have been properly removed. Dressing nonconformances are those defects which occur on the carcass as a result of errors in the handling, slaughtering, or dressing operations performed by establishment employees. They include, but are not limited to, such things as bruises, hair, dirt, ingesta, organ remnants, and machine grease. Designated trimmable conditions are those abnormal conditions that are not caused by improper dressing procedures, that are readily identifiable, and that do not affect the disposition of the carcass. They include, but are not limited to, fractures, arthritis, localized abscesses, and pigmentation. The identification and directing for removal

¹ A copy of the Meat and Poultry Inspection Manual is on file in the office of the FSIS Hearing Clerk.

of these conditions have become a significant part of the inspection job and require 70-90 percent of carcass inspectors' time. These carcass dressing nonconformances and designated trimmable conditions are obvious and easily identifiable by a skilled person. Agency officials have concluded that responsibility for controlling the dressing operation and removing obvious and readily identifiable carcass dressing nonconformances and designated trimmable conditions could be shifted to the establishment. This would allow inspectors to direct their efforts toward the detection of cattle disease conditions and enable the cattle industry to assume full responsibility for dressing operations.

Since the greatest increase in inspector efficiency can be realized at the higher slaughter rates, SIS-Cattle and SIS/PQC-Cattle would apply only to those establishments slaughtering steers and heifers with three or more on-line inspectors. SIS-Cattle consists of a routine post-mortem inspection procedure whereby the inspector would focus on disease conditions and whole carcass disposition, while the establishment employee would focus on control of the dressing operations. For the purpose of monitoring the establishment's removal of dressing nonconformances and designated trimmable conditions, finished product standards for carcasses including tongues and heads, and standards for other edible byproducts have been developed and included in this proposal.

Finished Products Standards (FPS) were tested and then validated by additional tests in a number of establishments before the initiation of SIS-Cattle. These establishments were operating under traditional inspection, which is a carcass-by-carcass inspection. The standards are based on the average quality of product produced following good manufacturing practices that were monitored using traditional inspection procedures. Historically, this process has produced a product with a level of cleanliness that has been considered aesthetically acceptable within the requirements of the Federal Meat Inspection Act. Therefore, Agency officials have concluded that when good manufacturing practices are followed, a process that yields products meeting the FPS have an inherent level of cleanliness and are acceptable. Carcasses whose degrees of cleanliness are found to be within the action level, are not injurious to health or otherwise unfit for human food, and are therefore considered by the Agency not to be adulterated.

The process of monitoring compliance with finished product standards will utilize the CUSUM statistical concept, which is defined as a statistical method for comparing the output of a process against finished product standards to determine compliance. The point at which product action is required is determined by an "action" number, "subgroup absolute limit," or "subgroup maximum limit." The action number for this process was determined by statistically weighing the test data results collected for NCIS.

Tolerance number, start number, subgroup absolute limit, subgroup maximum limit values and number of defects per sample were given values based on professional judgement of experienced veterinarians and other field personnel after analyzing the test data. In determining these values, defects are weighted on the basis of public health significance or by how obvious the defect was in terms of expected good manufacturing practice.

The standards for edible byproducts were developed in response to a need recognized by both industry and the Food Safety and Inspection Service (FSIS) for objective standards for such product. The Slaughter Inspection Standards and Procedures (SISP) Division of Technical Services collected data from randomly selected federally inspected establishments nationwide to determine the level of quality at which inspectors were accepting finished byproducts. The standards for edible byproducts were determined in the same manner as for carcasses.

A PQC program along with the SIS-Cattle system would be required in establishments that slaughter cattle at rates greater than 275 head per hour. The velocity of the conveyer at speeds in excess of 275 head per hour has multiple effects on the slaughter operation as well as on the inspection operations. Successful high speed operation require installation and maintenance of optimum facilities, close supervision of operators' techniques, and an aggressive, problem-solving attitude by management personnel in order to produce carcasses and parts which meet the FSIS Finished product standards. A prevention-oriented process control program is essential for the successful maintenance of a high speed operation which routinely produces a wholesome product. Agency officials have determined that establishments with speeds in excess of 275 head per hour must operate under a quality control program to ensure the uniform production of a wholesome, unadulterated product. The selection of a speed of 275 head per hour was based upon the results of interviews with experienced field veterinarians and FSIS supervisors, and the results of work measurement studies. In their professional judgement, speeds above that rate required the additional assurance afforded by a partial quality control program. The application of the finished product standards and the PQCA program would be the responsibility of establishment employees and would be monitored by inspectors to ensure the production of wholesome product.

The provision for uniform presentation standards is a key element in the streamlined inspection system. The presentation standards would have to be met to ensure the effectiveness of inspection when the proposed staffing standards are used. Presentation standards would be applied by inspectors, when not included in a PQC program. A separate PQC program for presentation would be optional for establishments operating under the SIS-Cattle program at slaughter rates of 275 head per hour or less.

A. The SIS-Cattle Post-Mortem Inspection Procedure

A study comparing the effectiveness of the traditional procedure to that of the proposed procedure was conducted in four establishments slaughtering steers and heifers using the New Cattle Inspection System (NCIS), the forerunner of SIS. FSIS evaluated a total of 28,800 samples—7,200 from each establishment (3,600 inspected by the traditional procedure and 3,600 by NCIS). An analysis was made of the percentage of units that were free of errors. The results of the study showed that the inspection error rate with NCIS is equal to, or lower than, the inspection error rate with the traditional procedure.² FSIS officials, using data obtained during the effectiveness study, determined that the procedures eliminated under the SIS inspection system were not necessary to make an accurate disposition of cattle carcasses and parts.

In 1986 a feasibility study was performed using the NCIS with changed presentation requirements for the head and heart. This new system was called the Streamlined Inspection System (SIS) for Cattle. Since there was no change in the inspection procedure, no additional

² A report of this study is available upon request from the Slaughter Inspection Standards and Procedures Division, Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250 Area Code (202) 447-3219.

testing was required. Now industry's presentation for inspection must meet a minimum presentation standard to ensure that there is adequate time to perform inspection.

1. **Cervical (head) inspection.** Under the traditional cervical inspection procedure, the inspector performs the following: (1) Observes the eyes and surfaces of the head; (2) incises the mandibular, parotid, lateral retropharyngeal (atlantal), and medial retropharyngeal (suprapharyngeal) lymph nodes; (3) incises the lateral and medial masticatory muscles (cheeks); and (4) observes and palpates the tongue.

The SIS cervical inspection procedure would differ from the traditional one in three principal ways. First, the new procedure would eliminate the requirement to incise the lateral retropharyngeal (atlantal) lymph nodes. Instead, the lateral retropharyngeal lymph nodes would be observed by inspectors for abnormalities. Second, the inspector would observe the masticatory muscles only after an establishment employee presents the incised muscles for inspection. Third, the inspector would observe the surfaces of each tongue and routine palpation would be eliminated. In the development of the New Cattle Inspection System, it was determined that abnormalities found in the tongue do not affect whole carcass disposition. This premise was tested and documented in four test establishments and found to be valid. Therefore, as part of the routine dressing operation, an establishment employee would palpate each tongue for abnormalities prior to the cervical inspection station and notify the cervical inspector of any abnormal findings. Thus, the palpation of tongues by establishment personnel is considered a sorting function only. The cervical inspector would then determine the significance of the findings and take appropriate action. These procedures are monitored by inspection personnel who are not working on the line, such as the inspector in charge or an offal inspector. In addition, prior to chilling, all tongues would be subject to finished product standards using a statistically based sampling program.

2. **Viscera/carcass inspection.** Carcass inspection would be performed together with viscera inspection at the viscera/carcass inspection station.

a. *Viscera inspection.* Under the traditional cattle inspection procedure, the inspector performing viscera inspection is required to: (1) observe the mesenteric lymph nodes, the abdominal viscera, the esophagus and spleen, and the ventral surfaces of the lungs; (2) observe and palpate the rumenoreticular junction, the dorsal (costal) surfaces of the lungs, and the surfaces of the liver; and (3) incise and observe the tracheobronchial (bronchial) and mediastinal lymph nodes, the heart, the hepatic (portal) nodes, and the bile duct. Under the SIS-Cattle inspection procedure, the viscera inspector would not observe the ventral surfaces of the lungs, but would continue to observe and palpate the dorsal (costal) surfaces of the lungs. The SIS procedure would eliminate the requirements to incise and observe the right tracheobronchial (bronchial) lymph node, to incise the heart, to incise the hepatic (portal) lymph nodes, and to palpate the rumenoreticular junction. The heart would be inspected by observation only after an establishment employee presents the incised organ for inspection.

b. *Carcass inspection.* The traditional carcass inspection procedure includes palpation and observation of the superficial inguinal lymph nodes in the male or mammary (supramammary) lymph nodes in the female, medial (internal) iliac lymph nodes, diaphragm, and kidneys. Inspection also includes the observation of the lumbar region, pillars of the diaphragm, peritoneum, pleura, cut surfaces of muscles and bones, and the exterior surface of the carcass.

The SIS carcass inspection procedure would eliminate palpation of the diaphragm, superficial inguinal (mammary) lymph nodes, medial (internal) iliac lymph nodes, and kidneys. The procedure, however, would include the observation by the inspector of the diaphragm, lymph nodes, and kidneys. The inspector would not observe the split vertebral column and surrounding tissues.

Under the SIS procedure, the inspector would observe the dorsal surfaces of the carcass with the aid of a large mirror strategically placed behind the moving carcasses at the viscera station. The establishment would be required to furnish adequate lighting for the minor examination.

In order to achieve maximum inspector efficiency at the lower speeds, the new procedure would require the kidneys to be exposed and removed from the carcass for presentation along with the viscera at the viscera/carcass station. An exception to the kidney removal requirement would be offered to establishments slaughtering at rates greater than 234 per hour. Based on work measurement studies, an additional inspector is required at a rate of 234 per hour. The work measurement study showed that kidney removal did not improve inspector efficiency if the additional inspector was dedicated to carcass and kidney inspection only.

By combining viscera inspection and carcass inspection into a single viscera/carcass inspection station, FSIS would be able to maximize inspector efficiency. Also, the elimination of the traditional carcass inspection station would facilitate the establishment's assumption of its responsibility for the identification and removal of dressing nonconformances. Since inspection would be completed at the viscera/carcass inspection station, there would be greater assurance that all carcass parts and organs are accurately identified with the corresponding carcass throughout the dressing operation. Under traditional inspection there is physical separation of the carcass and viscera after the viscera inspection station. An inspection decision at the carcass station which might affect carcass disposition creates a logistical possibility of loss of identity of the viscera. Under SIS-Cattle, inspection has complete visual control of the viscera and carcass until inspection is completed.

B. The Slaughter Partial Quality Control (PQC) program

Recent field studies in selected pilot establishments have reinforced FSIS' long-standing view that Federal meat inspection is more efficient and effective in establishments where the concepts of production control are practiced, in contrast to establishments which do not maintain the facilities, personnel, or procedures necessary to ensure control of their production operations. Establishments without production operation control tend to rely on the inspection service as a substitute for proper management and control of their operations. This subsequently requires Federal meat inspectors to carry out quasi-supervisory functions that are inherently an establishment's responsibility. An establishment's PQC program would eliminate the need for the inspection service to act in a quasi-supervisory role and would greatly improve inspector efficiency.

Under SIS-Cattle, establishments that operate at slaughter rates greater than 275 head per hour would be responsible for designing their own slaughter PQC program. The PQC program would be optional for establishments that operate at slaughter rates of 275 head per hour or less. The PQC program, developed by the establishment, would consist of three major elements: (1) Identification of points (generally known as critical control points) in the slaughter and

dressing operation which are critical to the production of carcasses in compliance with the finished product standards for dressed cattle carcasses; (2) development of certain standards at each control point; and (3) specification of a series of predetermined actions to be taken if critical control point standards are not met. The last critical point of each program would involve the examination of samples of finished carcasses, heads, tongues, and other edible byproducts to determine compliance with the finished product standards program. The PQC program would further define how often each critical point is checked by the establishment and would include a recordkeeping system.

The establishment's PQC program would be submitted to and approved by the Administrator under section 318.4 (9 CFR 318.4) of the Federal meat inspection regulations and the requirements outlined in this document. The establishment would conduct the program, and FSIS would monitor the operation to ensure that the provisions of the PQC program and regulations are met. FSIS' monitoring activities would consist principally of reviewing critical control point records and periodically sampling and examining products at the slaughter line critical control points to ensure the production of dressed carcasses which meet the finished product standards.

C. Presentation Program

The provision for uniform presentation standards is a key element in the streamlined inspection system. Presentation of the head, tongue, viscera, and carcass has traditionally been a responsibility of the establishment based on standards established by the inspector in charge. Uniform presentation is important in maintaining inspection efficiency and is critical at the higher rates of slaughter. When the carcass or its parts are not uniformly presented in a predetermined manner, time allotted for inspection must be used to correct or compensate for presentation errors. The adequacy of presentation, in turn, depends on such factors as disease conditions, establishment operating conditions, lighting, and facilities. FSIS has developed guidelines for the presentation of the head, tongue, viscera, and other parts of the carcass in official slaughter establishments.³ These guidelines provide objective criteria for determining acceptable presentation and for reducing the line speeds when presentation is less than acceptable. These guidelines would be applied by FSIS as a part of SIS-Cattle. In the SIS/PQC-Cattle program, the guidelines would be included in the establishment's PQC program which is monitored by FSIS.

III. Operational Requirements for the Streamlined Inspection System-Cattle.

There would be three areas of responsibility for an establishment under SIS-Cattle: (A) Inspection of the carcass, viscera and head. (B) equipment, facilities, and inspection space, and (c) removal of carcass and edible byproduct nonconformances. These responsibilities are described below along with a discussion of how they may affect the cattle industry.

A. Presentation of the Carcass and Its Parts For Inspection

The primary difference between SIS-Cattle and SIS/PQC-Cattle is the party responsible for assuring proper presentation of the head, tongue, viscera, kidneys, and other parts of the carcass for inspection according to standards set by FSIS.

The presentation guidelines for establishments operating under SIS-Cattle would be applied by FSIS. Establishments may request a PQC program for presentation. If approved, the establishment would have the responsibility of applying the guidelines with inspectors monitoring its application. Establishments operating under SIS/PQC-Cattle must include the presentation program in their PQC program and would be responsible for applying it. If post-mortem inspection cannot be performed at the current line speed under SIS-Cattle or SIS/PQC-Cattle because of preparation of presentation deficiencies or because of disease incidence, the inspector in charge would have the authority to require the establishment to reduce speed and take other corrective actions necessary for proper presentation for inspection. The following presentation standards are applicable to both SIS-Cattle and SIS/PQC-Cattle:

1. *Head and tongue presentation.* Prior to the inspector's examination of the tongues, an establishment employee would palpate the tongues and notify the inspector if abnormalities were found. Notification to the inspector would be accomplished either directly or by means of a marking system developed by the establishment and acceptable to the inspector in charge, such as tags, rings, cuts, or other markings. The inspector would visually inspect and incise the lymph nodes of each tongue and palpate any tongue identified as abnormal by the inspector or by an establishment employee on examination. A finished products standards program, which is statistically based, would be applied to ensure that only wholesome tongues would pass. This procedure is effective in detecting conditions relating to adulteration and wholesomeness as the current procedure. (See footnote 2 which refers to the study done to validate this point)

Prior to the inspector's examination of the head, an establishment employee would incise both lateral and medial masticatory muscles (cheeks) for inspection. The establishment would be responsible for assuring that the cheek muscles were properly incised and presented for inspection.

2. *Viscera.* An establishment employee would open all chambers of the heart and incise the interventricular septum before it reaches the inspector. The inspector would observe all surfaces of the heart for abnormalities.

3. *Carcass.* The establishment would be required to spread the carcasses at the viscera/carcass station so that carcass inspection could be performed.

B. Equipment, Facilities and Inspection space

The facilities required by SIS-Cattle for viscera/carcass inspection would include a mirror for viewing the dorsal surface of the carcass, additional lighting for the mirror, and lighting to adequately view the interior of the unsplit carcass at the combined viscera/carcass station. In addition, the space required to perform cervical (head) inspection would be based on three interrelated variables: (1) The velocity of the head chain; (2) the number of heads presented per hour, and (3) the spacing between heads. In some establishments, the cumulative effect of these variables would require additional workspace to perform cervical inspection. Table 1 in § 307.2(m) of this proposal supplies the maximum required workspace for cervical inspectors when heads are spaced 4 feet apart. Additional tables for head spacings of other than 4 feet will be available from the Agency. As discussed earlier, additional workspace may be needed in those establishments where kidneys must be removed prior to the viscera/carcass inspection station. Most establishments should gain workspace

³ These guidelines are available for public inspection in the office of the FSIS Hearing Clerk. Copies may be obtained free upon request from the Slaughter Inspection Standards and Procedures Division, Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

as a result of the removal of the inspector from the traditional carcass inspection station.

1. *Line speed indicator.* A digital line speed indicator for both the head chain and the evisceration chain would be required at a location which is readily accessible to the inspector in charge. Knowledge of the line speeds is necessary to ensure that the inspection stations are properly staffed.

2. *Mirror.* For cattle slaughter lines with a moving top viscera table and requiring three or more inspectors as prescribed by the new staffing standard, a one-piece, distortion-free, glass or plastic mirror would be required. This mirror would be mounted and positioned, (i.e. angled or tilted) so the inspector may have a clear unobstructed view of the dorsal surface of the carcass.

3. *Lighting.* Shadow-free lighting with a minimum Color Rendering Index (CRI) of 85⁴ would be required at each inspection station. In addition, a diffuse light source (such as a double tube fluorescent light fixture) would be mounted at the top of the carcass mirror to provide adequate light at the carcass shoulder level. Directional lighting would also be required at the viscera/carcass inspection station so that adequate light would be provided inside the thoracic cavity of the carcass. This lighting would be carefully adjusted so that it would pass through the relatively narrow opening in the ventral surface of the carcass lighting the sides and back of the cavity in sequence.

4. *Inspection space.*

a. *Cervical inspection station* Cervical inspection is currently required to be completed prior to viscera inspection (Meat and Poultry Inspection Manual, section 11.1(h)(1). See footnote¹). In some instances, when establishments have added new equipment and/or remodeled their slaughter facilities, it has been necessary, when a moving chain is used, for them to increase the velocity of the head chain in order to meet this inspection requirement. There would be new requirements for cattle cervical inspection when the heads are spaced evenly on the head chain at 4-foot intervals. The interrelationships between the speed of the head chain, the rate at which heads are presented for inspection, the number of inspectors needed, and the required workspace for inspectors to inspect them are defined in the proposed regulation.

If the head spacing is less than 4 feet, the head chain velocity must be proportionally decreased. Establishments which desire to space heads at distances greater than 4 feet would be handled on an individual basis as discussed earlier (Section III B). The velocity of the head chain would not be allowed to exceed the maximum limits.

b. *Tongue and head reinspection station.* For evaluating samples of finished tongues and heads, as required by the finished product standards program, a reinspection area would be required where the manufacturing process is determined to be completed. It would be required to be illuminated as defined in the facility requirements of this proposed rule. The area would include a reinspection table or stand with hooks. It is proposed that the reinspection area be located as close as possible to the head chain and/or area of head processing completion in order to minimize work and maximize the flow of product.

c. *Viscera/carcass inspection station.* The inspection space at the viscera/carcass inspection station for slaughter rates of 234 head per hour or less would remain unchanged at 8 feet. However, the space for the inside carcass inspector would increase to 9 feet and be arranged with 5 feet along the viscera table and 4 feet along the line of travel of the carcasses. When kidneys are presented in the carcass (slaughter rates greater than 234 head per hour), the kidneys and carcasses would be inspected from an adjustable platform, the height of which can be easily and rapidly adjusted from the platform. The platform would have to meet specific minimum width and length requirements. Under these specifications, establishments would be required to submit blueprints for approval to FSIS' Facilities, Equipment, and Sanitation Division. The complete specifications may be obtained from Facilities, Equipment, and Sanitation Division, Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250; (202) 447-5627. Slaughter rates greater than 400 head per hour would require additional facilities, developed by the establishment, to allow organs to remain at the inspection station until the inspector has completed routine inspection tasks. In addition these facilities will allow proper identification of the carcass and its parts throughout the inspection process.

d. *Carcass reinspection station.* For evaluating samples of finished carcasses, as required by the finished product standards program, a reinspection area would be required off the main conveyer chain, large enough to adequately hold six to nine carcasses for defect examination and illuminated as defined in the facility requirements of this proposed rule. The area would also include a stationary platform. The space is best located after the carcass wash end before entry into the cooler. However, it may alternatively be located before the carcass wash.

C. Carcass Dressing Requirements

Establishment employees would be responsible for independently removing dressing nonconformances and other designated trimmable conditions. This would include, but not be limited to, bruises, certain abscesses and adhesions, larvae of *Hypoderma bovis* and *Hypoderma lineata* (cattle grubs), hair, dirt, organ remnants, and grease and oil.

IV. Inspector Staffing Requirements

Preliminary inspector staffing requirements (known as inspector staffing standards) have been developed for establishments that slaughter steers and heifers at rates requiring three or more on-line inspectors. Proposed SIS staffing standards are under development for establishments which slaughter steers and heifers and require less than three inspectors, and for establishments slaughtering cows and bulls. It is anticipated that the inspection rates for cows and bulls would be less than those for steers and heifers. Cows and bulls are not subject to this proposed regulation.

V. Impact of Implementation

SIS-Cattle would enable FSIS to inspect cattle more efficiently and effectively. The change in location of the kidney inspection operation would accomplish two desirable goals. First, kidneys may be inspected at the same time as other organs to allow correlation of all Findings simultaneously by the inspectors. The traditional method of kidney inspection in the United States has been criticized by foreign inspection officials because Findings cannot be correlated simultaneously with all visceral organs. Second, combining the carcass and viscera inspection stations would allow both industry and inspection personnel greater assurance that the correct viscera remains identified with the corresponding carcass until disposition of the carcass and all of its parts has been made.

Combining the carcass and viscera inspection stations in the slaughtering establishment should benefit both the industry and the government. SIS-Cattle

⁴ This requirement may be met by using deluxe cool white or high intensity fluorescent type lighting

would be utilized in establishments using three or more on-line inspectors. These establishments may elect to use the SIS/PQC-Cattle. As discussed in the preamble summary and section II of this document, those establishments currently slaughtering at rates greater than 275 head per hour would be required to convert to SIS/PQC-Cattle in order to control their operation. Those establishments which do not develop and implement a PQC program to control their operation would be required to reduce their rate of production to 275 head per hour. Establishments slaughtering at rates of 275 head per hour or less can demonstrate sufficient process control without a formal QC program and QC personnel Those establishments wanting to exceed 400 head per hour would be required to develop methodology, i.e., side tables to allow organs to remain accessible to the inspector until inspection is completed.

It is anticipated that the cattle slaughtering industry would experience a net gain if this new system of inspection were implemented, in spite of the initial costs of facility modifications which may be necessary in some establishments. Based on pilot testing, the industry as a whole should realize a savings because of increased productivity and reduced overtime. Also, the pilot tests indicated that by assuming a more active role over the control of its dressing operations, the industry should be better able to control its rate of production and its cost per unit produced.

List of Subjects

9 CFR Part 307
Facilities
9 CFR Part 310
Meat inspection
For reasons set out in the preamble, Title 9, Parts 307 and 310 of the Code of Federal Regulations would be amended as follows:

Part 307—Facilities for Inspection

- 1. The authority citation for Part 307 continues to read as follows:
Authority: 41 Stat. 241. 7 U.S.C. 394; 34 Stat. 1264, as amended, 21 U.S.C. 621; 62 Stat. 334, 21 U.S.C. 695, 7 CFR 2.15(a), 2.92.
- 2. Section 307.2(m) introductory text. (1) and (2) would be revised and (m)(7) through (11) would be added to read as follows:

§ 307.2 Other facilities and conditions to be provided by establishment.

- (m) In addition to any facilities required to accomplish sanitary dressing procedures, the following inspection station facilities for cattle and swine slaughter lines described in paragraphs 310.1(c) and (d) of this subchapter are required:
- (1)(i) An inspection station consisting of 5 feet of unobstructed line space for each head or carcass inspector and, for viscera table kills, 8 feet for each viscera inspector on the inspector's side of the table, except as provided in paragraphs (1)(ii) of this section.
- (ii) Streamlined inspection System—Cattle. A cattle viscera/carcass inspection station consisting of 8 feet for each inspector on the inspector's side of the table for slaughter rates of 234 head per hour or less. The inside carcass inspector requires 5 feet of viscera table space and 4 feet of inspection space along the line of carcass travel at slaughter rates of 234 cattle per hour or less. At slaughter rates greater than 234 cattle per hour, an adjustable platform described in § 307.2(m)(10) shall be required. The cervical inspection station space requirements for steers and heifers are listed in Table 1 of this paragraph.

TABLE 1 —CATTLE CERVICAL INSPECTION REQUIREMENTS UNDER STREAMLINED INSPECTION SYSTEM
STEERS AND HEIFERS TONGUE-OUT PRESENTATION

(Preliminary Staffing Standards).			
Inspection Rate (Heads/Hour)	Maximum ¹ Heed Chain Speed (Feet/Minute)	Number of Heed inspectors Required	Total Minimum Required Length of Work-space (in feet)
² 59-180	12.1	1	5
181-233	16.9	2	10
234-290	21.0	2	11
291-341	25.7	2	12
342-393	26.2	2	13
394-471	31.5	3	19

¹ Head chain speed is based on head spacings of 4 feet per head.
² 59 heads per hour is based on the current inspection standard in 9 CFR 310.1

- (2)(i) A minimum of 50 foot candles of shadow-free lighting at the inspection surfaces of the head, viscera, and carcass, except as provided in paragraph (2)(ii) of this section. (ii) Streamlined Inspection System—Cattle. A minimum of 100 foot candles of shadow-free lighting with a color rendering index of 85 ¹ or more at each inspection station. In addition, a light source is required to be mounted at the top edge of the carcass mirror to provide a minimum of 100 foot candies of shadow-free lighting at carcass shoulder level. To provide light inside the thoracic and abdominal cavity of the carcass for inspection, a directional shadow-free light of at least 50 foot candles, measured inside the thoracic cavity, is required.

- (7) Streamlined Inspection System—Cattle. A digital line speed indicator for both the head chain and the evisceration chain shall be provided at a location on the slaughter floor which is readily accessible to the inspector in charge.
- (8) Streamlined Inspection System—Cattle. One glass or plastic distortion-free mirror, at least 40 inches by 90 inches, shall be so mounted that an inspector standing at the viscera/carcass inspection station may clearly view the dorsal surface of the carcass.

¹ This requirement may be met by deluxe cool white or high intensity type of fluorescent lighting.
² This requirement may be met by deluxe cool white or high intensity type of florescent lighting.

points. The platform shall be equipped with handwashing facilities for persons working at the station. A 24-inch stationary, protective wall or shield shall be provided around the movable platform.

(11) Additional facilities, which will allow organs to remain at the inspection station until inspection is completed and ensure that the identity of the carcass and its parts is maintained, are required when slaughter rates exceed 400 cattle per hour.

Part 310—Post-Mortem Inspection

3. The authority citation for Part 310 continues to read as follows:

Authority: 34 Star 1280, 79 Stat. 903, as amended, 81 Stat 584, 84 Stat 91, 438; 21 U.S.C. 71 *et seq.*, 601 *et seq.*, 33 U.S.C. 1254

(b).

4. Section 310.1 would be amended by redesignating paragraph (b)(1) as (b) and revising the first sentence of new paragraph (b); by redesignating paragraph (b)(2) as (c)(1) and revising (c)(1) introductory text and the fourth sentence of new paragraph (c)(1)(i)(A) revising the sixth sentence of new paragraph (c)(1)(i)(B), and revising the charts for Heifers and Steers in new paragraphs (c)(1)(i), (c)(1)(ii), and (c)(1)(iii); by adding a new paragraph (c)(2); and by redesignating paragraph (b)(3) as (d), to read as follows:

§ 310. 1 Extent and time of post-mortem inspection: post-mortem staffing standards.

(b) The staffing standards on the basis of the number of carcasses to be inspected per hour are outlined in paragraphs (c) and (d) of this section. * * *

(c) *Cattle inspection.* (1) For all cattle staffing standards, an "a" in the "Number of Inspectors by Stations" column in the tables in this paragraph means that one inspector performs the entire inspection procedure and a "b" means that one inspector performs the head and lower carcass inspection and a second inspector performs the viscera and upper carcass inspection.¹

(i) Inspection Using the Viscera Truck.

STEERS AND HEIFERS			
Maximum slaughter rate (head per hour)	Number of inspectors by stations		
	Head	Viscera	Carcass
1 to 27	a	a	a
28 to 56	b	b	b
57 to 84	1	1	1
85 to 87	1	2	1
87 to 143	2	2	1

(A) * * * The adjusted maximum rate is the maximum rate in paragraph (c)(1)(i) of this section minus total of the deduction figures. * * *

(B) * * * The adjusted maximum rate is the maximum rate in paragraph (c)(1)(i) of this section minus the number calculated above. * * *

(ii) Inspection Using Viscera Table, Tongue-In Presentation of Heads.

STEERS AND HEIFERS			
(Preliminary staffing standards)			
Maximum inspection rates ¹ (head/hour)	Number of inspectors (by stations)		Total number of inspectors
	Cervical station	Viscera/carcass station	
1 to 32	a	a	1
33 to 58	b	b	2
59 to 142 ²	1	2	3
143 to 180	2	2	4
181 to 232	2	3	5
233 to 285	2	4	6
286 to 322	2	6	7
323 to 375	3	6	8
376 to 400	3	6	9

¹ A uniform presentation of the carcasses by the establishment that is acceptable to the inspector in charge is essential to maintain the specific inspection rate.

² The head per hour is based on the current standard in §310.1.

STEERS AND HEIFERS			
(Preliminary staffing standards)			
Maximum inspection rates (head/hour)	Number of inspectors (by stations)		Total number of inspectors
	Cervical station	Viscera/carcass station	
1 to 32	a	a	1
33 to 58	b	b	2
59 to 180	1	2	3
181 to 233	2	2	4
234 to 290 ¹	2	3	5
292 to 341 ¹	2	4	6
342 to 393 ¹	2	5	7
(Preliminary staffing standards)			
Maximum inspection rates (head/hour)	Number of inspectors (by stations)		Total number of inspectors
	Cervical station	Viscera/carcass station	
394 to 471 ¹	3	5	8

"a" denotes that one inspector performs entire

"b" denotes that one inspector performs the head and lower carcass inspection and a second inspector performs the viscera and upper carcass inspection.

¹ denotes slaughter rates where kidneys not removed from the carcass.

(2) Streamlined Inspection System—Cattle. The inspection procedures for Streamlined Inspection System—Cattle are described in § 310.22 of this subchapter and apply to establishments which slaughter steers and heifers and have a staffing requirement of three or more inspectors. Staffing standards are predicated upon the use of a mirror as described on paragraph 307.2(m)(8) at the viscera/carcass station and are based on inspectors rotating through all inspection stations during the shift to equalize the workload.

(d) * * * *

5. A new § 310.22 would be added to read as follows:

§ 310.22 Streamlined inspection System—Cattle procedures.

(a) Streamlined Inspection System (SIS)—Cattle procedures apply only to establishments which slaughter steers and heifers and which have a staffing requirement of three or more inspectors. Inspection under this system is conducted in two phases, postmortem inspection and reinspection.

(b) Definitions. For purposes of this section, the following definitions shall apply:

(1) *Cumulative Sum (CUSUM).* A statistical method for comparing the output of a process against finished product standards to determine compliance. The level of conformance with finished product standards is determined by calculating the CUSUM of nonconformances found in consecutive, randomly selected sample subgroups. The current CUSUM equals the sum of the total value of nonconformances for a subgroup plus the starting CUSUM (either the start number or the CUSUM for the previously tested subgroup), minus the tolerance number. CUSUM may not be less than zero or greater than the action number.

¹ The "Maximum Slaughter Rates" figures listed in paragraph (c)(1)(i) of this section for one (a) and two (b) inspector slaughtering lines are overstated because the time required to walk from one inspection station to another is not included. To determine the proper adjusted maximum slaughter line speed, paragraph (c)(1)(i)(A) of this section for one inspector slaughtering lines or paragraph (c)(1)(i)(B) of this section for two inspector slaughtering lines must be used along with their accompanying rules.

(2) *Tolerance number.* The total value of nonconformances in each subgroup if product is being produced at a national average product quality level. See [Table 2](#) of this section.

(3) *Action number.* A CUSUM value which indicates that product action is required. See [Table 2](#) of this section.

(4) *Start number.* A value halfway between zero and the action number. The start number is used to determine the starting CUSUM for the first subgroup of a shift and to reset the CUSUM value if the CUSUM is equal to or greater than the action number. See [Table 2](#) of this section.

(5) *Subgroup.* For carcasses, three half-carass (three sides) sample units collected before product enters the cooler, for edible byproducts, except for tongues and heads, ten sample units of each byproduct; and for tongues and heads, five tongue and five head sample units collected prior to chilling.

(6) *Subgroup absolute limit.* The tolerance number plus 5. See [Table 2](#) of this section.

(7) *Maximum number.* For edible byproducts the maximum number of nonconformances for each of the 12 categories that may be recorded for a single sample unit. The maximum number for each category is contained in [Table 3](#) of this section.

(8) *Subgroup maximum limit.* For tongues and heads, when 3 or more sample units in a subgroup have nonconformances that equal or exceed the maximum number for any one nonconformance; for other edible byproducts the limit is 5 or more.

(9) *Rework.* Reprocessing the product to correct the condition or conditions causing the nonconformances listed in [Tables 1](#) and [3](#) of this section. Removal of the condition causing nonconformance shall be performed as prescribed in § 310.18 of this subchapter.

(10) *Corrective action.* The source of the problem is identified, and the problem is corrected at one or more locations in the slaughter process. Any affected product will be made acceptable prior to the product's entering commerce.

(11) *Nonconformances.* Defects which occur on the carcass or edible byproducts as a result of errors in the handling, slaughtering, or dressing operation performed by establishment employees. These are categorized for carcasses in [Table 1](#) and for edible byproducts in [Table 3](#).

(12) *Recondition.* Removing a carcass from the evisceration line for the removal of nonconformances.

(13) *Designated trimmable condition.* Designated trimmable conditions are those abnormal conditions that are not caused by improper dressing procedures, are readily identifiable and that do not affect the disposition of the carcass. See [Tables 1](#) and [3](#) in this section.

(14) *Process in control.* The process is in control when it is producing product that meets the standard, and has done so over a period time measured by having two or more consecutive subgroup test results at or below the tolerance number. The process will be monitored by random sampling.

(15) *Process out of control.* The process is out of control when process verification test results are above the tolerance number. The establishment may stop identifying product for rework after a verification test result is below tolerance; however, the process is not in control until a second consecutive verification test result is below tolerance. Random sampling is suspended while the process is out of control.

(c) *General.* (1) The inspector in charge shall have the authority to require the establishment to reduce line speeds as stated in § 310.1(b) of this subchapter.

(2) Adulterated product shall be condemned and destroyed, except that carcasses, parts of carcasses, and edible byproducts which may be made wholesome by rework under the supervision of the inspector may be passed after the condition causing the nonconformance is removed as prescribed in § 310.18. Inspectors shall monitor the sampling of finished carcasses and parts of carcasses for compliance with finished product standards (See [Table 1](#) of this section) and shall monitor edible byproducts for compliance with edible byproducts standards (See [Table 3](#) of this section). If nonconformances are present at certain statistical levels, the establishment shall take corrective action. If the establishment does not take corrective action, the inspector shall initiate corrective action.

(3) The inspector shall determine which carcasses and edible byproducts shall be condemned, retained for veterinary disposition, or allowed to proceed as a passed carcass or edible byproduct subject to trim and reinspection. Carcasses with nonconformances listed in [Table 1](#) of this section, which do not require condemnation of the entire carcass, shall be passed by the inspector, but shall be subject to reinspection to ensure the physical removal of the nonconformances. The inspector shall identify such carcasses for trim when the defects are not readily observable and shall identify carcasses for reconditioning. Trimming of carcasses passed subject to reinspection shall be performed by one or more establishment trimmers positioned after carcass splitting and prior reinspection.

(d) *Post-mortem inspection.* (1) *Facilities.* The establishment shall provide inspection stations in compliance with § 307.2(m) of this subchapter.

(2) *Presentation.* (i) *Head (cervical).* (A) *Tongue:* Prior to inspection, an establishment employee shall palpate the tongue and notify the inspectors at the cervical station of any abnormalities. Notification to the inspectors shall be accomplished either directly or by means of a marking system, i.e., tags, rings, cuts, or other markings, developed by the establishment and acceptable to the inspector in charge. The inspector shall palpate any tongue identified as abnormal.

(B) *Masticatory Muscles:* Prior to inspection, an establishment employee shall incise the muscles of mastication. The inspector shall observe the incised muscle surfaces.

(ii) *Viscera/carcass.* (A) *Heart:* An establishment employee shall open all chambers of the heart and incise the interventricular septum to fully expose the interior of the heart.

(B) *Kidney:* An establishment employee shall open the kidney capsule, separate the kidneys from the carcass and present the kidneys for inspection with the viscera at viscera/carcass station. An exception to this kidney presentation requirement may be requested for slaughter rates greater than 234 per hour to permit the exposed kidneys to remain attached to the carcass. An inspector shall observe the kidneys for abnormalities.

(C) *Carcass.* The establishment will ensure the carcass is spread. An inspector shall observe the dorsal surface of the carcass for abnormalities with the aid of a mirror as described in § 307.2(m)(7) of this subchapter. Carcasses infested with the larvae of the oxwarble fly (*Hypoderma lineata* and *Hypoderma bovis*), external parasites, or carcasses with heavily bruised areas shall be promptly trimmed in a manner satisfactory to the inspector before the carcass is split.

(e) *Reinspection.* (1) *Disposition:* The establishment shall apply the finished product standards and edible byproduct standards. An inspector shall monitor the establishment's compliance with the standards and shall take corrective action if the establishment has failed to apply the standards.

(2) *Finished product standards (FPS)*: Finished product standards are criteria applied to carcasses. These criteria consist of nonconformances (listed in [Table 1](#) of this section), measured on randomly selected, consecutive subgroup samples collected on the slaughter line at a point after all trimming is completed. The total value of nonconformances for each subgroup is reduced to a CUSUM number and measured against the finished product standards (See [Table 2](#) of the this section). Compliance with FPS is measured by determining the CUSUM on consecutive subgroup samples. 0 may be performed before the carcass washer or immediately after the carcass washer.

(3) *Edible byproducts standards*: (i) Edible byproduct standards apply to fully processed brains, cheeks, cheek trimmings, feet (front and hind), heads, hearts, small intestines, kidneys, lips, livers, mountain chain, pancreas, spleens, tails, thymus, tongues, tongue trimmings, tripe, and weasands.

(ii) Edible byproduct standards are criteria which consist of nonconformances (listed in [Table 3](#) of this section), measured on consecutive subgroup samples collected after all cleaning and preparation is completed. The total value of nonconformances for each subgroup test is reduced to a CUSUM number and measured against the edible byproduct standards (See [Table 4](#) of this section). Compliance with the standards is measured by determining the CUSUM on consecutive subgroup samples.

(iii) Except as provided elsewhere in Part 310, edible byproducts shall be examined using the criteria contained in [Table 3](#) of this section.

(4) Finished product testing:

(i) Actions to be taken when the process is in control. If the CUSUM is less than the action number, and the subgroup absolute limit for cattle carcasses is not exceeded, the process is in control. If the CUSUM is less than the action number, and the subgroup maximum limit for heads, tongues and all other edible byproducts is not exceeded, the process is in control.

(A) Establishment Actions. The establishment shall:

(1) Randomly select and record a subgroup testing time for each product. The record of randomly selected times must be available for the inspector to monitor.

(i) Carcasses, head, and tongues are to be sampled once each production hour.

(ii) Sampling frequency for edible byproducts, *except* tongues and heads.

Each edible byproduct shall be sampled at a frequency of an average of once every two hours, except that inspector in charge may allow an establishment which produces more than six types of edible byproducts, not including tongues and heads, to select by random method, a minimum of six types of edible byproducts for sampling, provided that each type of edible byproduct must be sampled at least once during the production shift. The process for selecting random sampling times for edible byproducts must give each hour of the production shift an equal chance of being selected.

(4) The inspector in charge may allow an edible byproduct to be sampled at a frequency on an average of once every 4 hours after the edible byproduct has completed 20 consecutive sample tests without any CUSUM scores reaching the action number or exceeding the subgroup maximum limit.

(B) If an edible byproduct, which has been sampled at a frequency of once every 4 hours, has completed 10 consecutive sample tests without any CUSUM scores reaching the action number or exceeding the subgroup maximum limit, the inspector in charge may allow the edible byproduct to be sampled at a frequency of an average of once every a hours, provided that the edible byproduct shall be sampled at least once during the production shift.

(C) If the CUSUM score for any edible byproduct that is sampled at a frequency of an average of less than once every two hours reaches either the action number or exceeds the subgroup maximum limit, the edible byproduct shall be sampled at a frequency of once every 2 hours. Each type of edible byproduct process must independently earn reduced frequency sampling.

(2) Conduct designated subgroup-tests at the preselected times.

(3) Total the value of the subgroup nonconformances and calculate the current CUSUM. Immediately record the current CUSUM score and inform the production supervisor about any process trend.

(B) Inspector Actions. The inspector shall:

(1) Conduct subgroup tests on carcasses, head, and tongues at random times twice during each shift. The randomly selected times shall be known only to the inspector until the sample is selected.

(2) Monitor subgroup tests conducted by the establishment.

(3) Compare subgroup test results with establishment's subgroup test results. If results are not in agreement, the inspector will correlate results with the establishment.

(4) Instruct the establishment to take corrective action when a subgroup total exceeds the subgroup absolute limit for carcasses or exceeds the subgroup maximum limit for heads, tongues and other edible byproducts.

(ii) Actions to be taken when the subgroup absolute limit for carcasses is exceeded, If an individual subgroup total exceeds the subgroup absolute limit, but is less than the action number, the establishment shall determine if any of the five previous subgroups resulted in a CUSUM above the start number.

(A) If none of the five previous subgroups resulted in a CUSUM above the start number, the establishment shall immediately conduct another subgroup test. If this retest subgroup total equals the tolerance number or less, then random testing may continue. If the retest subgroup total exceeds the tolerance number, the establishment shall immediately begin the actions described in subparagraph (iv) (A) of this paragraph. In either case, the retest results shall be used to calculate CUSUM.

(B) If any of the five previous subgroups resulted in a CUSUM above the start number, the establishment shall begin actions described in subparagraph (iv)(A) of this paragraph.

(iii) Actions to be taken when a designated trimmable condition is found on a carcass. If any designated trimmable condition is found during a subgroup test, the establishment shall immediately:

(A) Notify the inspector in charge of the findings.

(B) Identify the carcass and all subsequently produced carcasses for possible rework.

(C) Conduct a verification subgroup test examining only for designated trimmable conditions.

(1) If any designated trimmable condition is found, all carcasses, beginning with the last previous sampled subgroup that was passed, shall be reworked by the establishment. The establishment shall not be required to identify and rework carcasses produced after a second verification subgroup test results in the finding of no designated trimmable conditions. The establishment shall conduct another verification subgroup test for designated trimmable conditions within 30 minutes.

(i) If no designated trimmable condition is found, the establishment may continue random sampling.

(ii) If any designated trimmable condition is found, the tested carcass and all subsequently produced carcasses shall be identified and reworked by the establishment. The establishment shall not be required to identify and rework carcasses produced

after a subsequent subgroup test results in the finding of no designated trimmable conditions.

(2) If no designated trimmable condition is found, the establishment shall not be required to rework the identified carcasses. The establishment shall conduct a second verification subgroup test for designated trimmable conditions within 30 minutes.

(i) If no designated trimmable condition is found, the establishment may continue random sampling.

(ii) If any designated trimmable condition is found, the tested carcass and all subsequently produced carcasses shall be identified and reworked by the establishment. The establishment shall not be required to identify and rework carcasses produced after two consecutive, subsequent subgroup test results in the finding of no designated trimmable conditions.

(iv) Actions to be taken when the CUSUM reaches the action number for carcasses or for heads, tongues, and other edible byproducts or when the subgroup maximum limit for heads, tongues, and other edible byproducts is reached. When CUSUM reaches the action number for carcasses or heads, tongues, and other edible byproducts, the process may be out of control. When the subgroup maximum limit for heads, tongues, and edible byproducts is reached, the process may be out of control.

(A) Establishment Actions. The establishment shall immediately:

(1) Identify the product and subsequently produced product of the same type for possible rework. The initial test results which reach the action number indicate only the possibility that the process is out of control. The process is not out of control until a verification subgroup test exceeds the tolerance number. When the process is out of control, identify the product beginning with the last previous sampled subgroup that was passed. Product action (identification and rework) begins at that point in the process.

(2) Notify the inspector in charge and production supervisor that the CUSUM has reached the action number.

(3) Suspend random subgroup testing of the affected type of product.

(4) Examine establishment records with the responsible production supervisor to determine the cause of the problem.

(5) Conduct a verification subgroup test.

(i) If the subgroup total for the verification subgroup test exceeds the tolerance number for carcasses, all carcasses identified for possible rework shall be reworked by the establishment. The establishment shall not be required to identify and rework carcasses produced after a subsequent subgroup test results in a subgroup total equal to or less than the tolerance number.

(A) If the subgroup total for the verification subgroup test is less than or equal to the tolerance number, the establishment shall not be required to rework the identified carcasses. The establishment shall conduct a second verification subgroup test within 30 minutes.

(B) If the subgroup total for the second verification subgroup test exceeds the tolerance number, the tested carcass and all subsequently produced carcasses shall be identified and reworked by the establishment. The establishment shall not be required to identify and rework carcasses produced after a subsequent subgroup test results in a subgroup equal to or less than the tolerance number.

(ii) If the subgroup total exceeds the tolerance number or the subgroup maximum limit is reached for heads, tongues and other edible byproducts, all edible byproducts identified for possible rework shall be reworked by the establishment. The establishment shall not be required to identify and rework edible byproducts produced after a subsequent subgroup test results in a subgroup total equal to or less than the tolerance number and the subgroup maximum limit is not reached.

(A) If the subgroup total for the verification subgroup test is less than or equal to the tolerance number and the subgroup maximum limit is not reached, the establishment shall not be required to rework identified edible byproducts. The establishment shall conduct a second verification subgroup test within 30 minutes.

(B) If the subgroup total for the second verification subgroup test exceeds the tolerance number or the subgroup maximum limit is reached, the tested edible byproducts and all subsequently produced edible byproducts of the same type shall be identified and reworked by the establishment. The establishment shall not be required to identify and rework edible byproducts produced after a subsequent subgroup test results in a subgroup total equal to or less than the tolerance number of the subgroup maximum limit is not reached.

(6) The process is in control and random sampling may be resumed after two consecutive subgroup tests are equal to or less than the tolerance number for carcasses; or are equal to or less than the tolerance number for edible byproducts; or the subgroup maximum limit for edible byproducts is reached:

(i) Establishment continues random subgroup testing.

(ii) CUSUM may be reset. If the two consecutive subgroup totals do not cause CUSUM to fall to the start number or below, CUSUM is reset at the start number.

(B) Inspector Actions. The inspector shall:

(1) Monitor the establishment's corrective actions to ensure that the FPS requirements for actions are met.

(2) Suspend random monitoring when the establishment is conducting product action.

(3) Correlate nonconformance criteria with the establishment as needed.

(f) After the subgroup tests are completed, nonconformances on carcasses, parts of carcasses, and edible byproducts sampled should be removed before the carcasses, parts and byproducts are returned to the product flow, or if such nonconformances cannot be removed, the articles shall be handled under the provisions of Part 311 of this subchapter.

(g) Slaughter Line Partial Quality Control. Establishments slaughtering cattle at rates greater than 275 head per hour must develop a quality control program for carcass dressing defects. Establishments slaughtering cattle at 275 head or less per hour are not required to, but may participate in a slaughter line quality control program. Participating establishments must comply with the following provisions:

(1) A slaughter floor carcass reinspection station shall be located off the main conveyor and shall comply with the facility requirements prescribed in § 307.2(m)(9). Specific reinspection activities shall be based on the establishment's quality control system and its performance under that system as determined by the circuit supervisor and inspector in charge. Carcass reinspection shall be handled in accordance with the provisions and the finished product standards in this section.

(2) Application for slaughter line partial quality control. Any owner or operator of an official slaughter establishment who has a plan for controlling post-mortem activities through a quality control system may request the Administrator to evaluate it to determine if the system is adequate to result in product being in compliance with the requirements of the Act. Such a request shall include the following:

(i) A letter to the Administrator from the establishment owner or operator stating the company's basis and purpose for seeking an approved slaughter line partial 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 for the period provided in § 320.3 in this subchapter to enable the Department to monitor compliance and to be available to Department personnel; that quality control personnel will have authority to halt production or shipping in cases where the quality control system requires it; and that the operator or owner (or his/her designee) will be available for consultation at any time the Department considers it necessary.

(ii) If an establishment has one or more full-time persons whose duties are related to quality control systems, an organizational chart shall be included showing that such person ultimately reports to an official whose quality control responsibilities are independent of production responsibilities. In cases of an establishment which does not have full-time quality control personnel, state the nature of the duties and responsibilities of the person who will be responsible for the slaughter line partial quality control system.

(iii) Detailed information concerning the manner in which the system will function must be included in the letter. Such information shall include, but not necessarily be limited to, carcass dressing control, the critical control points from animal unloading to the cooler, the nature and frequency of tests to be made, the nature of charts and other records which will be used in the system, the length of time such charts and other records will be maintained in custody of the official establishment, the nature of deficiencies the quality control system is designed to identify and control, the limitation or parameters used and the points at which corrective action will occur, and the nature of corrective action from least to most severe.

(iv) 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 slaughter line partial quality control system. This list shall also identify which part of the slaughter line partial quality control system will serve to maintain compliance with the applicable regulations.

(3) The Administrator shall evaluate the material presented in accordance with paragraph (f)(2) of this section. The Administrator shall approve the system if it is determined, on the basis of the evaluation, that the proposed slaughter line partial quality control program will result in carcasses being in full compliance with the requirements of the Act and regulations issued under the Act.

(4) If the Administrator determines that the proposed slaughter line partial quality control system is unacceptable, written notification of the basis for denial by the Administrator shall be sent to the applicant. The applicant shall be afforded an opportunity to modify the system in accordance with the notification. The applicant will also be provided an opportunity to submit to the Administrator within 30 days of the date of the notification, a statement challenging the merits or validity of the denial and to request an oral hearing with respect to the denial decision. An oral hearing shall be granted if there is any dispute in material fact joined in such responsive statement. The proceeding shall thereafter be conducted in accordance with the applicable rules of practice which shall be adopted for this proceeding. Any such denial shall be effective upon receipt by the applicant of the notification and shall continue in effect until Final determination of the matter.

(5) The establishment owner or operator shall be responsible for the effective operation of the approved slaughter line partial quality control system to ensure compliance with the requirements of the Act and regulations issued under the Act. The Secretary shall continue to provide the Federal inspection necessary to carry out responsibilities under the Act.

(6) Termination of slaughter line partial quality control.

(i) The approval of the slaughter line partial quality control system may be terminated at any time by the owner or operator of the official establishment upon written notice to the Administrator. Upon termination the maximum slaughter rate shall not exceed 275 head per hour.

(ii) The approval of the slaughter line partial quality control system may be terminated upon the establishment's receipt of a written notice from the Administrator under the following conditions:

(A) If the establishment fails to comply with the approved slaughter line quality control system after being served with written notification from the Administrator, or his designee, of its failure to comply. Termination will be effective 30 days after service of the notification. During this 30 day period, opportunity shall be provided to the establishment owner or operator to present views to the Administrator. If there is a conflict of facts, a hearing under applicable rules of practice shall be provided to the establishment owner or operator to resolve the conflict. The Administrator's termination of an approved slaughter line quality control system shall remain in effect pending the Final determination of the proceeding.

(B) If adulterated or misbranded meat food product is found by the Administrator to have been prepared for or distributed in commerce by the establishment or not prepared in compliance with the requirements of the Act. In such cases, opportunity shall be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of termination of the approval. If there is a conflict of facts, a hearing under applicable rules of practice shall 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.

(iii) If approval of the slaughter line 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 partial quality control system will not be evaluated by the Administrator for a least two months from the termination date. Such application must include those additional actions the establishment will perform to correct the previous failure to comply with the approved slaughter line quality control program.

TABLE 1. —DEFINITION OF NONCONFORMANCES FOR BEEF CARCASSES

1. SPECKS.
—Includes any speck or piece of extraneous material EXAMPLES Ingesta, feces, of, grease, dust, rust etc. When specks are so numerous that counting is impractical, or they are larger than .5 cm, they should be scored under dressing nonconformances.
—Factor is one.
—Count and total the number of specks sample unit, (1/2 carcass).
—Number of defects per sample unit is determined by dividing the total accumulated count per sample unit by 10 and rounding to nearest whole number such that. 0 to 4 specks = 0 defects, 5 to 14 specks = 1 defect, 15 to 24 specks = 2 defects, 25 to 34 specks = 3 defects, etc. NOTE Do not count bone dust or tat.

2. CONTAMINATION, SMEARS, AND STAINS:

—Include s areas of contamination, smears, and stains. EXAMPLES: Areas of contamination, smears or stains resulting from contact with ingesta, hide, personnel, equipment, other carcasses, etc.

—Factor is three.

—Measure and total the accumulated measurements for each area of nonconformance per sample unit.

—Number of defects per sample unit is determined by dividing the total accumulated measurements per sample unit by 5 and rounding to nearest whole number such that 0 to 2.4 cm = 0 defects, 2.5 to 7.4 cm = 1 defect, 7.5 to 12.4 cm = 2 defects, 12.5 to 17.4 cm = 3 defects, etc. NOTE: An area of contamination less than .5 cm in its longest dimension should be counted as a speck.

3. HAIR STRANDS (Loose):

—Includes all her not attached to hide.

—Factor is one.

—Count total number of hairs on sample unit.

—Number of defects is determined by dividing total accumulated number of hairs per sample unit by 10 and rounding to nearest whole number such that 0 to 4 hairs = 0 defects; 5 to 14 hairs = 1 defect; 15 to 24 hairs = 2 defects, 25 to 34 hairs = 3 defects, etc.

4. HAIR CLUSTERS:

—A cluster of has is a group or groups of hairs contained in a 12.5 cm by 12.5 cm area that is either (1) too numerous to count or (2) arranged in such a manner that individual hairs cannot be counted. The 12.5 cm by 12.5 cm area must be fixed to include the greatest number of hairs. Areas greater than this may be scored as more than one cluster, provided the definition continues to be met. When the definition is not met, the hags outside the area will be scored as loose hair.

—Factor is three.

—Count each 12.5 cm square area such that 0 to 12.5 cm = 1 defect, 12.6 cm to 25 cm = 2 defects, 26 to 37.5 cm = 3 defects,

5. HIDE:

—Only hide with hair is considered.

—Factor is four.

—Measure and total the accumulated measurements for each piece of hide per sample unit.

—Number of defects per sample unit is determined by dividing thee total accumulated measurements per side by 5 and rounding to the nearest whole number such that: 0 to 2.4 cm = 0 defects, 2.5 to 7.4 cm = 1 defect, 7.5 to 12.4 cm = 2 defects, 12.5 to 17.4 cm = 3 defects, etc.

6. PARASITES:

—Factor is one.

—Include each area which is partially or not adequately trimmed for the presence or evidence of a grub.

—Count

—Each area is a defect.

7. OIL, GREASE:

—Factor is one.

—Measure the total accumulation of oil or grease or thew resulting stains round per sample unit.

—Number of defects is determined by dividing total accumulated measurements by 5 and rounding to nearest whole number such that. 0 to 2.4 cm = 0 defects, 2.5 to 7.4 cm = 1 defect, 7.5 to 12.4 cm = 2 defects, 12.5 to 17.4 cm = 3 defects, etc. NOTE: Oil and grease spots less than .5 cm will be scored under specks.

8. IMPROPER TRIM:

—Factor m one.

—Includes non-meat tissue attached to the carcass. EXAMPLES: Remnant of liver, lung, trachea, crura of the panis (pczzle eye), urinary bladder, larynx, udder (lactating, blood clots 2.5 cm or larger, uterus, ovaries, vagina, talloptan tubes. muscle, butbo-cavernosus muscle,

—Measure and total the accumulated measurements of all remnants found per sample unit.

—Number of defects per sample unit is determined by dividing total accumulated measurement by 5 and rounding to nearest whole such that 0 to 2.4 cm = 0 defects, 2.5 to 7.4 cm = 1 defect, 7.5 to 12.4 cm = 2 defects, 12-5 to 17.4 cm = 3 defects,

9. BRUISES:

—Factor is one.

—Each visible bruise measuring 5 cm or more in greatest dimension is a nonconformance.

—Count.

10. DESIGNATED TRIMMABLE CONDITIONS:

—This category includes those abnormal conditions of the carcass that are not caused by improper dressing procedures, that are readily observable, but that do not affect the Iron of the carcass.

—EXAMPLES: Localized abscesses, pigmentation, fractures, arthritis, etc., are some examples of designated trimmable conditions.

—Finding of a nonconformance in this category requires immediate notification of inspector in charge and a retest for that condition.

11. OTHERS:

—This category includes those abnormal conditions of the carcass that are readily observable, that do not affect the disposition of the carcass, and that are not included in 1 through 10 above.

—EXAMPLES: Glass, metal, plastic, etc.

—Record each incidence and immediately notify the inspector in charge or his designee.

TABLE 2. —SIS FINISHED PRODUCT LIMITS

Washed Beet Carcasses.	
Tolerance	35
Absolute Limit (T+5)	40
Action	20
Start	10
Unwashed Beet	
Tolerance	80
Subgroup Absolute Limit (T+5)	85
Action	20
Start	10

TABLE 3. —DEFINITION OF NONCONFORMANCES—HEADS, TONGUES AND OTHER EDIBLE BYPRODUCTS**1. INGESTA PARTICLES:**

—Single individual pieces of gastro-intestinal material of plant life origin, such as grain, straw, wood, etc.

—Factor is one.

—Count.

—0 to 4=0 defects; 5 to 14=1 defect; greater than 14=2 defects.

—A maximum of 2 defects may be scored per unit.

2. SMEARS:

—Group 04 single ingesta particles which are so arranged or so numerous that counting is impractical.

—Factor is one.

—Measure.

—0 to 2.9 cm = 0 defects; 3 to 7.9 cm = 1 defect; 8 to 12.9 cm = 2 defects; greater than 12.9 cm=3 defects.

—A maximum of 3 defects may be scored per unit.

3. FOREIGN OBJECTS:

—Extraneous materials that are other than gastro-intestinal material of plant life origin. They include loose broken teeth, bone fragments, cartilage, toenails, claws, rust flakes, rosin, rings, tags, sand, dirt, etc. Also included are non-encapsulated (loose)

parasites such as flukes, worms, etc. When foreign objects are so arranged or mixed with particles that are so numerous that counting is impractical score as smears (item no. 2.).

—Factor is one.

—Count.

—Each incidence = 1.

—No maximum on the number of defects per unit

4. HAIR/WOOL STRANDS OR SCURF (loose):

—All, hair/wool or scurf not attached to the skin or hide.

—Factor is one.

—Count

—9 to 4=0 defects; 5 to 14=1 defect; greater than 14=2 defects.

—A maximum of 2 defects may be scored per unit

5. HAIR/WOOL CLUSTERS (attached or loose) and SCURF (attached):

—A cluster is a collection of hair/wool that is so arranged that counting is impractical Scurf is a piece of attached epidermal layer

of the skin.

—Factor is one.

—Measure.

—0 to 29 cm = 0 defects; 3 to 17.9 cm = 1 defect; 8 to 12.9 cm = 2 defects; greater than 12.9 cm = 3 defects.

—A maximum of 3 defects may be scored per unit.

6. BLOOD CLOTS (loose):

—Must be greater than 2 cm to be scored. Blood clots must not be part of an inflamed Blood clots found clinging to the out-aside of

sheep hearts are not to be scored.

—Factor is one.

—Measure.

—Each Incidence greater than 2 cm = 1 defect.

—No maximum on the number of defects per unit.

7. MUCOSA (loose or attached)

—Must be greater than 2 cm to be scored. It is usually found loose or attached to acalded stomachs or scalded tongues.

—Factor is one.

—Measure.

—Each incidence greater than 2 cm = 1.

—No maximum on the number of defects per unit.

8. STAINS:

—Discolorations on the product caused by such materials as bile, oil, grease, rust, etc.

—Factor is one.

—Measure.

—0 to 2.9 cm = 0 defects. 3 to 7.9 cm = 1 defect, 8 to 12.9 cm = 2 defects; greater than 12.9 cm = 3 defects.

—A maximum of 3 defects may be scored per

9. SCAR TISSUE:

—Not associated with an active inflammatory process, such as liver spots caused by parasites. and other non-parasitic scar tissue such as healed ulcers, tetanglectasis and sawdust lesions, etc.

—Factor is one.

—Count.

—0 to 2=0 defects; 3 to 7=1 defect; 8 to 12=2 defects, 13 to 17=3 defects, etc.

—No maximum on the number of defects per unit.

10 LACERATIONS/PUNCTURES, BRUISES AND HEMORRHAGES

—Lacerations/punctures are breaks on the surface of the product with no inflammatory process (not included are knife cuts made during the dressing operations) Bruises are bc reddened areas caused by physical means. Hemorrhages are collections of blood outside the vascular system such as blood splash, hematomas, etc Localized hemorrhagic areas (collection of pin point lesions or larger) must be greater than 2 cm to be scored. Do not score products with extensive or generalized hemorrhages which must be retained for the HC's disposition.

—Factor is two

—Count.

—Each incidence = 1.

—No maximum on the number of defects per unit.

11. PARTS OF OTHER ORGANS

—Improper trimming of remnants of adjacent organs such as intestines, ureter, spermatic cord, diaphragm, eyelids, lips, tonsils, gall bladder, hide, pancreas, thymus, etc. With chitterlings, lymph nodes and ??eocecal valves are considered parts of other organs.

Score aortas attached to hearts only when greater than 3 cm in length.

—Factor is one

—Count.

—Each incidence = 1.

—No maximum on number of defects per unit.

12. OTHER CONDITIONS:

—This category includes abnormal conditions of edible byproducts that do not affect the disposition of the carcass or defects which are not included in 1 through 11 above.

—Examples sclerotic bile duct, kidney cyst, hear sore. ulcer, abscess, etc

Finding of a condemnable condition requires ate notification of the insepector in charge

TABLE 4. —FINISHED PRODUCT STANDARDS—EDIBLE BYPRODUCTS, BEEF

	Tolerance	Action No.	Start No.
Brains	3	7	4
Cheeks	10	4	7
Cheeks Trimmings	5	10	5
Feet:			
Front	5	10	5
Hind	5	10	5
Heads	5	10	6
Hearts	10	14	7
Small intestines	3	7	4
Kineys	1	5	3
Lips	6	11	6
Livers	5	10	5
Mountain Chain	20	20	10
Pancreas	3	7	4
Spieens	2	6	3
Tails	7	12	6
Thymus	6	11	6
Tongues	3	7	4
Tongue Trimmings	16	18	9
Tnpe	30	25	13
Weasands.	1	5	3

Done at Washington, DC, on: September 9, 1988.

Lester M. Crawford,

Administrator, Food Safety and Inspection Service.

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Appendix B

Information Provided by USDA-FSIS to Committee

January 22, 1990

- Outline of USDA/FSSIS presentation to the committee by Dr. John Prucha, Assistant Deputy Administrator for the Technical Support of FSIS Science and Technology Program.
- Introduction to SIS-C by Dr. Jill Hollingsworth, Director, Slaughter Inspection Procedures and Standards Division, FSIS.
- Federal Register. 1988. Proposed Rule. Streamlined Inspection System-Cattle and Staffing Standards. Fed. Regist. 53:38262-48275.
- Wesson, K.M. 1983. A Study on the New Cattle-Post-Mortem Inspection Procedures for Steers and Heifers. USDA/FSSIS, Slaughter Inspection Standards and Procedures Division, Washington, D.C., October 1983. 52 pp.
- FSIS (Food Safety and Inspection Service). 1989. Streamlined Inspection System Guidelines. USDA, FSIS, Washington, D.C., December 1989. 85 pp.

March 1, 1990

- Prevalence of disease and conditions of fed cattle.
- Lesions and conditions detected using SIS-C organoleptic procedures.
- Development of finished product standards for the cattle SIS inspection procedures.
- Slaughter and condemnation data for steers and heifers.
- Results of finished product standards for SIS-C pilot plants.
- Microbiological comparison of product procedures in plants under SIS or traditional inspection.
- Data provided by a pilot plant to FSIS on microbiological data on carcasses or parts.
- Data collected by FSIS, as part of its NRP on antibiotic and chemical residue, between October 1986 and January 1990.
- A chart showing USDA/FSSIS slaughter modernization plan.
- FSIS comments on committee site visits to traditional and SIS plants in Texas.

March 29, 1990

- Response to questions asked by the FNB Project Director, Dr. Farid E. Ahmed, on behalf of the committee to FSIS Administrator, Dr. Lester M. Crawford, in letters dated January 24 and March 13, 1990.
- Condemnation rates in steers and heifers of the 25 most frequent postmortem dispositions for 1986-1989, including a list of all diseases and conditions in cattle, and information on the most prevalent diseases diagnosed in steers and heifers

- in the feedlot.
- Tables showing rate of cysticercosis in SIS-C plants compared to control plants in the same state for fiscal years 1986-1989.
- Tables showing rate of tuberculosis in nonreactors at SIS-C plants before and after the implementation of streamlined inspection, and rate compared to control plants in the same state for fiscal years 1986-1987.

May 11, 1990

- FSIS (Food Safety and Inspection Service). 1986. Future Agenda Response to the NAS Recommendations. Policy and Planning Staff, FSIS/USDA, Washington, D.C., June 1986. 145 pp.
- FSIS (Food Safety and Inspection Service). 1989. Response to the National Academy of Sciences Report. Elements of an Optimal Inspection Program. Policy Evaluation and Planning Staff, FSIS/USDA, Washington D.C., May 1990. 26 pp.

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Appendix C
Public Meeting Agenda

Committee on the Evaluation of USDA Streamlined Inspection System for Cattle

	NAS Auditorium Public Meeting-January 23, 1990 10:00 a.m.-1:30 p.m
10:00 a.m.	Scope and Origin of the Study Robert F. Kahrs, Committee Chairman
10:10 a.m.	Testimony by Carol Tucker Foreman, Principal Foreman & Heidepriem, Washington, D.C.
10:25 a.m.	Questions
10:30 a.m.	Testimony by James H. Hodges, Vice President, American Meat Institute, Washington, D.C.
10:45 a.m.	Questions
10:50 a.m.	Testimony by David Carney, National Joint Council of Food Inspection Locals, Salem, Ohio
11:05 a.m.	Questions
11:10 a.m.	Testimony by Gerald F. Kuester, Former Microbiologist with USDA, Kensington, Maryland
11:25 a.m.	Questions
11:30 a.m.	BREAK
11:40 a.m.	Testimony by Thomas Devine, Director, Government Accountability Project, Washington, D.C.
11:55 a.m.	Questions

12:00 p.m.	Testimony by Rodney E. Leonard, Executive Director, Community Nutrition Institute, Washington, D.C.
12:15 p.m.	Questions
12:20 p.m.	Testimony by Edward L. Menning, Executive Vice President, The National Association of Federal Veterinarians, Washington, D.C.
12:35 p.m.	Questions
12:40 p.m.	Testimony by Carl L. Telleen, Former Veterinarian with USDA, Annandale, Virginia
12:55 p.m.	Questions
1:00 p.m.	General Discussion
1:15 p.m.	Closing Remarks Robert F. Kahrs, Committee Chairman
1:20 p.m.	ADJOURNMENT

Appendix D

Reports on Site Visits

Between February and May 1990, the committee visited five large fed cattle slaughtering plants located in four states (Colorado, Kansas, Nebraska, and Texas). These plants were slaughtering cattle at rates between 225 and 400 head per hour. Two plants operated under traditional inspection, one with SIS-C, and two with SIS-C/PQC.

Each visit was based on a similar format, which consisted of:

- A meeting with local and Washington-based FSIS personnel for a pre-visit briefing.
- A guided tour of the plant, focusing on the livestock pens, kill floor, coolers, and fabrication area.
- Meetings with plant management, quality assurance staff, and USDA inspection personnel, both supervisory and on-line, largely through interviews, although written comments were also received.
- Committee meeting at conclusion of site visit.

Routine visits were made to company laboratories and a feedlot. Plant visits were scheduled to ensure that committee members could observe all phases of the operation from preoperation inspection to afternoon shift.

Observation on Plant Tours

The committee observed in detail antemortem and postmortem inspection procedures in all plants. In SIS-C/PQC, attention was also focused on plant record keeping and quality control checks, together with the monitoring procedures initiated by FSIS.

Carcass dressing procedures, carcass and byproduct organoleptic quality, and plant environment were all observed. Considerable variation was noted between the plants visited. This was particularly apparent in areas such as dressing procedures, congestion in certain areas, lighting at critical points, employee clothing (e.g., hair nets, gloves), line stoppages for dressing problems (e.g., dropped carcasses), and trimming and the carrying out of required inspection procedures. The committee's observations of finished products on the line and in the coolers indicated that the carcasses were generally clean, although there were obvious variations between the plants.

Summary of Relevant Comments by Plant Management Personnel and USDA Inspectors

For SIS-C and SIS-C/PQC

Commitment of management is vital to the success of the program. Plant management indicated the following: SIS-C gave them more responsibility for product quality and more control over the operation; they observed more carcasses than in AQL and made judgments allowing corrective measures to be taken earlier than under the traditional system where action often could not be taken until the following day; fewer repetitive motion injuries occurred among inspectors since the presentations in SIS-C are consistent; SIS-C promoted cooperation between inspectors and plant management; SIS-C/PQC allowed higher yields due to less trimming with PQC programs in effect; attitudes among plant employees were improved because of the new responsibility for quality assurance; and after SIS-C was properly explained and demonstrated, employee attitudes toward the program became more positive.

Against SIS-C and SIS-C/PQC

The negative comments from FSIS inspectors and veterinarians related to SIS included the following: loss of inspector control and authority; poorer detection rate for lesions due to reduced number of inspection procedures (especially conditions involving the injury of tissue where observation and tactile senses were considered to be required); inability to check required rework, no inspection after splitting; no control over quality of trimming and failure to observe final carcass condition in 100% of cases after trimming; lack of confidence in statistical procedures; lack of confidence in plant management's ability to be responsible for producing a wholesome, safe product; no backup from FSIS supervisors when action needed to be taken; inadequate training in the concepts of the program; and reduction in number of inspectors.

Appendix E

Summary of Verbal and Written Testimony by FSIS Inspectors

The present committee interviewed 24 FSIS food inspectors and received sworn affidavits signed by more than 50 inspectors. Although some were supportive, many statements were critical of SIS-C. Many criticisms leveled at SIS-C described events or situations that could occur or exist in traditional inspection as well as SIS-C. There was a disgruntled employee attitude that may be characteristic of labor-management interactions throughout the highly regulated food processing industry. Nonetheless, it was disheartening to conclude that the most severe critics of FSIS and SIS-C were FSIS's own employees—its lay inspectors and a few of its veterinarians. These inspectors, who work daily on the front lines, appeared to be sincerely concerned that the USDA stamp of approval had lost its credibility. Many said that they had lost faith in the agency because of its pilot SIS project and feared that nationwide implementation of the program would create serious public health hazards.

Although the present committee was unable to investigate criticisms of specific incidents, it heard repeated claims that SIS-C guidelines were too lenient and that under SIS-C, inspectors had lost control of the slaughter process. Some monitoring is left to company quality control personnel who participate in corporate profit-sharing programs and who are allegedly urged (or, it is claimed, intimidated) by management to speed the process and increase productivity at the expense of sanitation and good inspection techniques. Some inspectors also believe that SIS-C deputizes industry to police itself and that industry is incapable of shouldering this responsibility because it cannot resist the temptation to cut corners to increase profits.

The most repeated specific criticisms of SIS-C were:

- SIS-C structure is vulnerable to company abuse.
- Sample sizes for statistical sampling were small, and many lots of cattle never appeared in the sample (this concern may reflect misunderstanding of the purpose of statistical sampling as a device for monitoring the process—not preventing exposure).
- The washing process, which is not unique to SIS-C, diffuses bacteria, hides fecal stains, and adds water to the carcass.
- Inspectors do not get a good look inside eviscerated carcasses because carcasses are not split until after they have passed all inspection stations. Thus, the insides of split carcasses are examined only if they happen to fall in the random sample.

- Inspectors see random sampling as an obstacle that permits them from closely examining carcasses.
- The CUSUM score required to trigger reworking (trimming) of dirty carcasses is too high.
- Inspectors see need for an inspector at a final check point or rail inspection station just before the carcass is washed and moves into the cooler.
- The inspectors believe that the certified trimming portion of plant PQC program is ineffective because the training of the trimmers is meager, the turnover of these personnel is high, and many trimmers do not speak English and thus cannot understand what little training is given to them.
- Inspectors no longer palpate tongues, hearts, diaphragms, and esophagi.
- Inspectors no longer observe and direct the trimming process.
- The agency does not support its own personnel in disputes over inspection interpretations but frequently supports company positions, thereby leaving their own employees with the feeling that their authority and status have been undermined.
- Some line speeds are so fast that effective inspection is impossible and line speed hypnosis is created.
- Inspectors agree that industry should assume greater responsibility for product quality but believe that SIS-C provides a blank check for faster line speeds, less qualified workers, fewer inspectors, and less government oversight.

Appendix F

Bacteriological Study of Beef Carcasses in Quebec

This study is described here as an example of how to collect and analyze data for microbiological determination on beef carcasses.

Purpose of the Study

To make bacterial counts on some beef carcasses, from the dressing stage up to boning, in three registered Quebec plants and to assess whether a specific stage of processing can be identified with regard to its contribution to the total bacterial count.

Materials and Methods

3 abattoirs
18 carcasses/plant
1 stamp (see annex 2) and an inker
2 pincers, 2 scalpel handles, disposable blades
2 bottles of alcohol
2,000 Wirlpack bags (54 carcasses x 7 sites x 6 work areas)
54 Ice paks (3 plants x 3 days x 6 paks) 4 insulated foam boxes for samples
2 calibrated thermometer-hygrometers
2 calibrated meat thermometers
60 data collection sheets
1,620 samples (laboratory costs)

For reasons of confidentiality, the establishments concerned will be called A, B, and C. At each one, 18 beef carcasses (cows) will be marked at the dressing stage.

A half-day pilot project will be conducted at least 3 weeks before the project starts to validate procedures. This pilot project will consist of taking samples from three carcasses selected at random during the morning at one establishment only. This will also allow the three Veterinarians in Charge, who will be responsible for collecting samples in their respective plants, to become familiar with all aspects of the experimental procedure. This exercise will also verify whether there are variations in bacteria count (total count) on the surfaces of the carcasses between a carcass put to one side in relation to another in the center of the cooler.

The rate of flow (volume/mixture) and pressure of the water used as well as the average time spent on washing a half carcass (average washing time for 10 half-carcasses) will be recorded.

Collection of data specific to each establishment will be done before the study begins. At that time, the procedure will be explained to the plants' management.

The carcasses will be selected at random during the day and must be handled as usual, that is, with no extra sanitation measures taken. They will be set aside when put into the cooler.

At each plant, samples from three carcasses will be taken each Tuesday, Wednesday, and Thursday for 2 weeks. The first week, the three carcasses will be selected in the morning; the second week, in the afternoon. The carcasses will be selected at random at fixed times: 9:00, 10:00, and 11:00 a.m., and 1:45, 2:15, and 3:15 p.m.

To achieve uniformity of sampling techniques, the following procedure must be followed. After skinning, the selected carcass will be identified with a label containing a reference number. This number will be written on a data sheet (see Annex 1) to be used for this carcass. Samples from the carcasses must be taken with sterile instruments (flame-sterilized scalpels, pincers, and stamps). The selected carcass will be marked with the stamp (see Annex 2) in the areas listed below (see Annex 3):

1. Brisket
2. Hind hock—cranial surface
3. Flank
4. Front shank—caudal surface
5. Neck—lateral surface at about 10 cm from the end
6. Rump—at about 5 cm from the pelvic cavity
7. Leg—in the middle at the semitendinous/semimembranous area

The needles of the stamp will delineate three 2 cm by 3 cm areas. The areas should be considered as being numbered as shown in Annex 3, and samples should be taken in that order. Thus, at the abattoir, all the No. 1 samples will be taken with a sterile scalpel and pincers before trimming from the seven areas mentioned above. After washing, when the carcass goes into the cooler, the No. 2 samples will be taken and so on. In the cutting room, the No. 3 samples will be taken from the seven areas before boning. The samples should be cut 0.5 cm thick and follow the pattern marked by the stamp. They should never be touched with hands. They will then be placed in sterile bags (Wirlpack) and refrigerated at 2°C until analyzed. The samples must be refrigerated and sent to the laboratory by courier as soon as possible after slaughter—the same day, if possible, or the next day at the latest. **CAUTION!** You must be sure to identify each sample clearly by writing on the plastic bag the carcass reference number, the sample area, and sequence (example: CO3-1-A). The same number will be marked on the carcass with indelible pencil to avoid loss of data.

In the cutting room, in addition to sampling the carcasses identified in the

slaughter room, 18 other carcasses in each cutting establishment will be selected at random one Monday from among those that have been in the cooler over the preceding weekend. This sampling will verify whether this waiting period can lead to higher counts.

At the laboratory, the samples will be handled as follows: they will be homogenized and cultured in the usual way for doing total bacterial count. Total bacteria count at 37°C will then be taken.

Relative humidity and temperature readings will be taken as follows:

1. In the evisceration area, read and note the temperature and relative humidity at about 30 cm (1 foot) from the carcass at the height of the patella and the brisket.
2. When the carcasses are put into the cooler, take the same readings.
3. Before the quarters are boned, take the internal temperature of the quarters 0.5 cm below the surface.
4. In the cutting room, record the temperature and humidity of the room at about 30 cm (1 foot) from the surface of the boning table as the quarters of the carcasses being sampled are boned.
5. After boning, and after the samples have been taken, take a temperature reading at the neck and the rump at 0.5 cm below the surface, near the sample area.

Results

The results obtained can be expressed with tables of the following types:

1. Bacterial counts at different work areas at each of the three abattoirs.
2. Bacterial counts at the different sample sites at each of the three abattoirs.
3. Other data collected (e.g., temperatures, relative humidity) at the three establishments.
4. Three-dimensional graphic: sampling site compared to bacteria count and sampling day.
5. Bacterial count and relative humidity.

6. Bacterial count and temperature of slaughter floor.
7. Bacterial count after evisceration compared to transit time on the slaughter floor.
8. Bacterial count before cutting and total storage time.
9. Bacterial count and type of washing.
10. Average reduction of count and type of washing
11. Bacterial count after cutting and temperature after transport or after cutting.
12. Bacterial counts in the morning and in the afternoon.

Annex 1 Data Sheet for Establishment

Establishment

1.	Type of skinning machine: upward_____	downward_____
		roll-off_____
2.	Spray chilling system _____ yes _____ no	
	Attach details of use	
3.	Types of carcass washing: _____ manual	
		_____ mechanical
4.	Approximate flow rate (vol/min)_____ liter/minutes	
5.	Pressure of water used: _____	
6.	Average washing time (half carcass): _____ seconds	
7.	Are carcasses transported by truck to the boning room?	
	_____ yes	_____ no

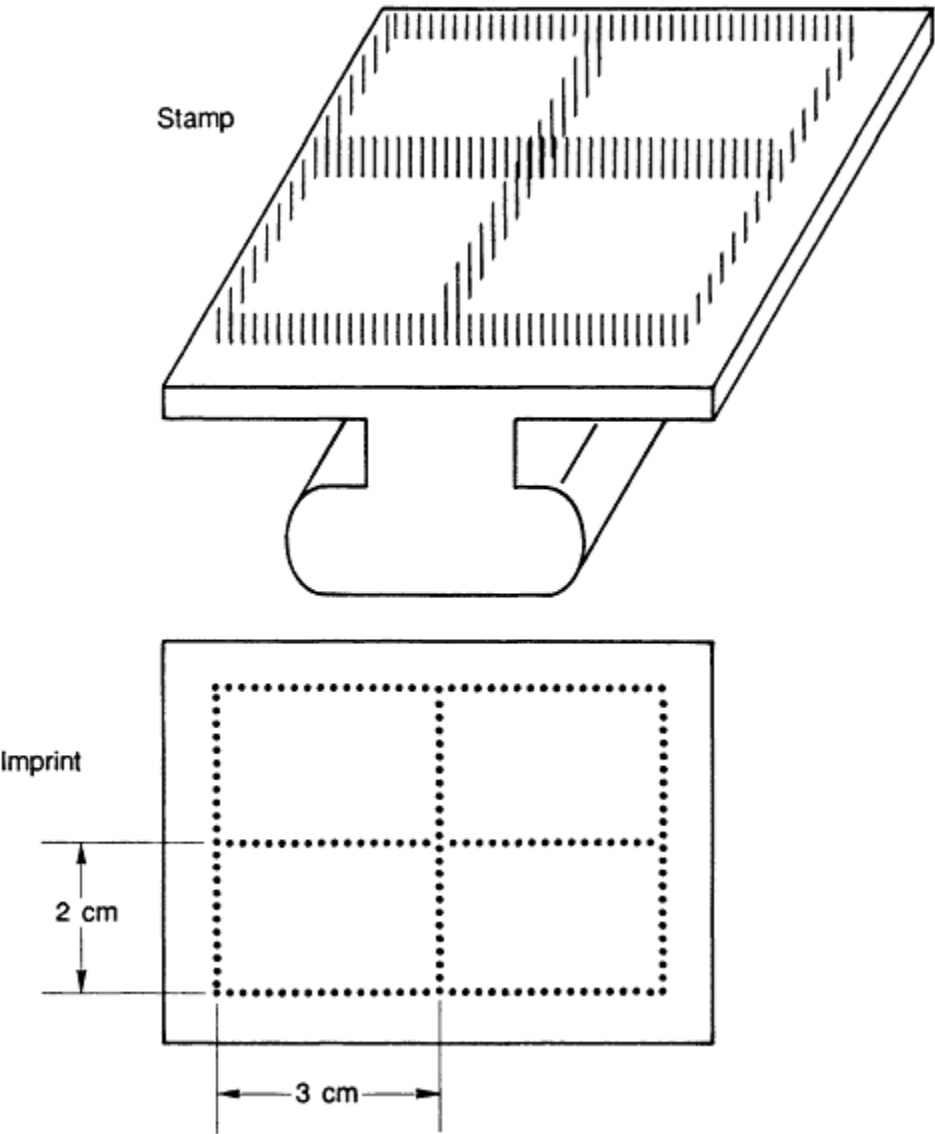
Carcass

Reference no.: C-DATE: __/__/__/	
Carcass of __ dairy __	
Carcass weight before chilling: __ kg	
Skinning	Date: __/__/Time: __: __
put reference number on carcass, label, and form	

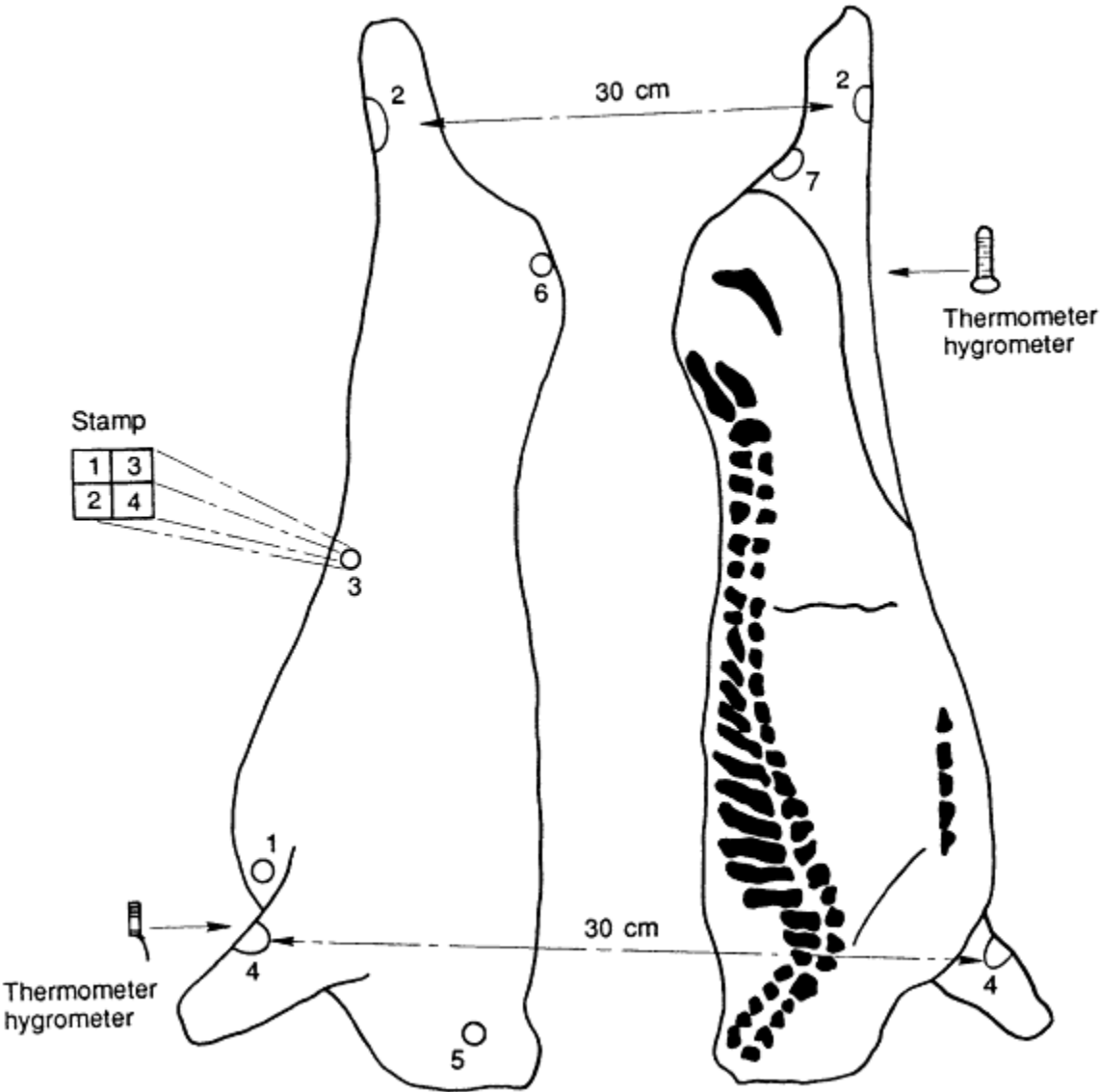
Evisceration	Temperature + relative humidity of carcass (front quarter) _____ °C _____ % Temperature + relative humidity of carcass (hind quarter) _____ °C _____ % Note time _____
Before Trimming	Mark carcasses with stamp
Holding Rail	Sterilize instruments in flame and take No. 1 samples
Weighing	Note warm weight of <u>carcass</u>
Placed In Cooler	Note time Temperature + relative humidity of carcass (front quarter) _____ °C _____ % Temperature + relative humidity of carcass (hind quarter) _____ °C _____ % Sterilize instruments in flame and take No. 2 samples
Transport Optional)	
Before Cutting	Note date: _/_/_/Time: __: __ Temp. of quarters--front ____ °C --hind ____ °C Sterilize instruments in flame and take No. 3 samples
During Cutting	Temperature + relative humidity of piece <u>during</u> boning of front quarter _____ °C _____ %
After Cutting	Sterilize instruments in flame and take No. 4 samples. Temperature of neck 0.5 cm below surface ____ °C Temperature of rump 0.5 cm below surface ____ °C

Number of Samples Taken per Week Per Establishment					
	Abattoir (carcass)	Cutting	Cutting (piece)	Cutting (suppl. carc.)	Total
Monday	—	—	—	63	63
Tuesday	42	—	—	—	42
Wednesday	42	21	6	—	69
Thursday	42	21	6	—	69
Friday	—	21	6	27	—
Total	126	63	18	63	270
Total number of samples taken: 2 weeks per establishment = 2 X 270 = 540					
For the three abattoirs: 3 x 540 = 1,620 samples					

Annex 2 Needle Point Stamp for Marking Samples to be Taken



Annex 3 Areas from Which Samples are to be Taken and Location of Points at which to take Temperature and Relative Humidity Readings



Appendix G

Glossary of Terms and Acronyms

ACCEPT-ABILITY	The degree or status of meat or food product sanitation, equipment, or other items dealing with inspection or quality that meet minimum standards as established by the agency
ADRS	Animal Disease Reporting System of FSIS
ALPHA (α)	ERROR Refers to the error made if a true hypothesis is rejected (also referred to as type I error)
APHIS	Animal and Plant Health Inspection Service of USDA
AQL	Acceptable Quality Level—A beef carcass reinspection program used in traditional cattle slaughtering facilities to evaluate wholesomeness and acceptability of carcasses and edible products
ARS	Agricultural Research Service of the USDA
BETA (β)	ERROR Refers to error made if a false hypothesis is accepted (also referred to as type II error)
CDC	Centers for Disease Control, Public Health Service
CHEMICAL RESIDUES	Includes any of the following: pesticides, agricultural chemicals, heavy metals, antimicrobials, mycotoxins, and other metabolites, exogenous hormones, and growth stimulants
CLEANLINESS	Sanitation and reasonable freedom from contamination or extraneous material involving food products, including meat, and all items having contact with these products
CMS	Consumer Marketing Service of USDA
CSRS	Cooperative State Research Service of USDA
CUSUM	Cumulative Sum—A statistical procedure developed by FSIS for use with SIS-C that compares the output of a process against finished product standards to determine compliance

DEFECTS	Any minor, major, or critical type of nonconformance
DESIGNATED TRIMMABLE CONDITIONS	Abnormal conditions that are not caused by improper procedures, that are readily identifiable, and that do not effect the disposition of the carcass
DRESSING NONCONFORMANCES	Defects on the carcass that result from errors in the handling, slaughtering, or dressing operations performed by establishment employees
EEC	European Economic Community
FDA	Food and Drug Administration, U.S. Public Health Service
FED CATTLE	Young castrated males (steers) and young females that have never calved (heifers); both are being fed special finishing rations in feed lots immediately prior to slaughter
FNB	Food and Nutrition Board of the IOM
FPS	Finished Product Standards. Standards used with SIS-C to define criteria that the product must meet to avoid the risk of having to rework the product
FSIS	Food Safety and Inspection Service (formerly FSQS, Food Safety and Quality Service) of USDA
HACCP	Hazard Analysis Critical Control Point Program
IOM	Institute of Medicine of the NAS
LESION	An abnormal change in structure of an organ or part due to injury or disease
MICROBIAL CONTAMINANTS	Includes microorganisms (e.g., bacteria and viruses) that intrude on, or cause infection, by contact or association
MPI	Meat and Poultry Inspection Division of USDA
NAHMS	National Animal Health Monitoring System of APHIS
NAS	National Academy of Sciences

NONCONFORMANCES	Defects that occur on the carcass or edible by-products as a result of errors in the handling, slaughtering, or dressing operations performed by slaughter facility employees
NRC	National Research Council of the NAS
NRP	National Residue Program of FSIS
ORGANOLEPTIC	Affecting or relating to qualities perceived by special senses. These qualities include appearance, color, odor, and texture
PALPATION	To examine medically by touch
PRESENT COMMITTEE	The Committee on Evaluation of USDA Streamlined Inspection System for Cattle (SIS-C), Food and Nutrition Board, Institute of Medicine
PQC	Partial Quality Control. A program of quality control standards established by slaughter facilities for presentation of head/viscera/carcass or for the entire slaughter dressing process. These programs can be approved by FSIS for the entire slaughter dressing process or for presentation only. In facilities operating without an approved PQC program, all the tests are conducted by the FSIS inspector in charge or by his or her designee
QUALITY	Relative to meat, refers to palatability and organoleptic characteristics such as tenderness, juiciness, and flavor, based on the maturity, marbling, color, firmness, and texture of the meat. However, the term quality is often interpreted to mean the visible acceptability, freshness, and cleanliness of the product. It should not be confused with the wholesomeness or safety of the product from a human health standpoint. In general, meat quality is identified by the USDA Meat Grading Service and is designated as USDA Prime, Choice, Select, Standard, Commercial, Utility, Cutter, and Canner for beef
REWORK	Reprocessing the product to correct the condition or conditions causing the nonconformances
SAFETY	Refers to the condition of meat and food indicating freedom from harmful ingredients or organisms that could be a hazard to human health. No raw food products are completely sterile or free of all possible organisms or chemicals

SIS	Streamlined Inspection System
TOLERANCE	Identifies a limit above which the product is deemed to be unacceptable
USDA	U.S. Department of Agriculture
WHOLESOMENESS	The general term used to imply that meat and other foods are processed in a sanitary and healthful manner and are safe to eat. Meat inspection is performed by the USDA-FSIS, which identifies what is acceptable to be classified as U.S. inspected and passed
ZOONOTIC-DISEASES	Diseases transmissible from animals to humans.

Appendix H

Affiliations and Major Research Interests of Committee and Staff

Committee

Robert F. Kahrs, DVM, Ph D Chairman Dean, College of Veterinary Medicine University of Missouri-Columbia Columbia, Missouri Major Interests: Epidemiology of cattle diseases

Helen M. Acland, BVSc Associate Professor of Pathology School of Veterinary Medicine University of Pennsylvania Kennett Square, Pennsylvania Major Interests: Large animal pathology

Roger G. Breeze, BVMS, Ph D, MRCVS Center Director, USDA-ARS Plum Island Animal Disease Center Greenport, New York Major Interests: Food animal diseases

Graham C. Clarke, B Vet Med, MRCVS Chief of National Programs Meat and Poultry Products Division Food Production and Inspection Branch Agriculture Canada Ottawa, Ontario Major Interests: Meat inspection

Donald M. Kinsman, Ph D Professor Emeritus Department of Animal Science University of Connecticut Storrs, Connecticut Major Interests: Animal and meat science

Farrel R. Robinson, DVM, Ph D Chief of Toxicology Service Animal Disease Diagnostic Laboratory School of Veterinary Medicine Purdue University West Lafayette, Indiana Major Interests: Toxicology

Consultants

Stanley M. Martin, MS Chief of Statistical Services Activity Division of Bacterial Diseases Centers for Disease Control Atlanta, Georgia Major Interests: Biostatistics

J. Glenn Morris, Jr., MD, MPH & TM Associate Professor of Internal Medicine Division of Geographic Medicine, University of Maryland, School of Medicine Baltimore, Maryland Major Interests: Public health, epidemiology, and microbiology

Morris E. Potter, DVM, MS Epidemiologist Division of Bacterial Diseases, Center for Disease Control Atlanta, Georgia Major Interests: Public health, epidemiology, and food safety

Staff (FNB/IOM)

Farid E. Ahmed, Ph D *Project Director* Major Interests: Food safety, toxicology, risk assessment, biotechnology, and environmental carcinogenesis and mutagenesis