

MINUTES OF THE HOUSE COMMITTEE ON AGRICULTURE.

The meeting was called to order by Chairperson Joann Flower at 9:00 a.m. on March 14, 1997, in Room 423-S of the Capitol.

All members were present except: Representative Faber - absent
Representative Showalter - absent

Committee staff present: Raney Gilliland, Legislative Research Department
Gordon Self, Revisor of Statutes
Jill Wolters, Revisor of Statutes
Kay Scarlett, Committee Secretary

Conferees appearing before the committee:

Dr. Bob Fetzner, Director of Federal State Relations, USDA Food Safety Inspection Service, and Staff

Others attending: See attached list

Hazard Analysis and Critical Control Points (HACCP)

Dr. Bob Fetzner, Director of Federal State Relations, USDA Food Safety Inspection Service, and staff answered committee questions concerning HACCP via a telephone conference call.

Representative Thimesch distributed copies of two Food Safety Inspection Service reports both dated July, 1996, for the committee's reference: *Key Facts: Impact of HACCP Rule on Small Businesses* and *The Final Rule on Pathogen Reduction and HACCP Systems*. (Attachments 1 and 2, respectively)

Dr. Fetzner and staff assured the committee and those in attendance that there should be no additional facility requirements for small meat processing plants because of HACCP, and only nominal fees for training and possibly hiring someone to write their HACCP plan. He said there has been much misunderstanding concerning anticipated costs to implement a HACCP System; there is no reason to lose the large number of small processing plants that some are projecting. He told the committee that the time and temperature requirements originally proposed have been waived, as long as there is a separation of cooked meat and raw meat. Dr. Fetzner said there has been very few problems with implementation of HACCP in federally inspected plants, and the 26 states with state-inspection programs are all in the process of implementation.

It was explained that small plants will bear the cost of testing thirteen samples for E. coli between the months of June and August; testing for Salmonella will be conducted by and the costs borne by state or federal inspection. The committee was told that with advanced technology, the cost for E. coli testing has gone down from \$30 to as low as \$5 per sample. Dr. Fetzner said costs to the small meat processor will include developing the initial HACCP plan and the training of personnel; cost of the thirteen test samples for E. coli, annually; and the time devoted to additional paper work. He explained that rather than have an inspector on the premises all the time, operators will be required to keep records verifying that procedures have been followed. He said estimated costs are broken down by category in the Federal Register Vol. 61, No. 144/Thursday, July 25, 1996/Rules and Regulations (Attachment 3, February 20, 1997).

Dr. Fetzner said the National Academy of Science had warned USDA about pathogens in meat and poultry and the need for more scientific inspection requirements for many years; however, it took the E. coli scare in the Northwest before specific action was taken. Dr. Fetzner said the United States is the leading nation in the world for meat and poultry inspection; the department's goal is food safety from the farm to the table.

This concluded the conference call with Dr. Fetzner and staff of the USDA Food Safety and Inspection Service.

CONTINUATION SHEET

MINUTES OF THE HOUSE COMMITTEE ON AGRICULTURE, Room 423-S Statehouse, at 9:00 a.m. on March 14, 1997.

Chairperson Flower reminded the committee that upon adjournment of the House, they would be touring the Grain Inspection Department in preparation for the hearings next week on **Sub SB 317**.

The meeting adjourned at 10:00 a.m. The next meeting is scheduled for March 17, 1997.



U.S. Department of Agriculture
Food Safety and Inspection Service
Washington, DC 20250

Key Facts: HACCP Final Rule

July 1996

Key Facts: Impact of HACCP Rule on Small Businesses

A number of comments received on the proposed Pathogen Reduction and HACCP Systems rule raised concerns about the impact of the rule on small businesses. Comments submitted by all parties, including small plants, on all aspects of the rule were carefully considered when putting together the rule in its final form. Several important changes, which the agency made to strengthen food safety and improve the rule's effectiveness, while minimizing its cost impacts generally, have also significantly reduced the final rule's economic impact on small business.

The changes still accomplish the rule's original objectives and strengthen the new food safety system. The changes bring more meat and poultry products under HACCP earlier than the proposed rule and minimize the impact on small business by reducing the rule's economic burden and giving small plants more time, training, and assistance. The net result is a final rule that maintains a comprehensive approach to a preventive control system that achieves a variety of objectives that will improve food safety.

The issues raised by smaller plants--the lack of sufficient time, training, and preparation to implement HACCP and the additional costs associated with daily testing, antimicrobial treatments, and cooling requirements--have all been addressed in the final rule.

Revised Implementation Schedule for Small and Very Small Businesses

In accordance with Small Business Administration guidelines, the definition of *small business* has been expanded to encompass establishments with 500 or fewer but 10 or more employees.

A new category for *very small businesses* has been added and is defined as an establishment with fewer than 10 employees or annual sales of less than \$2.5 million.

Size and amount of sales, not process type, will determine the implementation date. Larger plants will come under HACCP sooner, while smaller plants will be given more time to implement and comply with the new regulation. Because large slaughter plants account for 75 percent of slaughter production, most of the Nation's meat and poultry supply will come under HACCP-based process control one year earlier than originally proposed.

Small plants will have 30 months to develop and implement HACCP plans and very small plants will have 42 months. At the same time, all plants must implement SOPs for sanitation and all slaughter plants, regardless of size, must institute *E. coli* microbial testing to verify process control for fecal contamination in 6 months.

All plants will have 180 days--rather than the originally proposed 90 days--to develop and implement sanitation standard operating procedures.

Microbial Testing Requirements

House Agriculture Committee
March 14, 1997
Attachment 1

Microbial testing requirements have been revised to ensure their scientific integrity and validity, based on review of comments and input from scientific conferences and meetings held during the comment period. Microbial testing for slaughter process control will be based on generic *E. coli* rather than *Salmonella*. One side benefit is that *E. coli* testing is easier and much less expensive.

Extending the effective compliance dates for microbial testing requirements will lessen their economic and regulatory impact on smaller slaughter plants by allowing plants more time to prepare.

Testing for all plants will not be required daily, as was initially proposed, but will be based on production volume. Plants with very low production will only have to sample for a limited time each year.

The Agency agreed with comments urging that a volume-based procedure--rather than one based on type of product--would be a more effective approach and improve the role of *E. coli* testing, benefiting everyone and reducing the cost burden to smaller operations.

FSIS will conduct testing for *Salmonella* to ensure slaughter and ground product plants are meeting performance standards under HACCP.

Only one HACCP-trained person will be required for each plant.

Time/Temperature Requirements and Antimicrobial Treatments

Time and temperature controls and *antimicrobial treatments* are not required. The time and temperature (or cooling) requirements originally proposed for raw products need more scientific input and public comment. FSIS plans to broaden the consideration of cooling requirements to remedy problems in plants, during transportation, in storage and in retail establishments. This critical issue will be considered in an extended and expanded rulemaking. The agency also concluded separate requirements for antimicrobial treatments were unnecessary, since plants can use them when necessary to meet performance criteria and standards.

24 hr Clock ?

Training and Assistance

The HACCP demonstration projects requested by small and very small plants will be conducted during the two-year period following the rule's publication at sites nationwide to show how HACCP systems work for various products under operating conditions. Some of the demonstrations will address issues unique to very small establishments.

HACCP guidance materials to be made available to all plants include a *Guidebook for the Preparation of HACCP Plans*, a *Hazards and Preventive Measures Guide*, and 13 generic HACCP models addressing process categories in the regulation. These materials should be particularly helpful to small and very small businesses. Additional guidance materials addressing other parts of the final rule are also available.

FSIS will hold a 3-day HACCP implementation conference in Washington, D.C. about 60 days after the rule is published, as well as regional implementation conferences throughout the United States.

Consultation with small and very small business (and all other affected parties) will continue. Extensive preparatory meetings, material, sample HACCP protocols and plans, audio, video or computer training aids, guidelines, notices, pamphlets and training will be provided at least six months before any establishment must begin work on its hazard analysis and HACCP plan. Recommendations for any additional material, protocols, and training will be requested from all parties.

Annual Estimated Cost Lower Than Proposed

The annual estimated cost of implementing the final rule is about \$76 to \$89 million per year, or slightly more than 1/10 of a cent per pound of meat and poultry. This is significantly lower than the annual

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estimated cost of implementing the proposed rule, which was about \$244.5 million per year, or slightly more than 2/10 of a cent per pound of meat and poultry.

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U.S. Department of Agriculture
Food Safety and Inspection Service
Washington, DC 20250

Background Papers

July 1996

The Final Rule on Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) Systems

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SUMMARY

The Food Safety and Inspection Service (FSIS) is establishing new requirements for all meat and poultry plants to improve food safety and begin the long-awaited modernization of USDA's meat and poultry inspection system.

All slaughter and processing plants will be required to adopt the system of process controls to *prevent* food safety hazards known as Hazard Analysis and Critical Control Points (HACCP). To verify that HACCP systems are effective in reducing contamination with harmful bacteria, FSIS is setting pathogen reduction performance standards for *Salmonella* that slaughter plants and plants that produce raw, ground meat and poultry will have to meet. In addition, slaughter plants will be required to conduct microbial testing for generic *E. coli* to verify that their process control systems are working as intended to prevent fecal contamination, the primary avenue of contamination for harmful bacteria. FSIS is also requiring plants to adopt and follow written Standard Operating Procedures for sanitation to reduce the likelihood that harmful bacteria will contaminate the finished product.

FSIS expects this combination of HACCP-based process control, microbial testing, pathogen reduction performance standards, and sanitation standard operating procedures to significantly reduce contamination of meat and poultry with harmful bacteria and reduce the risk of foodborne illness.

This new food safety system will also enable USDA to modernize its inspection program by focusing its attention on the most significant food safety hazards and on ensuring that all plants have systems in place that are effectively preventing food safety problems.

The new requirements are summarized as follows.

Hazard Analysis and Critical Control Points (HACCP)

All plants must develop, adopt and implement a HACCP plan for each of their processes. Under

*House Agriculture Committee
March 14, 1997
Attachment 2*

All plants must develop, adopt and implement a HACCP plan for each of their processes. Under HACCP, plants identify critical control points during their processes where hazards such as microbial contamination can occur, establish controls to prevent or reduce those hazards, and maintain records documenting that the controls are working as intended. FSIS believes that HACCP-based process control, combined with appropriate food safety performance standards, is the most effective means available for ensuring the safety of food, including controlling and reducing harmful bacteria on raw meat and poultry products.

Implementation dates for HACCP are based on plant size; the largest plants are being required to have their HACCP systems in place first. Implementation dates range from 18 months to 42 months after publication of the final rule.

Pathogen Reduction and Microbial Testing

To be effective, HACCP-based process control must be combined with objective means of verifying that meat and poultry plants are achieving acceptable levels of food safety performance. FSIS will require all slaughter plants to conduct microbial testing for generic *E. coli*, a species of *E. coli* that is commonly found in the intestinal tract of food animals. Generic *E. coli* is an excellent indicator of fecal contamination, which is the primary pathway for contamination of meat and poultry with bacteria such as *E. coli* O157:H7, *Salmonella*, and *Campylobacter* that can cause illness. The testing requirement, which will be effective 6 months after publication of the final rule, will assist plants in maintaining adequate process control for fecal contamination. FSIS is establishing verification performance criteria that reflect the prevalence and levels of contamination of carcasses with *E. coli* as determined by FSIS baseline surveys.

In addition, FSIS is establishing pathogen reduction performance standards for *Salmonella* that slaughter plants and plants that produce raw ground products will be required to meet to verify that their HACCP systems are effective in reducing contamination with that pathogenic microorganism. The standards will provide incentives for innovation to improve food safety, and FSIS will conduct testing to verify compliance with the standards. Implementation dates for the standards are based on plant size and will coincide with those for HACCP. Prior to the implementation dates, FSIS will begin *Salmonella* testing to provide plants with information regarding their current level of performance relative to the pathogen reduction performance standard.

Standard Operating Procedures for Sanitation

All plants must prepare and implement plant-specific standard operating procedures (SOPs) for sanitation to ensure they are meeting their responsibility to keep their facilities and equipment clean. This requirement will become effective 6 months after publication of the final rule.

Safe Handling Beyond the Plant

These new requirements--mandatory HACCP, pathogen reduction performance standards and testing procedures, and SOPs for sanitation--are designed to reduce contamination of meat and poultry products with harmful bacteria when they leave the meat or poultry slaughter or processing plant. However, distributors, employees in retail stores and restaurants, and consumers must continue to store, handle, and prepare meat and poultry products carefully to keep food safe.

FSIS is working with the Food and Drug Administration (FDA) to adopt standards to control growth of harmful bacteria during transportation and storage and is working with FDA and state and local authorities to improve food safety practices at the retail level. FSIS works with other government agencies, the food industry, and others to educate consumers on safe food handling practices.

Implementation Costs

FSIS estimates the four-year implementation cost of the final rule to the meat and poultry industry at \$305 to \$357 million, or an average of \$76 to \$89 million per year. Annual recurring costs following the implementation period are estimated at \$99.6 to \$119.8 million. Estimates of yearly public health benefits from reduced foodborne illness costs, including medical care and lost work time, range from

benefits from reduced foodborne illness costs, including medical care and lost work time, range from \$990 million to \$3.7 billion. The total implementation costs amount to between one- and two-tenths of a cent per pound of product.

Request for Comments

FSIS is seeking comments, due by 60 days after the date of publication of the final rule, on certain technical issues that are associated with *E. coli* testing and the verification performance criteria. In addition, FSIS is requesting comments, due 120 days after the date of publication of the final rule, on the revised HACCP implementation schedule and guidance materials that have been prepared as appendices to the final rule.

BACKGROUND

Current FSIS regulatory requirements and inspection procedures contribute to the FSIS mission of ensuring that meat and poultry products are safe, wholesome, and accurately labeled. More than 7,400 FSIS inspectors are present in 6,200 slaughter and processing plants to ensure that diseased animals and birds do not enter the food supply and that sanitation and other requirements are met. Inspectors also monitor the meat and poultry supply for violative levels of chemical residues.

Despite the successes of the current program in removing diseased animals from the food supply and enforcing sanitation and other standards, there is a critical gap in its ability to protect public health. The current system of slaughter inspection relies largely on organoleptic (sensory) methods, which were appropriate when the first major meat inspection law was passed in 1906. At that time, animal diseases were the major concern, and invisible hazards such as pathogenic microorganisms and drug residues had not yet attracted the attention of public health authorities and regulators. Since that time, changes have been made in the inspection program to reflect changes in the production of meat and poultry, address chemical residues in slaughter plants, address bacteria in processed products, and increase the efficiency of inspection. However, the current program does not adequately target and reduce pathogenic microorganisms on raw meat and poultry. And it does not integrate systematic, preventive process control into the production process to make all meat and poultry products as safe as possible. Implementation of the final rule will help to correct these gaps.

While precise data on the incidence of illness associated with microbiological contamination of meat and poultry products is limited, foodborne illness is an important public health problem in the United States. Data from the Centers for Disease Control and Prevention suggest that foodborne microbial pathogens account for up to 7 million cases of foodborne illness each year, and up to 7,000 deaths. Of these, nearly 5 million cases of illness and more than 4,000 deaths may be associated with meat and poultry products.

The seriousness of the problem was illustrated by the outbreak of foodborne illness that occurred in several western states in early 1993. The outbreak was attributed to undercooked hamburgers contaminated with *E. coli* O157:H7 that were served at a chain of fast-food restaurants. This particular outbreak led to hundreds of cases of illness and four deaths.

This conclusion is consistent with many external studies conducted during the past decade. The National Academy of Sciences, the General Accounting Office, the National Advisory Committee on Microbiological Criteria for Foods, and many others have called for change in the current inspection system to better address microbial pathogens and make the system more prevention-oriented.

THE RULEMAKING PROCESS

To address these concerns, FSIS, on February 3, 1995, published a proposal on Pathogen Reduction and HACCP that would mandate HACCP, set targets for pathogen reduction, require daily microbial testing to determine compliance with the targets, and require three near-term initiatives--standard operating procedures for sanitation, antimicrobial treatments, and carcass cooling standards. FSIS conducted a thorough and interactive rulemaking process on the proposal by soliciting extensive public comment and encouraging dialogue between FSIS and interested parties on the many policy and technical issues

encouraging dialogue between FSIS and interested parties on the many policy and technical issues involved in the proposal.

During the comment period, which was extended twice, FSIS held seven information briefings, three scientific and technical conferences, a two-day public hearing, six issue-focused public meetings, a Federal-State conference, and a Food Safety Forum chaired by Secretary of Agriculture Dan Glickman. In addition, FSIS received approximately 7,500 written comments on the proposal.

FSIS carefully evaluated the written comments and input received through the various public events and addressed the many issues raised in formulating a final rule.

THE FINAL RULE

Hazard Analysis and Critical Control Points (HACCP)

FSIS is requiring that all federally inspected meat and poultry plants adopt HACCP systems to ensure that they have in place science-based process controls to prevent and reduce the significant food safety hazards that may arise in their particular processes and products. The HACCP approach is a system of process control that is widely recognized by scientific authorities and international organizations and is used extensively in the food industry to produce products in compliance with health and safety requirements. HACCP also provides a framework for better targeting FSIS inspection on the most significant food safety hazards and controls and more efficiently using inspection resources.

Implementation of HACCP will clarify the responsibility of industry and FSIS to produce safe meat and poultry products. FSIS's role is to set appropriate food safety standards and maintain vigorous inspection oversight to ensure that those standards are met.

Plants will be required to develop HACCP plans based on the seven principles articulated by the National Advisory Committee on Microbiological Criteria for Foods:

1. hazard analysis,
2. critical control point identification,
3. establishment of critical limits,
4. monitoring procedures,
5. corrective actions,
6. recordkeeping, and
7. verification procedures.

Plants will identify and evaluate the food safety hazards that could affect the safety of their products and institute controls necessary to prevent those hazards from occurring or to keep them within acceptable limits. HACCP systems will be required to cover those critical control points that affect product safety, as opposed to those related to economic adulteration and quality. Each meat or poultry product produced must be covered by a HACCP plan. Plants will be required to validate their own HACCP plans--that is, ensure that they do what they were designed to do. FSIS will not approve HACCP plans in advance but will review them for conformance with the final HACCP regulations.

Verification--making sure the plan is adequate and working on a day-to-day basis--will be the responsibility of both industry and FSIS. Industry will monitor and verify the performance of the controls in their HACCP plans and maintain records of this monitoring and verification. FSIS will evaluate the HACCP plan's adequacy and successful operation as part of the inspection process. HACCP plans found by FSIS to be inadequate will have to be corrected, or the plant will face appropriate regulatory action.

FSIS currently carries out carcass-by-carcass inspection in slaughter plants to remove diseased animals from the food supply. Carcass-by-carcass inspection will continue in these plants. However, in light of improvements in process control that are expected under HACCP, FSIS of illness and four deaths.

Improvements in process control that are expected under HACCP, FSIS of illness and four deaths. USDA's review of the outbreak concluded that the current food safety system does not adequately address the risk of microbial contamination.

This conclusion is consistent with many external studies conducted during the past decade. The National Academy of Sciences, the General Accounting Office, the National Advisory Committee on Microbiological Criteria for Foods, and many others have called for change in the current inspection system to better address microbial pathogens and make the system more to examine current tasks related to carcass-by-carcass inspection and determine what changes should be made to improve inspection effectiveness and make the use of inspection resources more productive.

FSIS is committed to implementing HACCP as rapidly as possible, taking into account the logistical effort required for such a fundamental change in industry practices and FSIS inspection strategy. FSIS has revised its proposed implementation schedule so that it is based on plant size rather than product category. Large plants with 500 or more employees will be required to have a HACCP system in place 18 months after publication of the final rule. The revised implementation schedule will ensure that 75 percent of slaughter production and 45 percent of processed products will be produced under a HACCP system within 18 months. As a result, most of the Nation's meat and poultry supply will come under HACCP-based process control one year earlier than originally proposed. Smaller plants, with 500 or fewer but 10 or more employees, must have a HACCP system in place 30 months after publication of the final rule. Very small establishments--those having fewer than 10 employees or annual sales of less than \$2.5 million--have until 42 months after publication of the final rule to have their HACCP systems in place.

ASSISTANCE FOR SMALL PLANTS

HACCP is a useful tool for improving food safety in plants of all sizes. FSIS recognizes, however, that many small plants may lack familiarity with HACCP. Thus, FSIS plans an array of assistance activities that will facilitate implementation of HACCP in small plants.

FSIS is developing 13 generic HACCP models for the major process categories, which will be available in final form before plants must begin work on their HACCP plans. The generic models will serve only as illustrations rather than as prescriptive blueprints for a specific HACCP plan.

FSIS will also conduct small-plant demonstration projects during the two-year period following issuance of the final rule at a number of sites around the country to show how HACCP systems can work in even the smallest plants under actual operating conditions.

FSIS is also making available guidance materials, as appendices to the final regulations, that will assist small, as well as large, plants in conducting their hazard analyses and developing HACCP plans. They include a *Guidebook for the Preparation of HACCP Plans* and a *Hazards and Preventive Measures Guide*. Additional guidance materials addressing other parts of the final regulations also are available.

App C Fed Reg 7/25/96

HACCP IMPLEMENTATION CONFERENCE

FSIS plans to convene a three-day HACCP implementation conference to be held in Washington, D.C., about 60 days after publication of the final rule and intends to hold regional HACCP implementation conferences at several sites around the country. The purpose of the conference is to continue the dialogue among a diverse array of interested parties on a variety of issues related to HACCP implementation such as training and enforcement issues.

PATHOGEN REDUCTION AND MICROBIAL TESTING

The HACCP requirement will ensure that all meat and poultry plants implement science-based process controls to prevent and reduce the significant food safety hazards that are reasonably likely to occur in their particular processes and products. But HACCP-based process control must be combined with objective means of verifying that meat and poultry plants are achieving acceptable levels of food safety performance. While FSIS has in place microbiological performance standards for ready-to-eat and other processed products, microbiological performance criteria or standards for raw products, with the exception of *E. coli* O157:H7 in ground beef, do not exist.

FSIS believes it is essential to the reduction of nationwide exposure to foodborne pathogens that slaughter establishments control their operations to prevent fecal contamination and that all plants producing raw meat and poultry products institute process controls to reduce the prevalence of *Salmonella*. These regulations provide both an objective means to verify process control in slaughter plants with respect to fecal contamination and pathogen reduction performance standards for raw products that will reduce the nationwide exposure to *Salmonella*, the most common cause of foodborne illness among enteric pathogens.

GENERIC *E. COLI* TESTING FOR PROCESS CONTROL

FSIS is requiring meat and poultry slaughter plants to test carcasses for generic *E. coli* as an indicator of the adequacy of the plant's process control for fecal contamination. Plants will be required to conduct *E. coli* testing 6 months after publication of the final rule. FSIS is seeking further comment on certain technical issues such as testing frequency and sampling procedures and will be holding a conference on these issues approximately 45 days after publication of the final rule. FSIS will make any appropriate technical amendments to the *E. coli* testing protocols at least 30 days before the effective date of the rule. FSIS inspectors will not use *E. coli* testing results as an indication of process control until 6 months after the effective date for the testing requirement. A second conference is tentatively planned for approximately 9 months following publication of this rule to provide an opportunity for members of industry and others to discuss with FSIS new information based on the three months of testing that will have occurred that might justify further adjustments to the protocol.

FSIS is adopting *E. coli* verification performance criteria for each species that reflect the frequency and levels of contamination of the microorganism on such carcasses produced nationwide as determined by FSIS baseline surveys. FSIS is using the term criteria because they are guidelines, not regulatory standards. FSIS will not use the test results by themselves to take any regulatory action but will consider them in conjunction with other information to evaluate whether a problem exists that requires regulatory action.

The required frequency of *E. coli* testing is based on production volume. Slaughter plants will be able to adopt alternative testing frequencies when they implement HACCP if the alternative is equally or more effective in verifying process control for fecal contamination. FSIS intends to update the *E. coli* criteria periodically, based on future surveys and data generated by the testing, to ensure that the criteria adequately reflect an appropriate and adequate level of performance with respect to prevention and removal of fecal contamination.

The requirement for *E. coli* testing in slaughter plants will become effective 6 months after publication of the final rule. *E. coli* test results will provide process control data that will help plants find and correct process control problems at this most fundamental phase of production. The results will also support more objective assessments by inspectors of whether plants are meeting current statutory requirements for sanitation and the prevention of adulteration. They will also play an integral role in the successful implementation of HACCP in slaughter plants.

PERFORMANCE STANDARDS FOR *SALMONELLA* AND FSIS TESTING

FSIS is adopting pathogen reduction performance standards for *Salmonella* to verify that plant HACCP systems are effective in reducing contamination with this pathogenic microorganism. FSIS believes that the production of raw meat and poultry with *Salmonella* prevalence below the current national level is readily achievable with available technology and production methods. *Salmonella* was selected as the target pathogen because it is the leading cause of foodborne illness among enteric pathogens, it is present at varying frequencies on all types of raw meat and poultry products, and it can easily be tested for in a variety of products. Furthermore, improvements in process control that result in reductions in *Salmonella* are expected to result in reductions of other pathogens found in the intestines of animals.

The microbiological performance standards FSIS is adopting are part of a fundamental shift in FSIS regulatory philosophy and strategy. FSIS is shifting from an extensive reliance on command and control regulations, which generally prescribe *how* desired objectives are to be achieved, to much greater reliance on performance standards, which generally express the objective but do not specify the means for achieving it. FSIS believes that its food safety and consumer protection goals can, in most cases, be achieved most effectively by establishing clear objectives in terms of performance standards, providing industry flexibility to devise the optimal means of achieving the objective, and then verifying through inspection and other forms of oversight that firms are meeting the established standard.

The pathogen reduction performance standards for *Salmonella* and the *E. coli* verification performance criteria complement one another. While *E. coli* testing is a good indicator of fecal contamination, it is not directly correlated with *Salmonella* contamination, which is affected by other factors as well, including the condition of incoming animals. The *Salmonella* standards will force plants not currently meeting the standards to take steps to reduce pathogens that can cause foodborne illness.

Plants will be required to achieve a prevalence of *Salmonella* contamination that is below the baseline prevalence for each raw product as reflected in the FSIS baseline surveys. These are regulatory standards that FSIS will require the plant to meet consistently over time as a condition to maintaining inspection.

FSIS, rather than the plant, will test for *Salmonella* to ensure compliance with the standards. FSIS will conduct initial testing prior to actual enforcement of the performance standards to determine whether each plant is meeting the standard. These results will assist plants in preparing for implementation of HACCP and the pathogen reduction performance standards. FSIS will continue its testing program once the standards become effective to ensure compliance. The frequency and intensity of testing will be based on past plant performance and other factors.

The *Salmonella* enforcement strategy embodies an objective, uniform systems approach that will be administered and applied in a fair, equitable, and common-sense manner. The Agency will continually monitor and adjust its enforcement program and activities to reflect these principles while ensuring food safety.

Implementation will coincide with the implementation schedule for HACCP. Slaughter plants and plants producing raw ground product or fresh pork sausage will be required to meet the standards at the same time the plant is required to implement HACCP.

Approximately 15 months after the publication of this final rule, FSIS will convene a public conference to review available data and discuss whether they warrant refining the *Salmonella* performance standards.

The *Salmonella* standards being established are a first step in what FSIS expects to be a broader reliance in the future on pathogen-specific performance standards for raw products. FSIS plans to repeat its baseline surveys and collect substantial data through other means and, on that basis, adjust the *Salmonella* targets and possibly set targets for additional pathogens, as appropriate.

Sanitation Standard Operating Procedures

Insanitary conditions during the production of meat and poultry products increase the likelihood that

pathogenic bacteria will contaminate the finished product. Poor sanitation is the most frequently observed problem in meat and poultry plants. FSIS is requiring that all meat and poultry plants adopt, maintain, and follow written Standard Operating Procedures (SOPs) for sanitation. The written sanitation SOPs must describe the specific activities plant management has determined are necessary to maintain good sanitation and prevent direct product contamination. The SOP must specify the persons responsible for carrying out these activities. Daily records must be kept showing when procedures are accomplished and when corrective actions are taken.

Sanitation SOPs will clarify that sanitation is industry's responsibility. They will make it easier for FSIS inspectors to perform their proper role of verifying that plant management is carrying out its sanitation responsibilities and will allow FSIS to focus on the prevention and correction of direct product contamination risks.

Requirements for Foreign Establishments and State Programs

Foreign countries exporting to the United States must establish inspection system requirements that are "equivalent" to U.S. requirements. Thus, all foreign meat and poultry plants that export to the United States must operate HACCP-type process control systems that are "equivalent to" HACCP and adopt equivalent performance standards.

State inspection programs must operate programs "equal to" the Federal program and will also be required to comply with the new requirements.

FOOD SAFETY FROM FARM TO TABLE

The new regulatory measures address hazards within slaughter and processing plants. FSIS recognizes, however, that these measures must be part of a comprehensive food safety strategy that addresses hazards at other points in the farm-to-table chain. To that end, FSIS is broadening the scope of its food safety activities beyond slaughter and processing plants, with particular new emphasis on hazards that arise during transportation, distribution, and retail sale.

To improve food safety at the animal production and intermediate stages before the slaughter plant, FSIS is working with industry, academia, and other government agencies to develop and foster measures that can be taken on the farm and through distribution and marketing of animals to reduce food safety hazards associated with animals presented for slaughter. FSIS does not intend to mandate production practices at this stage but instead believes that the voluntary application of food safety assurance programs based on HACCP principles can be useful in establishing risk reduction practices on the farm and during intermediate marketing stages. The Agency believes that continued public concern about foodborne pathogens and the adoption of HACCP and performance standards will increase incentives for producers to adopt food safety practices at the animal production level.

Food safety during transportation, storage and retail sale are also important links in the food safety chain. In these areas, FSIS, the Food and Drug Administration (FDA), and State and local governments share authority for oversight of food products. FSIS and FDA are working together to develop standards governing the safety of foods during transportation and storage, with particular emphasis on the importance of temperature control in minimizing the growth of pathogenic microorganisms. In the retail area, FSIS and FDA are working with state officials to ensure the adoption of uniform, science-based standards and to foster the adoption of HACCP-type preventive approaches. State and local authorities have primary responsibility for food safety oversight of retail stores and restaurants, but FSIS and FDA, working through the Conference for Food Protection, can provide expertise and leadership to support local authorities and foster the development of sound food safety standards and practices nationwide.

Even as progress is made in reducing contamination during these stages, it will remain critical that retail food handlers and consumers follow safe food handling practices. Proper storage, preparation, and cooking of meat and poultry products are essential to achieving the goal of reducing the risk of

after the effective date for the testing requirement. A second conference is tentatively planned for approximately 9 months following publication of this rule to provide an opportunity for members of industry and others to discuss with FSIS new information based on the three months of testing that will have occurred that might justify further adjustments to the protocol.

E. coli was chosen as a more appropriate microorganism to use as a verification of process control than the originally proposed *Salmonella* based on numerous comments and the results of the scientific and technical conference on the Role of Microbiological Testing in Verifying Food Safety conducted by FSIS during the comment period. Generic *E. coli* is present in all animal feces and thus is more effective than *Salmonella* as an indicator of fecal contamination, the primary avenue of contamination for pathogenic microorganisms.

To obtain paper or diskette copies of the final rule contact:

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- Consumer Inquiries:* Call the USDA's Meat and Poultry Hotline at 1-800-535-4555; in the Washington, D.C. area, call (202) 720-3333.

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