Notices

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This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Privacy Act; System of Records

AGENCY: Office of the Secretary, USDA.

ACTION: Notice; correction.

SUMMARY: The Food and Consumer Service, USDA is providing notice of a correction to a Privacy Act notice entitled, Food Stamp Program Retailer Information, USDA/FCS–9. This notice was published in the **Federal Register** at 61 FR 63815 on Monday, December 2, 1996.

Informaiton contained in this system of records is being used to determine whether retail or wholesale store owners and officers, and/or owners and officers associated with other entities authorized to redeem food stamps, such as private restaurants that qualify to participate in the special restaurant program to serve elderly, homeless and disabled Food Stamp Program (FSP) recipients, qualify to participate or continue to participate in the FSP to monitor compliance with program regulations and for program management.

A sentence was mistakenly placed in the Privacy Act notice published on December 2, 1996. Thus, the Food and Consumer Service is publishing this correction.

On page 63816 in the issue of the **Federal Register** published on December 2, 1996, FR Doc. 96–30088 is corrected by removing the last sentence under the heading ''Categories of Records in the System'' which begins in the first column.

Dated: June 3, 1997.

Dan Glickman,

Secretary of Agriculture.

[FR Doc. 97–15038 Filed 6–9–97; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 96–008N]

HACCP-Based Meat and Poultry Inspection Concepts

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Food Safety and Inspection Service (FSIS) must change how resources are allocated in order to improve regulation of the meat and poultry industries after implementation of the Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP)Systems final rule. Every aspect of traditional FSIS methods of inspection for slaughter and processing needs to be reconsidered. All methods are subject to change as long as the Agency can fulfill its responsibilities to ensure that the industries produce safe, wholesome, unadulterated and properly labeled meat and poultry products. The Agency is also considering adding methods to better ensure food safety and other consumer protections in distribution channels.

FSIS is seeking comments on the development of new inspection models for slaughter and processing in a HACCP environment. FSIS also invites the public to participate in the development of new inspection models and will hold a public meeting to facilitate that process.

DATES: The public meeting is scheduled for June 24, 1997, from 8 a.m. to 5 p.m.

COMMENTS: Comments are welcome at any time. Please submit written comments to Ms. Patricia Stolfa, Assistant Deputy Administrator, Office of Policy, Program Development and Evaluation, Room 402 Cotton Annex, 300 12th Street SW, Washington, D.C. 20250–3700. Comments may also be provided by facsimile (202–401–1760).

ADDRESSES: The public meeting will be held in Galleries 1, 2, and 3 of the Arlington Hilton Hotel, 950 North Stafford Street, Arlington, VA 22203. The hotel has reserved a block of rooms until June 13 for participants in the public meeting. Please contact the hotel at (800) 445–8667 and cite code USDAFSIS to make reservations.

FOR FURTHER INFORMATION CONTACT: To register for the public meeting, contact Ms. Mary Gioglio at (202) 501–7244, (202) 501–7138, or FAX (202) 501–7642. Persons wishing to speak at the public meeting are requested to submit an advance written summary of their remarks. Please submit written summaries pertaining to in-plant and/or in distribution inspection concepts to Ms. Patricia Stolfa, Assistant Deputy Administrator, Office of Policy, Program Development and Evaluation, Room 402 Cotton Annex, 300 12th Street SW,Washington, D.C. 20250–3700. Participants who require a sign language interpreter or other special accommodations should contact Ms. Gioglio at the above telephone or FAX numbers by June 10, 1997.

Background

This notice is organized into five sections. Section I (Introduction) explains the current status of the FSIS regulatory program and its food safety goals and strategy, and describes the Agency's consumer protection activities included in its current program. This section discusses the need for resource redeployment in light of the Agency's overall modernization effort. Section II (Current Inspection System) explains the current program and identifies significant inconsistencies between HACCP and the current program. This section also summarizes external support for inspection reform. Section III (HACCP-based Inspection Development Project) explains the project, describes inspection model development activities, announces a public process to assist in the development of new inspection models, and solicits volunteer establishments for participation in development activities. Section IV (New Inspection Models) presents current agency thinking on new in-plant and in-distribution models. Section V (Public Meeting) proposes material questions the Agency will address through the public process.

I. Introduction

Food Safety Goal

FSIS is committed to making fundamental improvements in the safety of America's meat and poultry supply in order to reduce the incidence of foodborne illness. In the preamble to the proposed rule ''Pathogen Reduction; Hazard Analysis and Critical Control Points (PR/HACCP) Systems'' (60 FR 6774; February 3, 1995), FSIS stated its

goal as follows: ''* * * to reduce the risk of foodborne illness associated with the consumption of meat and poultry products to the maximum extent possible by ensuring that appropriate and feasible measures are taken at each step in the food production process where hazards can enter and where procedures and technologies exist or can be developed to prevent the hazard or reduce the likelihood it will occur.'' (60 FR 6785.)

An essential first step in achieving that goal was accomplished with promulgation of the PR/HACCP Systems final rule (61 FR 38806; July 25, 1996).

The PR/HACCP final rule mandates substantial change within every inspected meat and poultry establishment. The new regulations: (1) Require that each establishment develop, implement, and follow written sanitation standard operating procedures (S-SOP's); (2) require regular microbial testing by slaughter establishments to verify the adequacy of their process controls for the prevention and removal of fecal contamination and associated bacteria; (3) establish pathogen reduction performance standards for *Salmonella* that slaughter establishments and establishments producing raw ground products must meet; and (4) require that all meat and poultry establishments develop and implement a risk-based system of preventive controls known as HACCP to improve product safety.

In mandating these reforms, FSIS recognized that in-plant technological and procedural solutions could not address foodborne illness hazards occurring in meat and poultry products outside official establishments. These components of the goal could be achieved only through a more comprehensive food safety strategy that would bring about improvements in risk management at each step in the meat and poultry production chain. Efforts must extend from just before slaughter, through slaughter, processing, distribution, and retail sale or food service, to consumers.

FSIS' Food Safety Strategy

The food safety strategy FSIS outlined in its PR/HACCP final rule included five major elements:

(1) Provision for systematic prevention or reduction of biological, chemical, and physical hazards through adoption by meat and poultry establishments of science-based process control systems.

(2) Targeted efforts to control and reduce harmful bacteria on raw meat and poultry products.

(3) Adoption of food safety performance standards that provide a catalyst for innovation to improve food safety and a measure of accountability for achieving acceptable food safety results.

(4) Removal of unnecessary regulatory obstacles to innovation.

(5) Efforts to address hazards that arise throughout the food safety continuum from farm to table.

FSIS also stressed, as a central theme of its strategy, a need to clarify and strengthen the responsibilities of establishments for maintaining effective sanitation, following sound food safety procedures, and achieving acceptable food safety results.

The PR/HACCP final rule included regulatory provisions to implement food safety strategy components (1) Hazard prevention through HACCP and other production control systems, (2) reduction and control of bacterial pathogens and (3) adoption of food safety performance standards. Earlier, FSIS had published an Advance Notice of Proposed Rulemaking (ANPR) (60 FR 67469 December 29, 1995) in pursuit of strategy component (4), the elimination of unnecessary regulatory obstacles to innovation. That notice announced a comprehensive review of all FSIS regulations to determine which will still be needed when the PR/HACCP final rule becomes effective and which ought to be revised, streamlined or eliminated. That review is well underway and a series of proposals will be published in the **Federal Register** to consolidate and remove or modify existing requirements to make them performance standards.

The PR/HACCP final rule did not address hazards arising at other points in the farm to table continuum: for instance, during the transportation, storage and retail, restaurant or food service sale of meat and poultry products. Yet each stage of production presents hazards of pathogen and other contamination and each provides opportunities for preventing or mitigating these hazards. Those in control of each segment of the farm to table continuum must accept their share of the responsibility for identifying and preventing or reducing food safety hazards that are under their operational control.

FSIS's food safety mandate requires that the Agency address foodborne illness hazards within each segment of the food production chain and that it implement and encourage prevention strategies that improve the whole system. FSIS remains committed to a farm to table food safety strategy based on these principles. Commenters on the PR/HACCP proposed rule supported FSIS modernization of its regulatory program to include all segments of the food production and transportation industries.

The Agency also will be cooperating with animal producers, academia, the Animal and Plant Health Inspection Service, the Food and Drug Administration, the States, and other government agencies to develop and foster voluntary food safety measures which can be taken on the farm to decrease the public health hazards in animals presented for slaughter.

The post-processing transportation, storage, and retail restaurant or food-service sectors are also important links in the chain of responsibility for food safety. In these areas, FDA and State and local governments share authority and responsibility for oversight of meat and poultry products outside of official establishments. FSIS, FDA, and the State and local agencies recognize that, if they are to reduce foodborne illness to the maximum extent possible, they must coordinate their food safety missions when addressing hazards that may arise in distribution and at retail. FSIS has initiated a number of activities which could form the basis for future regulatory activities at various points on the continuum.

In 1995, FSIS, FDA, and the Department of Transportation contracted with an expert group, the transportation Technical Analysis Group (TAG), to identify the hazards associated with transportation of perishable foods and to recommend reasonable controls that might be employed by industry to ensure food safety. Using the HACCP system, the TAG conducted a hazard analysis of the two major areas of concern in the trucking transportation chain: the transport of live animals or fresh materials, and the transport of processed or finished products that are perishable. The TAG concluded that a program to ensure more sanitary and temperature-controlled food transportation would benefit both the industry and consumers.

In conjunction with FDA, FSIS issued a November 22, 1996, Advance Notice Of Proposed Rulemaking (61 FR 59372) seeking comments and information on various issues and alternatives for ensuring the safety of potentially hazardous foods during transportation and storage. FSIS and FDA also co-hosted a conference in November 1996, focusing on transportation, storage and distribution of potentially hazardous foods. The conferees discussed ideas related to in-distribution regulatory activities to be considered by FSIS and FDA regarding meat, poultry, eggs,

seafood, dairy, and other potentially hazardous food products. A transcript of this conference is available from the FSIS hearing clerk.

Other Consumer Protection Activities

In addition to its food safety goal, FSIS also has other consumer protection responsibilities under the laws it administers that are the subject of many agency activities. These include ensuring that meat and poultry products are truthfully labeled and not economically adulterated with less valuable components such as water, and ensuring that consumers are protected from unwholesome meat and poultry products which, while not actually unsafe, might contain components which are undesirable.

Regulatory Objectives

The FSIS regulatory program of the future will be designed first to meet the Agency's food safety goal and strategy, along with our consumer protection responsibilities. The Agency realizes it must have the participation of all stakeholders to achieve our food safety goal and other objectives. FSIS is therefore seeking public input on the design and development of its HACCP-based program. FSIS believes that there are at least three essential objectives that will form the basis of this modern HACCP-based program.

- First, FSIS must ensure that any new inspection models do not diminish the current food safety and consumer protection achievements that result from (1) carcass-by-carcass and bird-by-bird slaughter inspection, and (2) Agency inspection oversight of production control systems in further processing establishments.
- The second objective is to effectively and efficiently oversee, evaluate, and verify industry implementation of the PR/HACCP final rule. HACCP, combined with other production control systems and FSIS inspection oversight, are complementary and interrelated, but independent activities that, taken together, enhance the safety of foods for consumers and thereby earn their confidence. Maintenance of such confidence shall be the critical test for any changes.
- The third regulatory objective is to ensure that meat and poultry products are handled and transported by allied industries under conditions which maintain their safety and integrity. FSIS intends to gather information about industry practices relative to handling, transport, and storage of meat and poultry products to determine whether businesses are effectively managing food safety risks and ensuring that other consumer protections remain intact.

Need for Resource Redeployment

FSIS will be unable to meet its food safety goal and other regulatory objectives unless it changes the way it deploys its resources. Currently, inspectors are fully, and frequently more than fully, occupied with carrying out the tasks of the present inspection system. Those tasks require that about 45% of the entire inspector field force be stationed at fixed positions along production lines in slaughter establishments. Current slaughter inspection staffing is directly related to industry production capacity. Higher production capacity requires the Agency to staff more inspection positions. Occasionally, staffing limitations negatively impact plant production rates.

FSIS recognizes that the opportunities for inspector redeployment are limited because current slaughter inspection regulations and procedures are, by design, resource-intensive. Seventy-two percent (72%) of the agency's in-plant inspection force is now assigned to slaughter or combination slaughter and processing establishments that make up only twenty-one (21%) of all establishments requiring federal inspection. Current slaughter inspection procedures obligate sixty-two percent (62%) of those in-plant slaughter inspectors (or 45% of the entire inspection force) to carcass-by-carcass and bird-by-bird post-mortem inspection.

FSIS believes it must explore alternatives to its current inspection design and resource deployment models. Redeployed resources would be allocated to new inplant functions associated with oversight, evaluation, and verification of the PR/HACCP final rule implementation. Other redeployed resources could be assigned to in-distribution oversight.

II. The Current Inspection System

This section describes current inspection system practices, especially within slaughter establishments, and illuminates several crucial problems with the current system that present barriers to the efficient and effective allocation of resources.

FSIS now carries out its meat and poultry food safety responsibilities primarily through in-plant slaughter and processing inspection programs. Under the current in-plant inspection system, FSIS inspects carcasses and parts of all livestock and birds to detect noncompliance with regulatory requirements, and requires correction of each product, production, facility, equipment and sanitation defect that occurs.

The current inspection system assumes that all livestock and birds and their carcasses and parts are presented for inspection with the intention of being prepared for use as human food. FSIS inspectors are required to determine which are wholesome, not adulterated, and capable of use as human food. FSIS inspectors decide whether to pass, condemn, or allow salvage of carcasses or parts thereof. Under the current system, FSIS uses inspectors at fixed stations on each slaughter line to organoleptically identify disease lesions or defects in carcasses, viscera and, in some species, heads.

Problems With Current Inspection

FSIS has identified several problems with the current approach. One major problem is that as slaughter establishments have come to rely on FSIS personnel to sort acceptable from unacceptable product, the establishments have no mandate or incentive to remove carcasses and parts prior to presentation for inspection. Thus, the proper roles of industry and inspection personnel are obscured. FSIS' resources are inappropriately and inefficiently used when FSIS slaughter inspectors take on the industry's responsibility for finding defects, identifying corrective actions, and solving production control problems.

A much more significant problem with the current inspection system is that it does not permit FSIS to allocate resources according to public health risk. For instance, the current line inspection system required by regulation in meat and poultry slaughter establishments focuses substantial FSIS inspection resources on areas that do not present significant food safety risks. The carcass inspection procedures carried out by FSIS inspectors today were designed many years ago in response to a higher prevalence of disease in the animal populations of that era. Over the years, significant advancements have been made in the control or eradication of many animal diseases, especially those that are transmissible to humans, such as tuberculosis and brucellosis. Also, animal production practices have become more efficient so that most livestock and poultry are slaughtered at a young age, generally free of diseases more common in older animals. Nonetheless, inspection methods have not changed.

Inspection methods have also not been modified sufficiently to address

the microbial causes of foodborne illness. Current inspection methods continue to rely on organoleptic identification of defects as indicators of possible microbial risk. Measuring microbial hazards in the design of HACCP plans through testing for actual microbial levels and validation of control measures will occur during implementation of the PR/HACCP final rule. Since new inspection models should reflect this focus on pathogen reduction and microbial monitoring and verification, the current reliance on organoleptic inspection should be carefully reassessed.

The following data illustrate the results of current FSIS line inspection. The overall level of carcass condemnation is low, 0.9 percent of young chickens, 0.1 percent of steers and heifers, and 0.3 percent of market hogs. Many carcass defects that result in condemnation by FSIS slaughter inspectors today are aesthetic rather than food safety related, such as pigmentary conditions and tumors. Condemnation for food safety reasons is even lower, 0.4 percent of young chickens, 0.08 percent of steers and heifers, and 0.23 percent of market hogs. Inspection resources are now used to directly observe 1,000 young chickens to find four (4) that should be condemned for food safety concerns. Similarly 10,000 steers and heifers are observed to condemn eight (8) and 1,000 market hogs (barrows and gilts) are observed to condemn two (2). Tables 1, 2 and 3 summarize carcass condemnation data from fiscal year 1995. These data underscore the need to reassess our current use of extensive inspection resources in this area and to ask what staffing levels and patterns are appropriate for the level of risk they address. FSIS believes that updating the diseases and conditions subject to condemnation or restriction under the PPIA and FMIA is long overdue and crucial to the development of new inspection models. Certain diseases and conditions unrelated to food safety, but currently addressed in the regulations, may be more appropriately addressed by industry monitoring.

TABLE 1.—FY 1995 CONDEMNATION DATA FOR YOUNG CHICKENS

Total slaughtered 7,512,916,376

Condemnation condition	Potential public health concern	Number condemned	Percent condemned [1]
Septicemia/toxemia	Yes	23,684,719	0.30
Synovitis	No	489,101	0.01
Contamination	Yes	6,190,429	0.08
Manufacturing defects	No	20,984,146	0.28
Aesthetic defects	No	18,990,884	0.25
Totals		70,339,279	0.94

[1] Percentages do not total 0.94 due to rounding.

The disease conditions with potential public health implications are easily identified by visual assessment. Manufacturing defects include such items as bruises, cadaver, over scalded, missing viscera, and plant rejects. Aesthetic conditions with no known food safety concern include leukosis, other tumors, and airsacculitis.

TABLE 2.—FY 1995 CONDEMNATION DATA FOR STEERS AND HEIFERS

Total slaughtered 28,807,882

Condemnation condition	Potential public health concern	Number condemned	Percent condemned [1]
Septicemia/toxemia	Yes	10,630	0.04
Inflammatory conditions	Yes	8,270	0.03
Tuberculosis	Yes	41	0.00
Ante-mortem conditions	Yes	1,802	0.01
Parasitic/fungal	Yes	2,678	0.01
Metabolic	No	2,081	0.01
Visually identifiable	No	2,352	0.01
Tumors	No	671	0.00
Totals		28,525	0.10

[1] Percentages do not total 0.10 due to rounding.

Some condemnable conditions are identified ante-mortem by visual assessment and animals with these conditions are not allowed to enter the slaughter department, including animals arriving dead, those with central nervous system disorders, moribund animals, those with tetanus, and those with fever (pyrexia). Metabolic conditions include cachexia and uremia and are identified by visual assessment. Other conditions are identifiable post-mortem by visual assessment, including icterus, eosinophilic myositis, tumors, and pigment conditions.

TABLE 3.—FY 1995 CONDEMNATION DATA FOR BARROWS AND GILTS

Total slaughtered 89,530,876			
Condemnation condition	Potential public health concern	Number condemned	Percent condemned [1]
Septicemia/toxemia	Yes	36,641	0.04
Inflammatory conditions	Yes	24,701	0.03
Tuberculosis	No	1,262	0.00
Ante-mortem conditions	Yes	137,998	0.15
Parasitic/fungal	Yes	47	0.00
Metabolic	No	1,448	0.00
Visually identifiable	No	14,717	0.02
Tumors	No	2,685	0.00
Totals		219,499	0.25

[1] Percentages do not total 0.25 due to rounding.

The conditions with potential public health implications are easily identified by visual assessment. Some condemnable conditions are identified on livestock and birds ante-mortem by visual assessment and not allowed to enter the slaughter department, including animals arriving dead (accounts for over one-half of all condemnations), those with central nervous system disorders, moribund animals, those with tetanus, and those with fever (pyrexia). Metabolic conditions include cachexia and uremia and are identified by visual assessment. Other conditions are identifiable at post-mortem by visual assessment, including icterus, eosinophilic myositis, tumors, and pigment conditions.

Despite the fact that many condemnations are unrelated to public health risks, today FSIS still fully staffs every meat and poultry establishment slaughter line inspection station. Assigning top priority to slaughter line inspection activities to detect quality as well as defects of public health concern directly affects the Agency's ability to staff other critical food safety inspection activities and may not be the best use of inspection resources. For example, FSIS inspectors in slaughter establishments are assigned the task of verifying establishment production control systems for sanitary dressing of slaughtered animals and operational sanitation of equipment and facilities. If, however, slaughter line inspection positions become vacant, inspectors are removed from these important verification duties to fill the line positions. This means that important production control systems, which prevent or eliminate hazards such as bacterial pathogens, are only monitored by plant employees with little FSIS inspection verification.

The current inspection system can also raise barriers to establishment innovation through new technology and improved production procedures. Establishments should have the flexibility to implement the PR/HACCP final rule and to make decisions about how they may best control food safety hazards and meet performance standards. Establishments should have the latitude to develop new production control methods to detect food safety and non-food safety related defects in carcasses and parts. Current slaughter inspection methods, particularly fixed inspector stations on establishment slaughter lines, limits industry innovation.

External Support for Inspection Reform

Recent outbreaks of foodborne illness have focused attention on the need for improving the current system. Studies conducted over the past decade by the National Academy of Sciences (NAS), the General Accounting Office, and by FSIS have established the need for fundamental change in the meat and poultry inspection program. Two elements have been commonly expressed: FSIS should revise and reform inspection to (1) Improve food safety through a reduction in foodborne illness caused by pathogenic bacteria on meat and poultry products and (2) make better use of its resources. Bacteria, including *Salmonella, E. Coli* 0157:H7, *Campylobacter* and *Listeria Monocytogenes,* are significant food safety hazards associated with meat and poultry products. The contamination of meat and/or poultry with these bacteria is estimated to result annually in as many as 4,000 deaths and 5,000,000 illnesses.

The theme of NAS's recommendations is that FSIS should reduce its reliance on organoleptic inspection and shift to prevention-oriented inspection systems based on risk assessment. The 1985 NAS report, *Meat and Poultry Inspection: The Scientific Basis of the Nation's Program,* recommended that FSIS focus on pathogenic organisms and require that all official establishments operate under a HACCP system for control of pathogens and other safety hazards. This report strongly encouraged ''FSIS to move as vigorously as possible in the application of the HACCP concept to each and every step in establishment operations, in all types of enterprises involved in the production, processing, and storage of meat and poultry products.''

Two later NAS studies reinforced this recommendation. The 1987 NAS report *Poultry Inspection: The Basis for a Risk Assessment Approach* concluded ''that the present system of inspection does very little to protect the public against microbial hazards in young chickens.'' The report continued to say that ''[Agency] resources are not always allocated to the right points and the resources that are properly directed are not achieving measurable results. Major changes are required in the poultry inspection system if public health is to be protected and if the investment of resources is to have maximum effect.'' It recommended that FSIS adopt an inspection strategy ''that is more likely to have a substantial impact on human diseases.'' The 1990 NAS report *Cattle Inspection: Committee on Evaluation of USDA Streamlined Inspection System for Cattle (SIS–C)* added that although ''traditional meat inspection, relying on organoleptic examinations, can ensure satisfactory meat product quality, it is not fully effective in protecting the public against foodborne health hazards not detectable with these techniques. 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.''

The General Accounting Office (GAO) has advocated similar improvements for meat and poultry inspection in its reports. (Food Safety: A Unified, Risk-Based Food Safety System Needed (1994); Meat Safety: Inspection System's Ability to Detect Harmful Bacteria Remains Limited (1994); Food Safety: Building a Scientific, Risk-Based Meat and Poultry Inspection System (1993); Food Safety and Quality—Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply (1992).) The GAO has endorsed HACCP as a scientific, risk-based system that would permit redeployment of FSIS resources in a manner that will better protect the public from foodborne illness. The 1994 GAO report, *Meat Safety: Inspection System's Ability to Detect Harmful Bacteria Remains Limited*, stated the resource problem clearly. ''Labor-intensive inspection procedures and inflexible inspection frequencies drain resources that could be put to better use in a risk-based system. To better protect the public from foodborne illnesses, FSIS must move to a modern, scientific, risk-based inspection system. Such a system would allow FSIS to target its resources toward the higher-risk meat and poultry products by increasing inspection of such products.''

Another proponent of inspection reform has been the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), which prepared reports on the development and implementation of HACCP. NACMCF supported the use of risk analysis for allocation of resources to control food safety.

III. HACCP-Based Inspection Development Project

With this notice, FSIS is initiating the process of dialogue with all interested parties to advance the design and development of new inspection models to be tested in a series of trials in volunteer meat and poultry slaughter establishments and in distribution channels. This project is intended to produce a fully integrated system of regulatory oversight and controls that will permit FSIS to deploy inspection resources more effectively in-plant and between in-plant and in-distribution sites in accord with food safety and other consumer protection requirements.

Objectives for New Inspection Models

The development of new in-plant and in-distribution inspection models will occur in three phases.

Phase I. Initiation: Conduct public meeting to explain the need for new inspection models and to commence a public dialogue on the available options for their design, complete preliminary designs, and prepare for development activities.

Phase II. Development: Conduct development activities in commercial establishments and at in-distribution points to refine the models, gather data, generate implementation strategies.

Phase III. Completion: Write the final report, publish results for comment, and initiate rulemaking, as appropriate, to change existing inspection procedures.

During each phase, the in-plant and in-distribution inspection methods will be developed separately. The purpose of a two-track development is to test and refine the new inspection concepts in both commercially operating meat and poultry establishments and with in-distribution activities at several geographic sites. Throughout the development phase, FSIS will be prepared to revise or suspend current inspection procedures provided that appropriate oversight controls are maintained in volunteer establishments.

This notice announces the first step in Phase I, a public meeting to present the need for new inspection concepts and to commence a public dialogue on these concepts. At this meeting, FSIS will describe its current thinking, seek information from all stakeholders, and use that input to complete preliminary designs for new in-plant and in-distribution inspection models suitable for testing and development. FSIS needs the broadest possible public participation in the development of these models.

FSIS will prepare a transcript of the public meeting. The transcript and copies of any papers presented at the meeting will be available in the FSIS Docket Clerk's Office, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250–3700.

Development Phase

FSIS development activities for new in-plant inspection systems will critically examine how well each design meets the Agency's regulatory objectives. In-plant tests will be conducted in establishments that predominantly slaughter young chickens, market hogs and steers/heifers. Volunteer establishments will be sought for each class. Young chickens, market hogs and steers/heifers were selected for these development activities because they tend to be healthy and uniform; they also represent over ninety percent (90%) of meat and poultry slaughtered in the United States.

Slaughter and combination slaughter and processing plants participating as volunteers will be required to have HACCP and other production controls in place to ensure that all consumer protection goals of the program are being met. Participating establishments must also have successful S–SOP's and a working generic *E. coli* testing program.

FSIS solicits establishments to volunteer for participation in the in-plant development phase. Establishments requesting to participate should request to do so in writing to FSIS at the address provided in the **ADDRESSES** portion of this notice. Written applications for participation in the development activities should provide a description of establishment operations that includes predominant species slaughtered, number and type of slaughter lines, and a certification that all applicable elements of the PR/HACCP final rule have been or will be fully implemented. FSIS will conduct an on-site visit to verify eligibility for participation in the development activities.

FSIS intends to assign inspection work more broadly during the in-plant development activities to explore new methods for performing regulatory work. For instance, if volunteer establishments conduct both slaughter and processing operations, inspectors might be assigned to perform work that cuts across traditional job lines. Within the slaughter operation, inspectors could provide oversight, evaluation, and verification of carcass-by-carcass and bird-by-bird industry determination of acceptable and unacceptable product. Inspectors would have access to perform hands-on inspection of carcasses or birds. They would perform additional tasks in slaughter and processing for assurance that products bearing the official inspection mark are not adulterated or misbranded, including verification of HACCP or S–SOP's. Such changes would provide FSIS with considerable data with which to evaluate the effectiveness of its inspection resources.

Staffing requirements for new in-plant inspection models could also vary depending on factors such as species of animal, the establishment's production system, and slaughter line configurations. Nontraditional staffing criteria are under development. In-plant slaughter inspection could (1) be staffed with available inspectors, (2) provide for rotation of inspection personnel between slaughter and processing duties, (3) provide continuous oversight of establishment production systems, (4) include scheduling of slaughter inspection tasks, and (5) provide unscheduled time for all inspection

personnel to conduct additional inspection activities in the establishment.

In view of the mix of skills to be found among slaughter inspection personnel, all slaughter inspectors currently assigned to the volunteer establishments will be trained for the project to perform (1) carcass-by-carcass and bird-by-bird slaughter inspection oversight, (2) verification of HACCP and related production control systems, (3) verification of establishment S–SOP's and (4) sampling.

The in-distribution development activities will be conducted on a separate track. In-distribution concepts will be studied in geographic areas selected to provide a variety of population densities and differing logistical challenges for scheduling work. In addition, two staffing options will be discussed at the public meeting: (1) Inspectors assigned only to in-distribution activities, and (2) inspectors who divide their time between in-plant and in-distribution work. Both options will be considered for application in rural as well as urban areas.

The in-distribution development activities will be staffed by experienced in-plant inspectors with prior training in processing inspection and supplementary training for the new work. This work will include in-plant tasks that have been identified to be supplemented or replaced by in-distribution oversight and tasks to determine the feasibility, efficiency, and effectiveness of performing food safety and other consumer protection tasks in distribution.

Completion

Upon completion of the development activities, FSIS will prepare a project report presenting a thorough evaluation of the in-plant and in-distribution inspection models tested. The Agency will decide at this point whether further testing of the models should be conducted or whether to initiate rulemaking to adopt and implement the new models nationally.

IV. New Inspection Models

The following criteria will be used to design and evaluate new in-plant and in-distribution models accepted for testing. The models should:

1. Emphasize industry responsibility for food safety and other consumer protection activities and government responsibility to verify that these objectives are met.

2. Include inspection procedures that detach inspectors from establishment production functions and from sanitation management.

3. Prioritize in-plant work to meet current inspection system objectives and verify that HACCP and other control systems and sanitation procedures are effective; provide appropriate priority to other consumer protection issues such as misbranding or economic adulteration.

4. Result from an assessment of all in-plant regulatory work to determine whether some tasks can be performed effectively and efficiently in-distribution and, where more appropriate, supplement some in-plant regulatory work with in-distribution oversight.

5. Identify and prioritize new in-distribution regulatory work, including oversight of how industry manages health and safety hazards that occur after meat and poultry products leave a USDA-inspected establishment and verification that products in-distribution are not misbranded or economically adulterated.

FSIS will develop new in-plant inspection models for slaughter establishments and combination slaughter and processing establishments to help the Agency properly allocate resources between oversight, evaluation and verification of PR/HACCP final rule implementation and activities to accomplish other consumer protection objectives. The new in-plant inspection models must also help the agency in properly allocating resources between in-plant and in-distribution work environments.

In-plant Inspection Models

A variation of the current inspection system has been identified as a model to be considered and discussed at the public meeting announced by this notice.

Under this in-plant model, the establishment would initiate HACCP and related control systems to distinguish acceptable from unacceptable carcasses and parts using current regulatory requirements for antemortem and postmortem disposition of carcasses and parts.

This model would provide establishments maximum flexibility to design and exercise more effective and more efficient production control systems. FSIS inspectors would have complete access to all carcasses and birds on each slaughter line to directly observe establishment production systems and verify process controls to ensure that products are not adulterated or misbranded. Consequently, establishment product flow plans crafted for compliance with the PR/HACCP final rule for other production control purposes would not include fixed FSIS inspection stations.

FSIS intends to judge products for safety and wholesomeness based upon the entire operation under which they are produced. FSIS inspectors could provide continuous regulatory oversight of the entire production operation to include each on-line processing step and all aspects of the establishment that contribute to product safety and wholesomeness.

FSIS envisions this inspection model as having three main components that collectively would ensure equivalent performance to that level of food safety and other consumer protections provided by the current regulatory system. Slaughter performance standards that define an acceptable carcass or part are the basis for the first inspection component. FSIS would establish performance standards to replace command and control regulations. Industry systems to meet the performance standards would satisfy the first component.

The second component is direct verification by FSIS inspectors of the establishment program. This would be accomplished by FSIS inspectors who would provide carcass-by-carcass and bird-by-bird inspection oversight at the slaughter line and by periodic checks to verify the condition of carcasses and parts the establishment has found to be acceptable.

The third component is verification of the overall establishment program for producing acceptable product including verification of HACCP, other production control systems, and S–SOP's.

This preliminary in-plant inspection model envisioned by FSIS would require fewer inspectors assigned to slaughter plants, making inspectors currently assigned to slaughter line positions available for redeployment. This is consistent with HACCP principles and would reduce or eliminate distinctions between slaughter and processing inspection by allowing inspectors to rotate from post-mortem oversight positions to work such as HACCP verification, finished product standards testing, Performance Based Inspection System (PBIS) task performance, S–SOP verification and microbial sampling.

FSIS Verification Activities

Under the new in-plant inspection model, FSIS would not prescribe how industry must accomplish production control. Establishments would instead be provided the flexibility, within performance and regulatory standards set by FSIS, to design specific processes that address hazards and defects unique

to their operations. FSIS would ensure that establishment HACCP and other control system plans for achieving regulatory standards are adequate and operating properly. Following is an illustration of steps FSIS inspectors would take to oversee, evaluate, and verify establishment production control systems.

- Observe the production control systems; verify that process control procedures are being followed by the establishment.
- Observe carcasses, parts, or viscera rejected by the establishment; provide information to the off-line inspector and veterinarian as to which diseases or conditions are prevalent.
- Observe carcasses, parts or viscera accepted by the establishment; verify removal of obvious condemnable conditions.
- Sample carcasses, heads or viscera accepted by the establishment; select and examine a specific number of carcasses, heads or viscera to verify the effectiveness of the establishment's system for ensuring accepted product is wholesome and otherwise eligible for the mark of inspection.
- Review records to determine whether the establishment is following its production control plans.
- Observe product (carcasses, heads, and viscera) to determine which conditions are present.
- Coordinate with establishment manager, who provides oversight of production control systems, to ensure that performance standards are being applied correctly.
- Conduct product standards testing (e.g., Finished Product Standards, Acceptable Quality Level) to determine the effectiveness of establishment production control systems for quality or wholesomeness defects.

FSIS also will conduct verification checks of establishment activities other than production control systems. For instance, FSIS inspectors will:

- Perform tasks related to the Performance-Based Inspection System, including those historically performed after slaughter during processing.
- Conduct HACCP record reviews to verify that the establishment is monitoring critical control points in accordance with their HACCP plan.
- Verify establishment disposition of rejected product.
- Conduct operational verification activities, such as assessing the establishment's execution of its HACCP plan.
- Take samples of product for microbiological, chemical and physical analysis to verify establishment compliance with its HACCP plan.
- Verify that the establishment is following its sanitation SOP.

The FSIS Veterinary Medical Officer (VMO) will work closely with inspectors to provide continuous oversight and thorough documentation of establishment production control systems. VMO expertise and responsibilities would include the following:

- Serve as the Inspector-in-Charge; supervise food inspectors.
- Evaluate the health of incoming animals through ante-mortem activities.
- Perform ante-mortem inspection of suspect animals.
- Verify establishment production control systems to ensure proper application of disposition standards by inspectors and establishment personnel.
- Verify microbial sampling and testing of product.
- Take microbial and histopathological samples of condemned carcasses to profile etiologies.
- Participate in the evaluation of testing or implementation of new technologies initiated by establishments for identifying condemnable carcasses.
- Serve as liaison with establishment management, industry technical experts and with local or State public health officials.

In-Distribution Concept

A new in-distribution inspection concept should provide for verifying industry management of food safety risks that arise after inspection. Resource allocation issues require an integrated approach for both food safety and other consumer protection initiatives. Thus, the in-distribution model may also supplement in-plant oversight of product labeling, economic adulteration and wholesomeness requirements. Although FSIS will develop and field-test new concepts for slaughter and in-distribution separately, FSIS envisions one fully integrated program that would permit movement of personnel and tasks between the two activities.

At present, FSIS has no comprehensive rules governing the in-distribution handling of meat and poultry products. The Agency now exercises its jurisdiction over product outside inspected establishments to a limited degree. For example, FSIS has promulgated safe handling labels for raw meat and poultry products (9 CFR 317.2 (l) and (m), and 381.125(b)); in many instances those labels are applied at retail locations. FSIS also verifies and enforces compliance with requirements concerning transportation to and among inspected establishments and allied industries, such as renderers and pet food establishments, conducts scheduled and unscheduled reviews of warehouses and other in-distribution locations, verifies the recall of product from in-distribution channels, performs scheduled and unscheduled product sampling, and investigates complaints from consumers and others about alleged adulterated or misbranded products.

This approach has been both proactive and reactive. FSIS has not focused systematically on in-distribution conditions and practices that contribute to the growth of microbes. FSIS uses resources to detect problems, educate industry, correct violations, and make appropriate dispositions on millions of pounds of product. However, the statutes provide USDA authority to oversee meat and poultry products after they leave inspected establishments. The statutes provide that one may not ''sell, transport, offer for sale or transportation, or receive for transportation'' any meat or poultry product that is capable of use as human food and is ''adulterated or misbranded at the time of such sale, transportation, offer for sale or transportation, or receipt for transportation * * *'' (21 U.S.C. 610 and 458(a)(2)). The statutes also prohibit any action ''intended to cause or [that] has the effect of causing such articles to be adulterated or misbranded.'' (21 U.S.C. 610(d) and 458(a)(3)).

This authority would encompass the establishment of safety standards for meat and poultry products from the time they leave an inspected establishment to final sale or service to consumers. As a first step, FSIS has yet to determine whether performance standards and Good Manufacturing Practices could and whether they can be established for meat and poultry products to prevent growth of harmful bacteria and introduction of other potential hazards during transportation.

FSIS is considering work accomplished by the transportation TAG, to identify primary hazards associated with transportation of perishable foods and controls that might be employed by industry to ensure food safety. The TAG noted ''that time, temperature, and sanitation are the three key elements of any control plan'' affecting the transportation sector. The TAG also concluded that sanitary conditions and practices, maintenance of product temperature in transit, time in transit, and practices to reduce opportunities for cross contamination all represent control points for which the development of regulatory standards, good manufacturing

practices, and suitable verification controls are possible.

During in-distribution inspection concept development, FSIS will gather data to describe impacts on pathogen levels attributable to present allied industry practices. Data collection sources will include allied industry members who volunteer to describe quality or safety problems they experience with meat and poultry received from their suppliers. These data will suggest points of concern within the distribution chain that FSIS may need to address in its inspection planning.

Another data collection effort could be to identify a microbial baseline for certain products or product lots as they leave inspected establishments and track them through the distribution chain to detect and record changes caused by allied industry handling practices. The nationwide status of the food safety and other consumer protection aspects of meat and poultry products could be evaluated and profiles developed. Evaluation of changes in profiles over time would measure the effectiveness of in-distribution efforts to maintain food safety and product integrity. Status reports on meat and poultry products might be correlated with sentinel site surveillance data for foodborne disease to track the public health impact of farm to table food safety initiatives.

While time, temperature, and sanitation play a key role in controlling hazards to perishable foods in transportation, they are not the only factors that could be verified in the distribution chain. FSIS will also determine whether some adulteration and misbranding inspections presently conducted in-plant can be supplemented or perhaps performed entirely in-distribution. Many meat and poultry products are prepared by regulated establishments in consumer-ready packages. Samples could be collected in the marketplace rather than in establishments and subsequently analyzed in a laboratory for product formulation, proper labeling, and compliance with microbial and residue standards. For example, samples could be taken in-distribution to profile water added hams to determine adherence to accurate labeling and restricted ingredients requirements. Similarly, products produced in bulk packages might also be sampled at points in-distribution beyond where it was initially processed.

In-Distribution Alternatives

Transportation and storage are vital links in the farm to table continuum. The Agency has been developing in-distribution concepts and identified both available information and information gaps. Allied industries responsible for transportation and storage of meat and poultry have addressed product integrity issues for sometime. For example, cold storage facilities, warehouses, depots, and similar kinds of businesses have temperature and product handling controls that they use to ensure the safe storage of foods. Such standards may have broad applicability to in-distribution activities. The details about these activities, however, are not adequately known to FSIS.

FSIS identified several alternatives to ensure safe transportation and storage of food in its ANPR of November 22, 1996: *Transportation and Storage Requirements for Potentially Hazardous Foods* (61 FR 59372). These alternatives include specific requirements, such as temperature standards, performance standards, record keeping to ensure that food safety controls are maintained, mandatory HACCP-type systems, voluntary guidelines, and combined approaches. These alternatives are summarized below.

1. Temperature Requirements

One approach is the promulgation of a performance standard that would require that potentially hazardous foods be cooled to and maintained at or below a specific temperature during transportation and storage from the food processing plant to the retail outlet, restaurant, or other establishment serving the consumer. If this approach is adopted, all potentially hazardous foods being transported to retail or food service establishments would have to be maintained at or below such a maximum temperature.

2. Shipper Recordkeeping

Another alternative could be recordkeeping requirements with respect to the conditions under which foods that pose a risk as vehicles for foodborne disease are transported interstate. The Agency may consider requiring carriers of potentially hazardous foods that are shipped in bulk (foods which directly contact a food conveyance) to provide food shippers with records that identify the last three cargoes for any conveyance being offered to the food shipper for use in transporting the food and that disclose the data of the most recent cleaning of the conveyance.

3. Mandatory HACCP-Type Systems

Another approach would be to require that a HACCP system be established specifically with respect to the transportation and storage of potentially hazardous foods to prevent the contamination of these foods. Such requirements could be modeled on the regulations recently adopted by FSIS that apply to establishments processing meat and poultry.

Such HACCP-type systems could be relatively simple. Essentially, they would likely require that potentially hazardous foods be maintained at a particular refrigeration temperature or frozen temperature, and that the temperature be recorded using a recording thermometer. The use of a temperature standard would allow processors to determine the acceptability of a food transport vehicle for the transport of certain bulk foods, i.e., those that pose a risk of foodborne disease, based on cargo records.

4. Voluntary Guidelines

Another approach under consideration is to make more use of voluntary guidelines. Some government agencies, industry groups, and other organizations have published guidelines or recommended practices that address the transportation and storage of potentially hazardous foods, whether fresh or frozen. Such guidelines, several of which are discussed in the ANPR of November 22, 1996 (61 FR 59372), could serve as the basis for developing joint government-industry guidelines for food transportation and storage.

V. Public Meeting

Public participation in the development and implementation of the new inspection models discussed in this notice is essential. In addition to commentary on FSIS resource redeployment, specific inspection models, and in-distribution inspection activities, the Agency believes that comments addressing the following questions will facilitate the public process.

- What are the priority food safety objectives that must be accomplished by FSIS' meat and poultry inspection system?
- What other significant consumer protections should the meat and poultry regulatory system provide?
- How should the agency prioritize food safety and other consumer protection objectives?
- How much emphasis should FSIS place on detection of aesthetic defects that are not related to food safety?
- A major objective of the S–SOP requirement in the PR/HACCP regulation was to make establishments more accountable for performing all necessary sanitation functions before

and during operations. What other establishment operations might benefit from similar regulatory approaches?

- Is it necessary or desirable to employ the same inspection methodology in all similar establishments?
- What roles should Federal, State, and local governments play in verifying the safe transportation and storage of potentially hazardous foods?
- How we can best coordinate with State and local authorities to minimize restaurant and institutional outbreaks linked to meat and poultry products?
- How can FSIS verify allied industry management of food safety risks as meat and poultry products move from the establishment to consumers?
- What systems do establishments have in place for ensuring in-distribution protection of meat and poultry products? How does industry measure the performance of these systems?
- What in-plant inspection objectives can be supplemented or replaced with in-distribution inspection models?
- What additional suggestions are there for data collection efforts to be carried out in distribution channels?
- Are the in-distribution alternatives identified in the ANPR of November 22, 1996 (61 FR 59372), useful? In what ways?

Done at Washington, DC on: June 4, 1997.

Thomas J. Billy,

Administrator.

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 97–037N]

Interstate Distribution of State-Inspected Meat and Poultry Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of public meetings; request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is soliciting comments on ways it can improve Federal and State cooperation in the implementation of the Federal meat and poultry inspection laws, and on whether, and if so how, those laws should be amended to permit meat and poultry products inspected by State inspection programs to be distributed in interstate commerce. State inspection programs are authorized under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) to inspect meat and poultry establishments that prepare products intended for use as human food solely for distribution within the State under requirements ''at least equal to'' those imposed under Federal inspection.

DATES: The meetings will be held on June 16 and 17, 1997, in Sioux Falls, SD, and on July 22, 1997, in Washington, DC. Written information and comments will be accepted and made a part of the record of these proceedings through August 22, 1997.

ADDRESSES: The first meeting will be held from 9:00 a.m. to 4:00 p.m. on June 16 and from 9:00 a.m. to 1:00 p.m. on June 17, 1997, at the Radisson Encore Inn, 4300 Empire Place, Sioux Falls, SD 57106–6525; telephone (605) 361–6684. The second meeting will be held from 9:00 a.m. to 5:00 p.m. on July 22, 1997, in the Ticonderoga Room of the Hyatt Regency Washington on Capitol Hill, 400 New Jersey Avenue, NW, Washington, DC 20001. Persons sending written comments should send an original and two copies to the FSIS Docket Clerk, Docket No. 97–037N, Room 102 Annex Building, 300 12th Street, SW, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: Persons wishing to participate in either of the two meetings are requested to register by contacting Ms. Traci Phebus by telephone at (202) 501–7138, by FAX at (202) 501–7642, or by E-mail at HACCP.Confer@USDA.GOV. Participants may reserve a 5-minute comment period when they register. More time may be available, depending on the number of people wishing to make a presentation and the time needed for questions, following the presentations. Reservations will be confirmed on a first-come, first-served basis. Written comments may also be submitted for the record at the meetings. For questions about the meetings contact Mr. Ralph Stafko at (202) 720–7774, or FAX at (202) 720–2345. Participants who require a sign language interpreter or other special accommodations should contact Ms. Jennifer Callahan at (202) 501–7138.

SUPPLEMENTARY INFORMATION: A number of State Departments of Agriculture operating their own meat and poultry inspection programs have expressed various concerns about the relationship between the State programs and the Federal meat and poultry inspection program, and, in addition, have advocated amendments in Federal laws to permit State-inspected meat and poultry products to be distributed in interstate commerce. FSIS will conduct public hearings to explore these concerns and any recommended alternative policies and procedures, including proposals to amend Federal laws to improve the cooperative relationship between Federal and State meat and poultry inspection programs. The following information is provided in order to encourage the discussion of these issues and the submission of relevant information and comment.

Background

FSIS must provide Federal inspection at any meat and poultry establishment that produces meat and poultry products for interstate or foreign commerce, or that produces such products for intrastate commerce if the State in which it is located does not operate its own program. Those approximately 6,500 establishments, encompassing very large to very small establishments, produce the vast majority of the nation's inspected meat and poultry products slaughtered and processed in the United States.

Twenty-six states operate their own inspection programs, which collectively inspect approximately 2,800 mostly small and mid-size meat and poultry plants (Table 1). Estimates of the proportion of the nation's meat and poultry products that are State-inspected have ranged as high as 7 percent. FSIS data, limited to slaughter operations and not accounting for processed products, show that State-inspected establishments slaughter commercially a little more than 1 percent of the nation's livestock and a small fraction of 1 percent of the nation's poultry by weight.

To ensure that States are enforcing requirements ''at least equal to'' the Federal requirements, FSIS inspection program personnel work directly with State inspection officials providing advice and guidance on Federal inspection requirements on a continuing basis and also conduct periodic reviews of the State inspection programs. FSIS reviews each State program's State Performance Plan (SPP) annually. The SPP is a compilation of applicable State laws and regulations, program resources, and current operations and enforcement activities (FSIS Directive 5720.2, Cooperative Inspection Programs). In addition, teams of FSIS experts periodically conduct comprehensive on-site reviews, including random sampling of records and inspection of conditions in State-inspected plants. State programs are rated as: 1, Acceptable; 2, Acceptable with Minor Variations; 3, Acceptable with Significant Variations; and 4,