

Withdrawal/Redaction Sheet

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
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001. memo	Andrew Moss to Elizabeth Drye re: SSNs and DOBs [partial] (1 page)	07/04/1996	b(6)
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COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10451

FOLDER TITLE:

HACCP [Hazard Analysis and Critical Control Point]

2014-0046-S

rc1407

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

Freedom of Information Act - [5 U.S.C. 552(b)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

b(1) National security classified information [(b)(1) of the FOIA]
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b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

U.S. DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY

DATE: _____

SENT TO: Elizabeth Dye

PHONE #: _____

FAX #: _____

NUMBER OF PAGES SENT: _____
(excluding cover sheet)

FROM: Erz OlsenPHONE #: 720-3631FAX #: 720-5437

Larry Elsworth suggested that you might be helpful with this request. We just sent it to Cabinet Affairs. Please let me know if you have questions. Thanks.



DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

July 2, 1996

MEMORANDUM FROM SECRETARY DAN GLICKMAN

TO: Kitty Higgins, Secretary of the Cabinet

SUBJECT: Scheduling Request for the President

Issue

Every year about 4000 people die and five million people get sick from eating meat and poultry contaminated with four pathogens: salmonella, campylobacter, E. coli 0157:H7 and listeria monocytogenes. Shortly after the Administration took office in 1993, E. coli 0157:H7 caused a major outbreak of foodborne illness in which several people died and hundreds became ill.

The Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) will soon issue a major regulation to reform and reinvent the meat and poultry inspection system -- a system that has remained fundamentally unchanged for 90 years. This regulation will save lives and reduce foodborne illness caused by meat and poultry products.

The release of this regulation will receive extensive national and regional press coverage. President Clinton or Vice President Gore or both should participate in the release of this historic reform to protect American families by improving the safety of American meat and poultry products.

Background

In 1993, shortly after the Administration took office, several children died and hundreds of people got sick in the Pacific Northwest due to an outbreak of E. coli 0157:H7 contained in undercooked hamburgers. The outbreak received extensive national media attention.

The Clinton Administration immediately and aggressively responded to this outbreak. Food safety became, and continues to be, a top priority of the Department of Agriculture, which embarked upon a comprehensive effort to improve the safety of American meat and poultry.

Last year, USDA issued a proposed rule to reinvent the meat and poultry inspection system -- the Hazard Analysis and Critical Control Point (HACCP -- pronounced ha-sip)/Pathogen Reduction regulation. The HACCP/Pathogen Reduction rulemaking has been the subject of intense media,

congressional, and constituency interest.

USDA's final rule is the most sweeping overhaul of how the government inspects meat and poultry in 90 years. Rather than the relying on an organoleptic (see, touch, feel, smell) system of inspection which attempts to identify problems after they occur, the new science-based rule will require industry to prevent systematically food safety hazards and require the use of microbial testing to confirm that the preventive system works. The rule also moves from a command-and-control approach to performance standards that encourage flexibility and innovation while improving food safety. The new rule will save lives and reduce foodborne illness.

In so doing, the Administration will have honored its commitment to improve the safety of American meat and poultry and kept faith with the families who demanded in the wake of the 1993 outbreak that the government take effective action against harmful bacteria like E. coli 0157:H7 and Salmonella. No previous Administration has done as much to make the meat and poultry supply safer for consumers.

The HACCP/Pathogen Reduction rulemaking also played a central role in the Senate debate on regulatory reform last summer, with both Senator Dole and Senator Daschle offering amendments to address concerns that the legislation would impair USDA's ability to issue and implement a final rule. Consumer groups actively opposed the legislation and members of Safe Tables Our Priority (STOP), a consumer organization comprised of families of victims of foodborne illness which was formed in the wake of the 1993 outbreak, met with the President regarding this issue.

An amendment to the House Agricultural Appropriations bill for 1996 also attempted to delay and stop the HACCP/Pathogen Reduction rulemaking. The amendment was ultimately dropped by the full House after Secretary Glickman intervened. He has been personally involved in this rulemaking since that time.

Message and Visuals

The HACCP/Pathogen Reduction rule should be announced at the White House by the President or Vice President or both and Secretary Glickman. The announcement would highlight the Administration's efforts to protect American families as well as its strong commitment to food safety and regulatory reform.

Food safety issues have received extensive national press coverage during the last three years, and parents pay particular attention to issues of food safety.

The Department recommends a large event, if possible. Families of E. coli victims, represented by Safe Tables Our Priority (STOP), should participate and be recognized for their role in pushing needed reforms. The Department recommends that any member of STOP who wishes to attend the event be allowed to do so. It is also important to note that STOP members will have to spend personal funds to fly into Washington, so we recommend as much advance notice as

possible. Also present at the event would be representatives of consumer groups, livestock producers, industry, the public health community, organizations such as AARP or the PTA, and Members of Congress.

We would anticipate four or five speakers: The President or Vice-President, the Secretary, one or two family members, and Mike Taylor, Acting Under Secretary for Food Safety.

Possible Issues

The HACCP/Pathogen Reduction regulation may be opposed by some members of industry as well as Members of Congress and may be challenged in court. This is not necessarily a negative, given the public's strong support for improved food safety.

Timing

USDA believes that the HACCP/Pathogen Reduction rule should be released in mid-July. New requirements would begin in six months.

We expect extensive national and regional media interest in the announcement and recommend advance briefings so that the public importance of these technically complex rules is clearly understood.

Status

The HACCP/Pathogen Reduction rule formally cleared USDA in May and is being reviewed by OMB. USDA expects that OMB will formally clear the final rule this week.

Summary

The participation of the President or Vice President or both in this event would highlight the Administration taking historic action to improve the lives of all consumers. The announcement of this regulation will be an important national and regional story.

*This will be one of the
highlights of the President's
commitment to food safety.*

Withdrawal/Redaction Marker

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United States Department of Agriculture
Food Safety and Inspection Service
Information and Legislative Affairs
Room 1175, South Building
Washington, D.C. 20250
Telephone: (202) 690-3774
Fax: (202) 720-9600 or 720-1843



Andrew Moss, Constituent Affairs Coordinator

July 4, 1996

TO: Elizabeth Drye
The White House
(202) 456-7028 (FAX)

Elizabeth--

I am forwarding the names, social security numbers, and birth dates of the 2 families (4 persons total) from Safe Tables Our Priority (STOP) that will be attending the President's Radio Address on Saturday. Also included is a brief (updated) bio on the two families.

Please let me or Mike know if you have questions or need additional information. Thank you for all your assistance.

Andrew Moss

Nancy J. Donley

DOB:

SS#:

(b)(6)

Thomas R. Donley

DOB:

SS#:

(b)(6)

[001]

Roni Denise Rudolph

DOB:

SS#:

(b)(6)

D. Michael Rudolph

DOB:

SS#:

(b)(6)

Nancy Donley (and husband Tom Donley)

Nancy Donley is a real estate agent from Chicago, Illinois whose 6 year old son Alex died from E. coli 0157 complications in July 1993. Alex was her only child. Nancy is a member of the group Safe Tables Our Priority (STOP) and has become a leading spokesperson in urging and supporting food safety reform by USDA. She is a STOP board member and founded the Chicago area STOP chapter, "The Friends of Alex." She is married to Tom Donley.

Roni Rudolph (and son Michael Rudolph)

Roni Rudolph is a founding member of STOP whose 6 year old daughter Lauren died of complications from E. coli 0157:H7. Lauren, who died in December 1992, is thought to be the first victim of the E. coli outbreak in the Pacific Northwest. A businesswoman who resides in Carlsbad, CA with her 15 year old son Michael, she has devoted nearly all of her time since Lauren's death to work to ensure food safety reform.

cc: Michael Taylor, Eric Olson

Secretary Dan Glickman
Deputy Secretary Richard Rominger
Deputy Undersecretary, USDA Mike Taylor

Nancy Donley - Nancy is a Real Estate Agent from Chicago whose 6 year old son Alex died from E. coli 0157 complications in July 1993. Alex was her only child. She is a member of the group Safe Tables Our Priority (STOP) and has become a leading spokesperson in urging and supporting food safety reform by USDA. She is a STOP board member and founded the Chicago area STOP chapter, "The Friends of Alex."

Tom Donley - husband

Roni Rudolph - Roni is a founding member of STOP whose 6 year old daughter Lauren died of complications from E. coli 0157:H7. Lauren, who died in December 1992, is thought to be the first victim of the E. coli outbreak in the Pacific Northwest. A businesswoman who resides in Carlsbad, CA with her 15 year old son Michael, she has devoted nearly all of her time since Lauren's death to work to ensure food safety reform.
Michael Rudolph - son

Bob Galler - Bob is from New York. His 3 year old daughter Lois Joy died in 1992 from E. coli-contaminated hamburger meat. He started a foundation in his daughter's name that supports research into better treatments for children stricken with E. coli related illnesses. He has also fought for tougher meat safety standards.

Laurie Galler

- Visitors Office -

6-2322

10-12 noon

15-20 min

15th St. near @ Street

United States Department of Agriculture
Food Safety and Inspection Service
Information and Legislative Affairs
Room 1175, South Building
Washington, D.C. 20250
Telephone: (202) 690-3774
Fax: (202) 720-9600 or 720-1843



1 - Page Follows

Andrew Moss, Constituent Affairs Coordinator

7/3/96

To: Elizabeth Dye

Mike Taylor asked me to send
the attached to you.

Feel free to contact me (or Mike)
if you have questions.

Thank you.

Deems -
- Deputy Secy Kohn
Jonathan Gardner -
call Kohn
letter

Arthur Kohn

After he does the
speech to
advisory
President's Office

Rebecca Cameron
6-2207

Eric Olsen
(720-3808)
Four -

Mandy Tress.

- Addendum -

(196)

2/F
DRAFT**Nancy Donley**

Nancy Donley is a real estate agent from Chicago, Illinois whose 6 year old son Alex died from E. coli 0157 complications in July 1993. Alex was her only child. Nancy is a member of the group Safe Tables Our Priority (STOP) and has become a leading spokesperson in urging and supporting food safety reform by USDA. She is a STOP board member and founding a Chicago area STOP chapter, "friends of Alex." She is married to Tom Donley.

Rainer Mueller

Rainer Mueller is currently serving as president of the group STOP. His son Eric, age 13, died of complications attributed from E. coli 0157. He owns a computer firm in Oceanside, California. He is married to Maryanne and has a 13 year old daughter Nikki.

Mary Heersink

Mary is a founding member of STOP. Her son Damien (now 15) became seriously ill from E. coli 0157. He survived after numerous operations and still faces serious medical complications. Mary recently published a book on their family's experience. She is married to Dr. Marnix Heersink, a Dothan, Alabama opthamologist. She recently gave birth to twin boys and has 3 other children.

Ronni Rudolph

Ronni is a founding member of STOP whose 7 year old daughter Lauren died of complications from E. coli 0157:H7. Lauren was the first victim of the outbreak in the Pacific Northwest in 1993. She resides in Carlsbad, CA with her 15 year old son Michael.

Bill Adler

A Washington, DC STOP member who became seriously ill from Salmonella about two years ago. He has become active in STOP during the past year at several of their DC events. Adler is a publisher in DC. He is married and has two children.

*E. coli**4
2 families**Rainer**Greg
Fraser**Andrew Moss**draft**3**Friday morning*

THE WHITE HOUSE
WASHINGTON

February 3, 1995

Mr. Robert C. Galler
President
Lois Joy Galler Foundation
for Hemolytic Uremic Syndrome
c/o Editorial Page
USA Today
1000 Wilson Boulevard
Arlington, Virginia 22229

Dear Robert:

I read your column in USA Today about former Agriculture Secretary Espy's efforts to reform the meat inspection system, and I appreciate your words of support.

Like you, I believe that Secretary Espy made great strides in many important areas during his tenure. His efforts have changed the nature and extent of USDA's involvement in food production and consumption, and his contributions will make a lasting impact.

I was so sorry to read about your daughter's death. I share your hope that these new reforms in the meat inspection system will prevent such tragic occurrences in the future.

Sincerely,

Bill Clinton

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and Prevention, Atlanta, GA

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Madison, WI

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Professor of Medicine
Center for Vaccine Development
University of Maryland
Baltimore, MD

"NO CHILD IS EXEMPT FROM HEMOLYTIC UREMIC SYNDROME"

OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL		# of pages 6
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Dept./Agency: WH	Phone: 720 4623	
Fax #: WH	Fax #: 720 4623	
NAN 7340-0-217 7388 5000-101 GENERAL SERVICES ADMINISTRATION		

6210
456

Bob Galler
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**LOIS JOY
GALLER
FOUNDATION**
FOR HEMOLYTIC UREMIC
SYNDROME, INC.



**LOIS JOY GALLER FOUNDATION
FOR HEMOLYTIC UREMIC SYNDROME, INC.**

734 WHITE WITMAN ROAD
MIDVILLE, NY 11747
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FAX (516) 673-3025

**"WITH MORE RESEARCH, WE
ARE CONFIDENT THAT THIS
IS A DISEASE THAT TRULY
CAN BE BEATEN!"**

DRAFT 5-28

Backgrounder

June 1996

Moving To a Safer Food Supply--The Final Rule on Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) Systems

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, which are scheduled to be published in the xxxxx Federal Register, are summarized as follows. [Date may have to be removed depending on how much notice we receive on publication].

Hazard Analysis and Critical Control Points (HACCP)

All plants must develop, adopt and implement a HACCP plan for each of their products. 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 and is an excellent indicator of fecal contamination. 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, 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. 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 identify plants requiring improvement to meet the pathogen reduction performance standards.

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 \$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, 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. 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 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 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 that the industry, not the inspection service, is responsible for producing safe meat and poultry products. With HACCP in place, FSIS will verify that the plant is controlling its processes and consistently producing products that comply with food safety requirements.

HACCP will not substitute for carcass-by-carcass inspection currently carried out by FSIS inspectors 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 plans 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.

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 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. The revised implementation schedule will result in most of the Nation's meat and poultry supply coming under HACCP-based process control one year earlier than originally proposed. Smaller plants, with fewer than 500 but more than 10 employees, must have a HACCP system in place 30 months after publication of the final rule. Very small establishments--those having 10 or fewer 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.

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 may arise 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 single most significant pathogen.

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.

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.

FSIS is adopting *E. coli* 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" rather than "standard" 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 and associated bacteria.

The requirement for *E. coli* testing in slaughter plants will become effective 6 months after publication of the final rule because the 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, 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 "standards" rather than "criteria" because FSIS will require that the plant meet the standard consistently over time as a condition to maintaining inspection. If a plant fails to meet the standard, it must institute corrective actions to lower the prevalence of *Salmonella* on all such product it produces or cease producing the product.

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.

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.

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 foodborne illness to the maximum extent possible. FSIS intends to augment its food handler education efforts by expanding its collaboration with industry, other government agencies, consumer and public interest groups, educators and the media to foster the effective delivery of food safety education and information.

CHANGE WITHIN FSIS

To achieve its food safety goals and carry out the new food safety strategy, FSIS must also change itself. FSIS has conducted a top-to-bottom review of its regulatory roles, resource allocation and organizational structure and is making fundamental internal changes required to successfully carry out its HACCP-based, farm-to-table food safety strategy.

First, the Agency is reforming its existing regulations to be consistent with HACCP

principles and greater reliance on performance standards and to remove unnecessary regulatory obstacles to innovation. On December 29, 1995, FSIS published an advance notice of proposed rulemaking and additional rulemaking proposals describing the Agency's strategy for regulatory and inspectional reform and initiating the rulemaking process required to achieve necessary changes. It also published, on May 2, 1996, two additional regulatory reform documents--a proposal to eliminate the prior approval system for facility blueprints, equipment, and most partial quality control plans and a proposal to add a performance standard alternative to the current command-and-control requirements governing cooked meat and poultry products. FSIS will ensure that current regulations are revised as necessary before the implementation dates to ensure consistency with the new rules.

Second, FSIS is planning a reorganization to prepare the Agency to implement a modernized system of inspection. FSIS must realign its structure with a HACCP-based, farm-to-table strategy.

Third, FSIS will soon begin a public process to develop and evaluate new approaches to inspection that would ensure that FSIS is making the best possible use of its resources to improve food safety while still meeting all the consumer protection objectives of the current system. FSIS anticipates a major redeployment of its inspection resources to successfully implement HACCP and better target food safety

hazards from farm to table.

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

National Technical Information Service (NTIS)

U.S. Department of Commerce

5285 Port Royal Road

Springfield, VA. 22161.

Orders must reference NTIS accession number xxxx-xxxxxx for a paper copy and xxxx-xxxxxx for the diskette version.

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Additional information materials on the new rules are available on the FSIS Home Page at <http://www.usda.gov/fsis/homepage.htm>

For internet access to the Federal Register, contact GPO Access at
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For More Information

Technical Inquiries: (202) 720-7773

Media Inquiries: (202) 720-9113

Congressional Inquiries: (202) 720-3897

Constituent Inquiries: (202) 720-7943

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

FSIS-96-0011BG D.Schor

Background

FSIS Pathogen Reduction/HACCP Proposal

SUMMARY

The Food Safety and Inspection Service (FSIS) is pursuing a broad, long term science-based strategy to improve the safety of meat and poultry products and better protect public health.

The strategy will address food safety issues from the farm to the table, including proposed requirements for all federally inspected meat and poultry plants to reduce pathogenic microorganisms that can cause foodborne illness. The strategy is based on the philosophy of prevention embodied in HACCP (Hazard Analysis and Critical Control Points), a science-based system for producing safe food.

The regulatory proposal would (1) target pathogens that cause foodborne illness; (2) strengthen industry responsibility to produce safe food; and (3) focus inspection and plant activities on prevention objectives.

The proposal addresses three major areas:

Near-term initiatives

FSIS is proposing that:

- All plants develop and use written standard operating procedures covering plant sanitation.
- Slaughter plants use at least one antimicrobial treatment on all carcasses.
- All finished carcasses and parts be chilled promptly after slaughter and be kept cool.

These requirements would have to be implemented within 90 days from the date of publication of the final rule and would remain in effect at least until a Hazard Analysis and Critical Control Points (HACCP) system is implemented.

Proposed Interim Targets for Pathogen Reduction and Microbial Testing

Under the proposal, FSIS would establish interim targets for pathogen reduction and require daily microbial testing in slaughter plants to determine whether targets

are being met or remedial measures are necessary. Raw products would be tested for *Salmonella*, a representative pathogen, and establishments would be required to achieve targeted reductions in the incidence of *Salmonella* in relation to the current national baseline incidence. Microbiological testing would be required to begin in 90 days and tracking of test results would begin 6 months after the final rule is published. Compliance with the interim targets would be determined by using a moving sum statistical procedure that focuses on a specific number of days within a production process.

Hazard Analysis and Critical Control Points (HACCP)

All plants would be required to develop, adopt, and implement Hazard Analysis and Critical Control Points (HACCP), a system of preventive controls designed to improve the safety of products. HACCP would be implemented during the three years following the publication of the final rule. FSIS expects the near-term initiatives and microbial testing requirements to provide the foundation for the later adoption of HACCP by plants.

Implementation Costs

FSIS estimates the total implementation cost of its proposed requirements to the meat and poultry industry at \$733.5 million, or an average of \$244.5 million per year. Yearly public health benefits from reduced foodborne illness costs, including medical care and lost work time, would range from \$990 million to \$3.7 billion. The increased cost to consumers is estimated at slightly more than two tenths of a cent per pound.

Comments

The proposed USDA HACCP/Pathogen Reduction rule was published in the February 3 Federal Register. Comments on the proposal should be submitted to Diane Moore, Docket Clerk, Room 3171 South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington DC 20250. Comments will be accepted through June 5.

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, there is a critical gap in its ability to protect public health. The current system largely focuses on organoleptic (sensory) inspection, which was 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 regulatory agencies. Since that time, changes have been made in the inspection program to reflect changes in the production of meat and poultry and to increase the efficiency of inspection. However, the current program still is inadequate to detect hazards such as pathogenic microorganisms that can cause foodborne illness. In short, it does not include integration of systematic process control into the production process to make meat and poultry as safe as possible.

While precise data on the incidence of illness associated with meat and poultry products is limited, it is clear that foodborne illness is a public health problem in the United States. Data from varied sources suggest that foodborne 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.

Microbiological surveys of meat and poultry products conducted over the past several decades show the frequency of pathogenic microorganisms in cooked, ready-to-eat meat and poultry products to be relatively low. The frequency of pathogenic microorganisms in raw products has been greater and varies from pathogen to pathogen and from species to species.

Even when the incidence of contamination is relatively low, the public health threat can be serious. An example is 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* 0157:H7 that were served at a chain of fast food restaurants. A study by FSIS completed in 1990 found the prevalence of *E. coli* 0157:H7 in raw beef to be only 0.1 percent. Nevertheless, this particular outbreak led to hundreds of cases of illness and four deaths. Although the Department of Agriculture's review of the outbreak revealed that the incident was not caused by a failure in the current inspection system, it concluded that the system as it exists is deficient because it does not adequately address the risk of microbial contamination.

This conclusion has been supported by 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, industry, producers and consumer groups have called for change in the current inspection system to better address microbial pathogens and make it more prevention-oriented.

FSIS Strategy

- Stimulate improvement in food safety practices by setting public health-oriented targets, guidelines, or standards that all plants must meet.
- Clearly define the minimum requirements all plants must meet to produce safe meat and poultry and ensure that plants are accountable for meeting them.
- Make meat and poultry plants responsible for microbial testing of their products to ensure proper process control and verify achievement of microbial limits.
- Foster scientific and technological innovation within the meat and poultry industry by removing any unnecessary regulatory obstacles to innovation.
- Build the principle of prevention into the operations of meat and poultry plants.
- Focus inspection on prevention objectives.
- Approach the food safety mission broadly and consider potential hazards that arise throughout the food production and delivery system, including before animals enter FSIS-inspected plants and after meat and poultry products leave those plants.

KEYFACTS : Microbial Testing Programs -- FSIS Testing for *Salmonella* and Plant Testing for *E. Coli*

The Food Safety and Inspection Service's Pathogen Reduction and HACCP Systems final rule mandates new measures to target and reduce the presence of pathogenic organisms in meat and poultry products. These measures include FSIS testing to verify pathogen reduction performance standards are being met, plant microbial testing to verify process control for fecal contamination, written sanitation standard operating procedures (SOPs), and mandatory Hazard Analysis and Critical Control Points (HACCP) systems in all meat and poultry plants.

Two of the four essential elements of the new food safety system involve microbiological testing:

- Testing by FSIS for the foodborne pathogen *Salmonella* on raw meat and poultry products to verify pathogen reduction performance standards for that pathogen are being met.
- Testing by slaughter plants for generic *E. coli* on carcasses to verify the process is under control with respect to preventing and removing fecal contamination, the principle source of pathogenic organisms that contaminate carcasses. Microbiological performance criteria are provided as performance benchmarks.

The presence of microorganisms on raw meat and poultry is unavoidable and highly variable. Process control systems can minimize initial contamination of the carcass, remove many pathogenic microorganisms during processing, control proliferation of remaining pathogens, and minimize recontamination. Performance standards set requirements for pathogen reduction goals producers must meet.

Under the Pathogen Reduction and HACCP Systems final rule, establishments must have process controls to achieve such reductions. FSIS considers the systematic reduction of pathogenic microorganisms in raw meat and poultry products to be a core responsibility of the producers of those products. HACCP provides the framework for industry to set up science-based process controls.

FSIS Testing -- Pathogen Reduction Performance Standards for *Salmonella*

- Performance standards to verify the reduction of the incidence of contamination of raw meat and poultry with pathogenic microorganisms are an essential part of FSIS's food safety strategy.
- *Salmonella* was selected because it is the most common cause of foodborne illness associated with meat and poultry products. Methods aimed at reducing *Salmonella* can also be expected to reduce other enteric pathogens that contaminate meat and poultry.

- The pathogen reduction performance standard is a process standard developed from FSIS baseline survey data on the prevalence of *Salmonella* in raw products that all establishments must achieve consistently over time through appropriate and well-executed controls. This is not a lot acceptance standard.
- Plants can meet the pathogen reduction standard for *Salmonella* by using careful process control to prevent contamination and readily available procedures to remove contamination.
- FSIS will begin collecting data in slaughter plants three months after publication of the final rule. Testing will be conducted in a manner designed to provide a reliable picture of the plant's performance in relation to the applicable pathogen reduction performance standards prior to implementation of the standards.
- Plants will be held accountable for meeting the applicable *Salmonella* standard at the same time they are required to implement HACCP, between 18 and 42 months from the date of publication of the final rule.
- After implementation of the standards, the frequency and intensity of testing will be determined by past plant performance, observations by FSIS inspectors, other data, and any reports of illness associated with the product produced at the plant.
- The Agency's responses will increase in severity with successive failures to meet the standard, ranging from requiring the plant to take whatever action it finds necessary to prevent a recurrence, to suspending inspection pending satisfactory reassessment by the plant of its HACCP plan.
- FSIS plans to consider all appropriate data in determining when and how to adjust the *Salmonella* standards, and possibly set standards for additional pathogens, as well.

Plant *E. Coli* Testing for Process Control of Fecal Contamination

- FSIS is requiring testing in slaughter plants for generic *E. coli* to verify that the process is in control for the prevention and removal of fecal contamination. Generic *E. coli* was selected by FSIS because of the scientific consensus that it is useful for this purpose, because the analysis is relatively easy and inexpensive to perform and because levels can be quantified. FSIS is seeking additional scientific and technical data that may support improvements to the testing protocol.
- Microbiological performance criteria, developed using data on the prevalence of *E. coli* from FSIS's national baseline surveys, will be available to help plants verify that their process controls are effectively preventing fecal contamination and will be used

similarly by the inspectors to help them assess the effectiveness of the plant's controls. The criteria are not enforceable regulatory standards but are intended to provide an objective point of reference that will help slaughter plants and FSIS ensure that plants are meeting their obligation to prevent and reduce fecal contamination of meat and poultry products.

- Implementation of *E. coli* testing begins six months after the final rule is published. Plants that do not test, or fail to keep records, will be subject to withdrawal of inspection. Twelve months after publication of the final rule, after plants have had an opportunity to gain experience in conducting the testing, FSIS personnel will start reviewing *E. coli* test results as part of their inspection routines.
- Sampling frequency will be determined by the plant's production volume, from many tests per day in high volume plants, to testing once a week in the smallest plants. Slaughter plants operating under validated HACCP systems will continue to use *E. coli* testing to verify that its process is controlling fecal contamination, but may use alternative frequencies.
- Plants will record test results and make them available to inspectors. The performance criteria require review of a moving "window" series of test results to provide a continuous picture of plant performance. This minimizes the risk that the plant's process control will be questioned due to a chance test result, but is sensitive enough to detect when performance falls short.
- FSIS expects slaughter establishments, in the context of their HACCP plans, to develop plant-specific process control verification methods which may be even more rigorous than the performance criteria in the regulations.

Antimicrobial Treatments -- Encouraged but not Required

- FSIS will not mandate antimicrobial treatments in slaughter plants as originally proposed. However, antimicrobial treatments will likely play an important role in HACCP plans as more plants establish controls that are effective in reducing pathogens and meet FSIS performance standards.
- FSIS believes that improvements in food safety are best accomplished if plants have the incentive and the flexibility to incorporate antimicrobial treatments they judge to be most suitable for their operations in meeting established performance standards.

Reviewed by: Pat Stolfa & Ralph Stafko On: May 30, 1996

File Name: 96-0027.kf

Last Update: May 30, 1996

KEYFACTS : Sanitation Standard Operating Procedures (SOPs)

Good sanitation is a fundamental requirement of federal meat and poultry inspection laws and is necessary for safe food production. Yet, poor sanitation practices, such as improper cleaning of facilities and equipment, are the most frequent deficiencies found in some meat and poultry plants. Recent FSIS unannounced reviews of 1,000 federally inspected meat and poultry plants found more frequent and serious deficiencies in sanitation than in other areas examined.

There is a direct and substantial link between insanitary practices in meat and poultry plants and the likelihood of product contamination with pathogenic bacteria. Traditionally, some federally inspected meat and poultry plants have relied heavily on inspectors to identify deficiencies on a daily basis.

The requirement for Sanitation Standard Operating Procedures (SOPs) in the Pathogen Reduction and HACCP final rule is one element of FSIS's strategy to modernize the inspection program and to reduce the incidence of pathogens in meat and poultry products. The SOPs will become effective 180 days from the date of publication of the final rule.

- Good sanitation in slaughter and processing plants is essential to preventing harmful contamination of meat and poultry products. Federally inspected meat and poultry plants must develop written sanitation SOPs to show how they meet basic sanitation requirements every day.
- The new rule will not impose new sanitation requirements, but will instead institute a process to ensure better compliance with existing Federal sanitation requirements.
- SOPs will include such activities as sanitation procedures the plant would conduct before and during operation to prevent direct product contamination or adulteration.
- Each plant must assume responsibility for identifying and addressing sanitation deficiencies.
- Meat and poultry plants will document and maintain daily records of completed sanitation procedures, corrective and preventive actions, and make them available to the USDA inspector for review and verification.
- Inspectors will verify that plants are complying with sanitation SOPs.
- If sanitation SOPs are not followed, USDA will take appropriate actions to ensure no product is produced under insanitary conditions.

Reviewed by: Dr. Jim Heminover, SISPD On: May 8, 1996

File Name: 96-0028.kf
Last Update: May 9, 1996

KEYFACTS : Impact of HACCP Rule on Small Businesses

Among the comments received on the proposed Pathogen Reduction and HACCP Systems rule, some 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. In recognizing the diverse needs of a diverse industry, several important changes, which the agency made to strengthen food safety standards in all plants, have also reduced the final rule's economic impact on small business.

Not only will changes decided on sound policy and regulatory grounds still accomplish the rule's original objectives, they also will strengthen the new food safety system. The changes bring more product under HACCP earlier than proposed and minimize the impact on small business by reducing the rule's economic burden and giving them 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, anti-microbial treatments, and cooling requirements--have all been addressed in the final rule.

Revised Implementation Schedule for Small and Very Small Businesses

- A *small business* has been redefined as an establishment with fewer than 500 but more than 10 employees.
- A new category for *very small business* has been added and is defined as an establishment with 10 or fewer 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.
- All plants will have 180 days--rather than the originally proposed 90 days--to develop and implement sanitation standard operating procedures.

Microbial Testing Requirements

- Microbial testing requirements have been revised to ensure their scientific integrity and validity, based on review of comments and input from conferences and scientific meetings. Microbial testing for process control will be based on generic *E. coli* rather than *Salmonella*. One side benefit is that *E. coli* testing is easier and less expensive.
- Effective compliance dates for microbial testing requirements have been extended to lessen their economic impact on slaughter plants, particularly small and very small businesses.
- Testing by the plant will not be required daily, as was initially proposed, but will be based on production volume, and FSIS (not the plant) will conduct testing for *Salmonella*.
- Process control sampling will be required only for plants slaughtering cattle, hogs, chicken or turkeys (but not for ground product). The number of samples required will be based on production volume, not the number of days a product is produced. 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.
- Only one HACCP-trained person will be required for each plant.

Time/temperature Requirements and Anti-microbial 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 information and public comment and will not be initially required. FSIS plans to broaden the scope 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 they can be included in HACCP plans.

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 three-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 material, protocols, and training will be requested from all parties.

Reviewed by:

On:

File Name: 96-0029.kf

Last Update: May 29, 1996

KEYFACTS : Implementation Schedule

The Food Safety and Inspection Service's Pathogen Reduction and HACCP Systems final rule mandates new measures to target and reduce the presence of pathogenic organisms in meat and poultry products. These measures include FSIS testing to verify pathogen reduction performance standards are being met, plant microbial testing to verify process control for fecal contamination, written sanitation standard operating procedures (SOPs), and a mandatory Hazard Analysis and Critical Control Points (HACCP) system in all meat and poultry plants.

FSIS remains committed to implementing HACCP as rapidly as possible, taking into account the logistical effort required to manage what will be for many establishments, as well as for the Agency, a fundamental change in work processes, roles, and responsibilities. To ease the transition, FSIS has modified the implementation schedule for HACCP.

Phasing in the implementation of HACCP remains essential. This is due in part to the widely varying stages of readiness to implement HACCP among meat and poultry establishments. A phase-in is also compelled, however, by the Agency's need to balance expediting implementation of HACCP with preparing its employees for the significant changes to be made in the inspection program and in their roles. One result of the change is that more product is covered earlier under the revised implementation schedule

In the revised implementation schedule, FSIS has taken into account the readiness of establishments of varying sizes to implement HACCP, the time it will take establishments to develop HACCP plans and train their employees, the time it will take to train FSIS employees for their new roles under HACCP and the most expeditious way of bringing the Nation's meat and poultry supply under HACCP-based process control.

FSIS originally proposed to phase in implementation of HACCP during a 12 to 36-month period primarily on a process-by-process basis, except that all "small" plants (defined as plants with annual sales of less than \$2.5 million) would be allowed the full 36 months to implement their HACCP plans. The revised implementation schedule will be based on the size of the establishment, with all processes in a single establishment coming under HACCP simultaneously, rather than on a process-by-process basis.

The HACCP regulations set forth in the final rule will be effective as follows:

- In large establishments, those with 500 or more employees, the effective date will be 18 months after publication of the final rule;
- In smaller establishments, those with fewer than 500 but 10 or more employees, the effective date will be 30 months after publication of the final rule;

- In very small establishments, those having fewer than 10 employees or annual sales of less than \$2.5 million, the effective date will be 42 months after publication of the final rule.

The *Salmonella* pathogen reduction performance standards regulations will be effective simultaneously with the effective dates for implementation of HACCP as set forth above.

Both the Sanitation SOPs and the *E. coli* process control testing regulations will be effective 6 months after publication of the final rule.

The principle advantages of the revised implementation schedule are as follows:

- Large slaughter establishments account for 75 percent of slaughter production and thus, most of the Nation's meat and poultry supply will come under HACCP-based process control one year earlier than originally proposed.
- Basing the implementation of HACCP on establishment size rather than on type of process will be simpler for both FSIS and the establishments and much less disruptive for plants that run multiple processes.
- The "very small" establishments will have an additional six months during which to implement HACCP, which will provide ample time for completion of the small-plant HACCP demonstration projects FSIS is planning in conjunction with State governments to provide practical experience with HACCP and HACCP-based inspection in many "very small" establishments.

FSIS believes that the revised implementation schedule effectively addresses and balances both the need to expedite implementation of HACCP for food safety reasons and the need to adopt a timetable that takes into account the magnitude of the changes HACCP will bring to industry and the FSIS inspection program.

Reviewed by: Paula Cohen
File Name: 96-0030.kf
Last Update: May 29, 1996

On: May 9, 1996

KEYFACTS : Training and Assistance

Effective training of both FSIS and industry employees is vital to the success of the Pathogen Reduction and HACCP Systems final rule. Various kinds of establishments, including small and very small plants, must have access to training, technical assistance, and other resources that will facilitate HACCP implementation. Therefore, FSIS has developed an approach to training and technical assistance that is designed to support HACCP implementation within available resource constraints.

FSIS believes that training and technical assistance should seek to establish a common understanding of HACCP objectives, philosophy, and the respective roles and responsibilities of both FSIS and industry employees in the practical implementation of HACCP. This goal of a shared understanding about HACCP is part of the cultural change and paradigm shift represented by this new regulatory framework, whether FSIS is providing training to its own employees or industry is providing training to plant employees.

- **New Roles.** A food safety strategy based on HACCP and performance standards requires important changes in the FSIS regulatory approach. Under the new Pathogen Reduction and HACCP regulations, the role of frontline FSIS personnel -- domestic and import inspectors, compliance officers and their supervisors -- will change significantly as establishment and Agency roles are redefined to accord with the HACCP philosophy. Therefore, the Agency will train frontline supervisors to serve as key leaders of the change, and will provide technical and cultural change training to all employees..
- **"Just-In-Time" Training.** FSIS plans to equip the workforce to carry out the redefined regulatory requirements using the "just-in-time" approach to training, under which training is delivered immediately before an employee must apply the redefined skill, knowledge and ability. This approach was selected because it will allow the Agency to link employee training to the implementation schedule, which requires plants to meet the new requirements within a span of 6 to 42 months from the date of this final rule. The "just in time" approach was also chosen because it will enable the Agency to make best use of scarce human resources and because it will minimize disruption of program services.
- **Technical Assistance for Industry.** Many small and very small plants may lack familiarity with HACCP. Thus, FSIS plans an array of assistance activities for industry designed to facilitate implementation of HACCP in small and very small plants. FSIS will hold a three-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.

- **Generic Models.** FSIS is developing 13 generic HACCP models for major process categories. The generic HACCP model plans, which will serve as illustrations or examples--rather than prescriptive blueprints--to aid plants in developing their own specific HACCP plans, will be available in final form at least 6 months before any establishment must begin work on its hazard analysis and HACCP plan.
- **Small Plant Demonstration Projects.** The Agency will conduct HACCP demonstration projects to show how HACCP systems can work for various products and product categories under actual operating conditions in small and very small plants. These demonstration projects will be conducted during the two-year period following the issuance of the final rule, at a number of sites around the country. The HACCP demonstration projects, like the generic models, should be helpful in reducing the guesswork and expenses incurred by small establishments in developing HACCP systems.
- **Guides.** FSIS is making available certain guidance materials to assist plants in conducting their hazard analyses and developing HACCP plans. They include a *Guidebook for the Preparation of HACCP Plans*, which has been designed to provide the small establishments with a step-by-step approach for developing a HACCP plan; it includes examples and sample forms for each step. Other guidance materials under development include a *Hazards and Preventive Measures Guide*.
- **HACCP Database.** The USDA/FDA Foodborne Illness Education Information Center has developed and maintains the *HACCP Training Programs and Resources Database*, which provides up-to-date listings of HACCP training programs, resources, and consultants offering training programs or resources. The Database can be accessed through the Internet.
- Development and implementation of HACCP systems is an industry responsibility and an important step in assuming responsibility for production of safe products. Therefore, each meat and poultry establishment will be responsible for training its employees.
- Nonetheless, FSIS is cooperating with the private sector to ensure a wide variety of training options. This coordination will ensure the compatibility and completeness of training courses offered to industry and Government employees. For example, FSIS is encouraging the active participation of the International Meat and Poultry HACCP Alliance, national and local trade and professional associations, State and local officials, State agricultural extension services, and local colleges and universities to help establishments incorporate HACCP into their operations.

Reviewed by: Jeanne Axtell
 File Name: 96-0031.kf
 Last Update: May 29, 1996

On: May 9, 1996

KEYFACTS : Plans for Continuing Dialogue

FSIS plans to hold special conferences, meetings, and other opportunities for continued dialogue with interested parties on issues related to the Pathogen Reduction and HACCP final rule. These activities will include the following:

- **HACCP Implementation National and Regional Conferences.** FSIS will convene a national HACCP Implementation Conference to be held in Washington, DC two months after publication of the Pathogen Reduction/HACCP final rule. This national meeting will be followed by a series of six regional implementation conferences to be held throughout the country. Topics to be discussed at the national conference will include developing generic model HACCP plans; draft guidance materials published in Appendices of final rule; revised HACCP implementation schedule and other HACCP implementation issues; achieving consistent training for FSIS and industry employees; alternative dispute resolution procedures; and other issues. A notice on the Washington, DC and regional HACCP implementation conferences will be published in the Federal Register.
- **Joint FSIS/FDA Conference on the Establishment of Food Safety Performance Standards for Temperature Controls Outside Processing Establishments.** Based on comments FSIS received, the Agency is extending and expanding its rulemaking process on the issue of cooling of raw meat and poultry products to consider alternative approaches to performance standards for cooling within establishments, and the adoption of standards for cooling of raw products during transportation, storage, and retail sale. FSIS will hold a joint conference with FDA on the establishment of appropriate food safety performance standards for temperature controls outside processing establishments in the transportation, storage, and retail marketing of meat, poultry, eggs, dairy products, and other perishable foods. This conference will coincide with the publication of a joint FSIS/FDA advance notice of proposed rulemaking on the issue. FSIS will also hold a separate meeting to discuss issues related to performance standards for temperature controls for meat and poultry products.
- **HACCP Demonstration Projects for Small Plants.** FSIS will conduct HACCP demonstration projects for small and very small plants during the 2-year period following publication of the final rule on HACCP/Pathogen Reduction. The purpose of the demonstration projects, which will be conducted at various sites throughout the country, is to show how HACCP systems can work for various products under actual operating conditions. (FSIS is also developing generic models for the major process categories that will be made available to assist small establishments in preparing their HACCP plans.) The demonstration projects will be completed prior to when any small plants are required to implement HACCP. Information gathered from the demonstration projects will be reflected in any required modifications to the generic HACCP models or other FSIS guidance materials and refinements to Agency regulations.

- **Generic *E. Coli* Testing Conferences.** 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 about 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 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 about 9 months following publication of this rule to provide an opportunity for industry and other parties to discuss with FSIS new information based on the three months of testing that will have occurred that might justify adjustments to the protocol.
- **Meeting on HACCP-Based Inspection Models.** FSIS believes it is time to test new approaches to inspection that would, within the Agency's current statutory mandate and still meeting all the consumer protection objectives of the current system, ensure that FSIS is making the best possible use of its resources to improve food safety. FSIS will publish a Federal Register notice within 30 day of issuing the final rule on Pathogen Reduction/HACCP that will announce plans to develop and conduct a pilot test of alternative models for deploying our inspection resources in the context of a HACCP-based farm-to-table food safety strategy. This public process will begin with a public meeting to discuss issues outlined in the Federal Register notice. This meeting will take place approximately 30-60 days after the notice on HACCP-based alternative inspection models is published. Interested parties will be encouraged to participate in the public meeting, the pilot studies, and evaluation of the data resulting from them.
- **Meeting with State Officials.** A meeting will be held this summer with State agriculture and inspection officials to discuss implementation and other issues related to implementation of the Pathogen Reduction/HACCP final rule within State inspection programs. This meeting will be held in conjunction with the Agency's annual meeting with State meat and poultry inspection directors.
- **Meeting with Foreign Governments.** FSIS will convene a special meeting with representatives of governments that import meat and poultry products into the United States. The purpose of the meeting will be to discuss implementation and other issues related to the final rule on Pathogen Reduction/HACCP.
- Detailed information on all of these meetings and conferences will be published in the Federal Register. For more information on any of these activities, contact:

Charles Danner: (202) 501-7138
 Andrew Moss: (202) 690-3774

Reviewed by: J Axtell	On: May 9, 1996
Revised by: A. Moss	On: May 15, 1996
File Name: 96-0032.kf	Last Update: May 24, 1996

KEYFACTS : Role of the Inspector Under HACCP

Implementation of the final rule on HACCP and Pathogen Reduction Systems will result in far reaching changes in the respective roles of industry and FSIS inspection personnel in assuring the public of a meat and poultry food supply that meets appropriate sanitation and safety standards and is not adulterated or misbranded.

The Pathogen Reduction and HACCP Systems rule represents a change in regulatory philosophy and thus will change the focus, tasks, behavior, and priorities of Agency employees--particularly frontline employees and supervisors. It will more clearly define and separate the role of the food producer and regulator.

- Traditionally some plants have relied on inspectors to identify deficiencies on a daily basis before the company would take action to correct food safety problems. This factor, and the prescriptive nature of the requirements, has often blurred the line between industry and regulator.
- The final rule clarifies that regulated establishments will be responsible for manufacturing products that are not adulterated or misbranded, and that are as free as possible of pathogenic microorganisms. The Agency and its inspectors will be responsible for inspecting products and facilities to verify that statutory requirements have been met and for taking enforcement action when there is sufficient evidence that requirements have not been met. These are the roles that will be established and maintained as a result of the final rule.
- Many of the activities carried out in the current inspection program, including carcass-by-carcass inspection – not only respond to some of the public's most basic expectations of its government, but are also required by law. These activities will continue. However, in light of improvements in process control that are expected under HACCP, FSIS plans to examine current tasks related to carcass-by-carcass inspection and determine what changes should be made to improve effectiveness and make use of inspection resources more productive.
- Under the new system, plants have clear, affirmative responsibilities for preventing food safety hazards.
- Under the new system, FSIS inspection personnel will exercise the following regulatory oversight responsibilities:
 1. Evaluation: To determine that each plant's sanitation SOP and HACCP plan conforms with regulatory requirements.
 2. Verification: To determine, on an ongoing basis, that a plant is carrying out its SOP and HACCP plan.

3. Documentation: To prepare written material to document failure to meet regulatory requirements.
4. Enforcement: To take appropriate actions when a plant is not in conformance with established regulatory requirements.

Reviewed by: Jeanne Axtell

On: May 9, 1996

File Name: 96-0033.kf

Last Update: May 24, 1996 (sc)

DRAFT

DRAFT

Mr. Dave Asman
Wall Street Journal
World Financial Center
200 Liberty Street Tower A
New York, NY 10281

BY FACSIMILE 212-416-2658

To the Editor:

Your February 4, 1997, news article "Clinton Issues Rule on Poultry Safety, Stunning Critics," fails to communicate the significance of this new rule to consumers and contains factual errors which, as administrator of USDA's Food Safety and Inspection Service, I feel need to be corrected. The article asserts that the new rule requires poultry inspectors to sample and check only a few birds for fecal contamination at the end of production lines, implying that inspection is being reduced. It is not. The rule, in fact, builds on existing FSIS visual inspection of every single poultry carcass, plus carcass sampling before and after the chiller. This new rule will require additional sampling by inspectors, the visual inspection and sampling they already do. Inspectors will carry out two additional checks into their routine sampling. These are new tasks to ensure compliance with the regulation.

Under this final rule, USDA's existing zero tolerance policy becomes a regulatory requirement each plant must meet every day. It explicitly prohibits poultry carcasses with visible fecal contamination from entering immersion chillers. FSIS will continuously verify that establishments are meeting the zero tolerance standard through sampling and visual observation and when contamination is found, FSIS will require immediate corrective action by the plant.

Thus, when one recognizes the combined effect of strengthened visual inspection through this rule with the new HACCP/Pathogen Reduction requirements announced by the President on July 6, 1996, which includes a new microbial testing requirement for generic E. coli to verify process control for fecal contamination, the increased consumer protection becomes clear. Plants will incorporate control measures to meet zero tolerance for fecal contamination into their individual establishment HACCP plans. This new rule requires plants to take additional steps to prevent such contamination, instead of just correcting it after the fact. The micro testing will scientifically verify process control through monitoring for what cannot be detected visually.

I hope this letter helps clear up the value of this new regulatory measure for U.S. consumers.

Thomas J. Billy
Administrator

TALKING POINTS

- Food Safety and Inspection Service inspectors visually and manually inspect every single poultry carcass. The WSJ article conveys the impression that inspectors are required to look at only a few birds. That is misleading.
- FSIS is already inspecting every single bird for wholesomeness.
- The final rule, for the first time, explicitly prohibits poultry carcasses with visible fecal contamination from entering immersion chillers.
- This rule eliminates “feces” from the list of defects that might be observed during sampling and from being counted in calculations to determine if the process is within a statistical tolerance, i.e., is in control. Under the final rule, if any fecal material is observed, immediate corrective action must be taken.
- Poultry processing plants are already required to sample birds before and after chilling to determine if the slaughtering and dressing process is under control and yielding product that is free of visible defects and contamination. This includes a check for fecal contamination. FSIS inspectors independently sample birds to verify that plants are maintaining control of their processes.
- The rule will be enforced through additional sampling by inspectors, on top of sampling they already do. There will be no reduction in on-line inspectors looking at every bird for wholesomeness; off-line inspectors will add 2 additional checks into their routine sampling.
- FSIS will continue to verify that establishments are meeting the zero tolerance standard through visual observation, data collection, and sampling.
- Action to correct a product contamination problem must be taken irrespective of sampling results.

Billing Code 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 381

[Docket No. 94-016F]

RIN: 0583-AC25

Poultry Inspection: Revision of Finished Product Standards With
Respect to Fecal Contamination

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule; Request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the poultry products inspection regulations to clarify and strengthen the enforcement of FSIS's zero-tolerance policy regarding visible fecal material on poultry carcasses. FSIS is amending its regulations to codify an existing standard that ensures poultry carcasses contaminated with fecal material do not enter the chilling tank. In order to clarify the enforcement of this policy, this rule removes "feces" as a nonconformance element in the finished product standards for poultry.

In addition, the Agency is seeking comments on the relationship between ingesta and the presence of microbial pathogens on raw poultry.

DATES: This rule is effective on May 5, 1997.

There is no due date for comments requested on

the relationship between ingesta and microbial pathogens on raw poultry.

ADDRESSES: Submit one original and two copies of written comments to: FSIS Docket Clerk, DOCKET #94-016F, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 3806 South Agriculture Building, 1400 Independence Ave., SW., Washington, DC 20250-3700. All comments submitted will be available for public inspection in the Docket Clerk's Office between 8:30 a.m. and 1:00 p.m. and 2:00 p.m. and 4:30 p.m., Monday through Friday. To review the research and other background information used by FSIS in developing this document, interested persons may visit the Docket Clerk's office during the times listed above.

FOR FURTHER INFORMATION CONTACT: Dr. Isabel Arrington, Staff Officer, Slaughter Operations, Office of Field Operations; (202) 720-7905.

SUPPLEMENTARY INFORMATION:

Background

To enforce the "zero tolerance" policy regarding visible fecal contamination on poultry, FSIS program employees look at every carcass to ensure it is not contaminated by visible fecal contamination. This visual check of all carcasses occurs after evisceration but prior to the separation of the viscera from the

carcass and prior to the final wash and entry of the carcass into the chilling tank. Should visible fecal contamination be observed, existing regulations permit establishments to reprocess contaminated carcasses by a number of approved methods, including washing and trimming on or off the line. Regardless of the method chosen, the end result must be removal of all visible specks of contamination prior to the carcasses' entering the chiller. This zero tolerance policy for visible fecal contamination is an important food safety standard because fecal contamination is a major vehicle for spreading pathogenic microorganisms, such as Salmonella, to raw poultry.

Under current rules, FSIS ensures removal of all visible fecal contamination subsequent to postmortem inspection through off-line reinspection, direct on-line observations by an inspector, and application of finished product standards (FPS). The FPS are applied to samples of product prior to its entering the chiller and after product has left the chiller as a means of measuring an establishment's performance in meeting organoleptic (detectable by the unaided senses) standards, including the removal of visible fecal contamination.

Under an FPS program, the poultry establishment checks carcasses entering and leaving the chiller for nonconformance to

the FPS. If the incidence of nonconformances determined by the FPS test indicates that the establishment's process is out of control, the establishment must take corrective action. Any bird in the sample taken found to be contaminated with feces is set aside for rework or condemnation. FSIS inspectors located before the chiller also evaluate performance by visually observing carcasses, checking quality control data, and sampling product. The establishment and FSIS apply a statistical method to determine if the establishment's processes are under control and producing consistently sound product. In the event an establishment does not meet statistical criteria, the establishment's process is determined to be out of control and corrective action is required. The application of FPS does not preclude the inspector's directing the establishment to take corrective action any time carcasses visibly contaminated with fecal matter are observed.

On July 13, 1994, FSIS published a proposed rule, "Enhanced Poultry Inspection," in the Federal Register (59 FR 35659) to clarify and strengthen substantially the Agency's zero-tolerance policy for visible fecal contamination. The proposed rule would have implemented a single system of postmortem inspection for all poultry species. Establishment personnel would have been

required to pre-sort birds before inspection to exclude those with diseases and condemnable conditions. In addition, the inspection sequence would have been changed to permit inspectors to conduct on-line checks for contamination. The proposal would have required all reprocessed birds to be returned to the main processing line for inspection.

FSIS also proposed the mandatory use of antimicrobial rinses in all establishments, use of establishment employees to sort poultry, revision of the FPS, and addition of recordkeeping and verification procedures. The proposal included the removal of "feces" from the list of nonconformances in the FPS and a mandatory line speed reduction triggered by any finding of visible fecal contamination during an FPS review or at other times when such contamination was detected.

Since the proposed rule was published, FSIS has adopted a comprehensive, preventive food safety strategy to reduce the incidence and prevalence of foodborne illness in the United States. The centerpiece of this strategy is the "Pathogen Reduction; Hazard Analysis and Critical Control Points (HACCP) Systems" final rule (61 FR 38805-38989, July 25, 1996). HACCP is a system of preventive controls designed to improve the safety of food products.

The Pathogen Reduction/HACCP regulations require each establishment to conduct a hazard analysis and develop a HACCP plan applicable to every product it produces. Fecal contamination is a reliable indicator of the likely presence of microbial pathogens, a food safety hazard which all slaughtering establishments will necessarily address in their HACCP plans. Poultry processing establishments must adopt HACCP controls that they can demonstrate are effective in reducing the occurrence of microbial pathogens; those controls include preventing the fecal contamination of carcasses and thus preventing fecally contaminated carcasses from entering the chilling tanks. They will be required to monitor, verify, and record results which demonstrate the effective operation of those controls on a continuing basis.

Under the Pathogen Reduction/HACCP rule, in addition to controls for reducing microbial pathogens, such as ensuring that all poultry carcasses are free of visible fecal contamination before entering the chiller, slaughtering establishments will verify their process controls by testing sampled carcasses for generic Escherichia coli (Biotype I). In addition, FSIS has established pathogen reduction performance standards based on Salmonella prevalence in raw product. These standards, which

FSIS will enforce through its own Salmonella testing program, complement the process control performance criteria for visible fecal contamination and E. coli testing.

The Pathogen Reduction/HACCP rule establishes a more comprehensive framework for food safety protection than did the 1994 proposal, and therefore supersedes it. It couples HACCP-based process control to prevent visible fecal contamination (and other hazards) with microbial testing and pathogen reduction performance standards to scientifically verify the effectiveness of the HACCP plan. Some of the concepts in the July 1994 proposal, such as antimicrobial processes and the role of FSIS inspectors, may be addressed by future rulemakings if the concepts appear to provide substantial food safety benefits in a HACCP context.

The zero-tolerance standard for visible fecal contamination, an indicator of likely microbial contamination, is one that must be achieved by processing control and therefore is consistent with the HACCP framework. The HACCP regulations require all establishments to identify all food safety hazards reasonably likely to occur in a specific process, and to identify critical control points adequate to prevent them. Fecal contamination is a food safety hazard because of its direct link

to microbiological contamination and foodborne illness. Preventing carcasses with visible fecal contamination from entering the chiller is critical for preventing cross-contamination of other carcasses. The final carcass wash before the carcasses enter the chiller is a critical control point for preventing cross-contamination of other carcasses. Critical control points to eliminate visible fecal contamination are predictable and essential components of the HACCP plans for all slaughter establishments. For establishments' HACCP plans to be validated, they will have to achieve the zero tolerance for visible contamination at the point where carcasses enter the chiller.

Though the zero-tolerance policy has not been codified in the regulations until now, it is implicit in some of the regulations. For example, § 381.91(b), provides that poultry accidentally contaminated with digestive tract contents need not be condemned if promptly reprocessed under the supervision of an inspector and found not to be adulterated. The codification of the zero-tolerance policy for visible fecal contamination and removal of "feces" as a nonconformance element in the finished product standards for poultry provide a clear and unambiguous standard that poultry slaughtering establishments must meet today

and, eventually, incorporate into their HACCP systems.

FSIS will continue to verify that establishments are meeting the zero-tolerance standard through visual observations, data collection, and sampling. However, consistent with the policy, any indication of visible fecal contamination will require establishments to take immediate corrective action after deviations occur, rather than after a certain statistical measure of control is exceeded over a period of time.

The bulk of the comments on the July 1994 proposal addressed provisions that are unrelated to this final rule. Of the 434 comments received, 64 addressed the zero-tolerance policy on fecal contamination. Forty-eight commenters were clearly in favor of the policy; 16 expressed various reservations, such as: (1) fecal material was undefined; (2) visible feces should be trimmed, not washed; (3) since FSIS has a zero tolerance policy for fecal contamination, a rule change is not necessary; and (4) a zero tolerance policy should also be established for ingesta and other intestinal tract contents.

In response to the commenters who stated that fecal material and/or feces should be defined, FSIS has developed guidelines for inspectors to use in identifying feces on carcasses. In these guidelines, three factors--color, consistency, and composition--

are essential in positively identifying fecal contamination. In general, fecal material color ranges from varying shades of yellow to green, brown, and white; the consistency of feces is usually semi-solid to a paste; and the composition of feces may include plant material. Inspectors use the feces identification guidelines to verify that establishments prevent carcasses with visible fecal contamination from entering the chilling tanks.

Several commenters also felt that any contamination on the carcass should be trimmed, and that washing, including reprocessing, should not be permitted as an alternative to trimming. The regulations (9 CFR 381.91(b)) permit poultry contaminated during slaughter with digestive tract contents, such as feces, to be reprocessed in lieu of being condemned. These regulations were promulgated in 1978 and were based, in part, on an Agricultural Research Service (ARS) study, published in the Journal of Food Science, which concluded that effective washing of contaminated poultry carcasses produced carcasses with microbiological levels essentially equal to normally processed and inspected carcasses.¹ A subsequent ARS study supported this

¹ Blankenship LC, Cox NA, Craven SE, Mercuri AJ, and Wilson RL. Comparison of the Microbiological Quality of Inspection-Passed and Fecal Contamination-Condemed Broiler Carcasses. J. Food Science 1975; 40:1236-1238.

finding.²

Several commenters stated that FSIS has a zero tolerance policy for feces and, therefore, a change to the regulations was not needed. However, the apparent incompatibility between FSIS's zero tolerance policy for fecal material on individual poultry carcasses and the existence of a process measure that includes a tolerance for "feces" in the finished product standards has continued to cause confusion. To clarify the zero tolerance policy, FSIS is amending the poultry products inspection regulations by removing "feces" as a nonconformance element from the finished product standards.

Several commenters stated that there should be a zero tolerance policy for ingesta and other digestive tract contents, in addition to feces. Ingesta are processing defects generally consisting of undigested feed remaining in a bird's crop, esophagus, and gizzard. Ingesta contamination and attached portions of the crop and esophagus are processing defects counted as FPS nonconformances. Ingesta contamination of poultry was not directly addressed in the July 1994 proposal.

² Blankenship LC, Bailey JS, Cox NA, Musgrove MT, Berrang ME, Wilson RL, Rose MJ, and Dua SK. A Research Note: Broiler Carcass Reprocessing, A Further Explanation. J. Food Prot. 1993; 56:983-985.

A research report³ recently identified the crop as a potential source of Salmonella contamination for broiler carcasses. The report noted that crops may be ruptured during processing, suggesting that the crop may serve as a source of carcass contamination if exposure to pathogenic microbes occurs during the last week before slaughter. The fact that birds are especially likely to pick up fecal droppings during the feed withdrawal period prior to slaughter could explain the presence of Salmonella in the crops.

Comments and information on ingesta contamination would be useful to the Agency in its consideration of the need for additional regulatory measures regarding ingesta. Such information would also be helpful to establishments in identifying hazards and determining critical control points in their HACCP systems. FSIS would like to have more information on how the presence of ingesta on dressed poultry carcasses relates to the presence of microbial pathogens and, consequently, the food safety profile of ready-to-cook raw poultry. Specific information is requested on (1) the capacity of current

³Hargis BM, Caldwell DJ, Brewer RL, Corrier DE, DeLoach JR, An Evaluation of the Chicken Crop as a Source of Salmonella Contamination for Broiler Carcasses. Poult Sci 1995; 74:1548-52.

technology to prevent ingesta contamination, (2) the consumer perspective on the presence of ingesta on ready-to-cook raw poultry, (3) the tolerance level and defect categories in the current FPS program for ingesta, crop, and esophagus, and (4) the availability and cost of new technology and its capacity to prevent ingesta contamination.

The Final Rule

In summary, this final rule amends the poultry products inspection regulations by explicitly prohibiting dressed poultry carcasses contaminated with feces from entering the chiller. It also removes "feces" from the list of nonconformance elements in the poultry finished product standards. Any visible fecal contamination found by the establishment during the finished product standards check means that the establishment has failed to meet the standard and that immediate corrective action is required, irrespective of the overall FPS results. Under this final rule, FSIS inspectors will continue their current practice of verifying the establishment's process control through visual observation of carcasses and off-line checks of sampled birds.

Additionally, beginning on the effective date of this rule and prior to HACCP implementation, FSIS inspectors will, during each shift in all poultry slaughtering operations, check at least

two more 10-bird samples on each evisceration line for visible fecal contamination after the final wash, before the carcasses enter the chiller. Any amount of visible fecal contamination found by FSIS inspectors during these checks will be regarded as a lack of process control requiring immediate correction.

FSIS will continue to verify the effectiveness of the establishment's corrective actions and, if the actions prove ineffective, will prohibit birds on affected lines from entering the chilling tank directly until the establishment demonstrates, and FSIS verifies, that the zero-tolerance standard for visible fecal contamination is being met. This prohibition may result in slowing or stopping the line until the problem is solved. FSIS also will check carcasses on the affected lines after they exit the chilling tank.

After HACCP systems are implemented in slaughtering establishments, FSIS personnel will determine the effectiveness of preventive controls and corrective actions for visible fecal contamination as they verify HACCP system adequacy. They will continue close oversight of processor efforts to prevent visible fecal contamination, sampling birds at the same frequency as before HACCP implementation. The presence of visible fecal contamination on poultry carcasses entering the chiller will mean

that controls to prevent such contamination have failed. The finding of fecal matter on carcasses entering the chiller even after corrective actions have been taken to prevent its recurrence will constitute evidence of a HACCP system failure. FSIS will consider a documented pattern of repeated system failures to be evidence that the establishment's HACCP plan is inadequate. The Agency will take immediate action to ensure proper disposition of adulterated product, including its condemnation. Additionally, if appropriate, the Agency will undertake proceedings to withdraw inspection from the establishment.

FSIS plans to review the application of this standard during the implementation of HACCP in affected establishments. The Agency would certainly welcome input from interested parties on the application of this standard in a HACCP environment.

FSIS expects that its zero-fecal-contamination policy, together with the Pathogen Reduction/HACCP rule, will improve the safety of raw poultry products and help bring about measurable declines in foodborne illness attributable to poultry consumption.

Executive Order 12866 and Effect on Small Entities

This final rule has been determined to be significant and

was reviewed by OMB under Executive Order 12866.

This rule codifies as a standard the existing FSIS zero-tolerance policy for the presence of visible fecal contamination on poultry carcasses entering the chilling tank, and removes "feces" as a nonconformance element in the FPS for poultry. The rule does not require any facility changes nor does it stipulate what steps establishments must take to comply with the standard. Furthermore, this rule is compatible with the mandatory HACCP program for meat and poultry establishments.

The rule will affect about 520 poultry slaughtering establishments subject to inspection under the Poultry Products Inspection Act. Approximately 360 of these are inspected by FSIS, about 300 operating under inspection systems incorporating FPS; the other 60 or so--most processing low-consumption-volume species, such as ducks and geese--operating under "traditional" systems. In the "traditional" establishments, inspectors check outgoing product using lot acceptance plans from which entries for "feces" are being removed by Agency directive. The final rule will also affect about 160 poultry slaughtering establishments where States maintain inspection that is "at least equal to" Federal inspection.

Alternatives Considered

As discussed in the preamble to the proposal, FSIS considered two alternatives to the proposed regulatory amendments that would have met the objectives of strengthening poultry products inspection, reducing the occurrence of pathogens on raw product, and enforcing a "zero tolerance" for visible fecal contamination of raw product. The first of the alternatives would have required detaching the viscera from the carcass before post-mortem inspection and presenting the organs and the carcass for inspection at the same time, rather than sequentially. A separate belt or tray would have been provided to prevent the viscera from contaminating the carcass. However, preliminary estimates indicated that costs to the industry of equipment acquisition and installation and downtime for construction would have approached \$1 billion.

The second alternative would have involved retaining the current postmortem inspection procedures while positioning an additional inspector at the end of the evisceration line at a point after viscera removal to examine each carcass for fecal contamination. Under this alternative, the Government could have incurred an additional \$16 million per annum in personnel costs, which was unacceptable to FSIS, and production rates could have

been slowed by 30 to 50 percent if fewer inspectors were assigned to perform the required tasks. The annual cost to the industry and consumers of slowed linespeeds could have been as high as \$5.2 billion. In the Agency's judgment, either of these alternatives would have posed unacceptable costs.

The alternative proposed by the Agency included a single postmortem inspection system for all kinds and classes of poultry, a requirement for the establishment to present for inspection birds that had been pre-sorted to exclude those with diseases and condemnable conditions, a change in the inspection sequence to include on-line checks for contamination, the return of all reprocessed birds to the main processing line for reinspection, and mandatory antimicrobial treatment of all dressed poultry. In addition, some establishments would have had to install adjustable inspection stands and enhanced lighting. A completely revised FPS, without a nonconformance element for feces, would have been applied to all poultry. An FSIS inspector would have been required to stop or slow the line upon finding any fecally contaminated bird. The Agency estimated the cost of the proposal to industry at about \$7 million. Cost estimates supplied by industry commenters indicated costs would substantially exceed the Agency's estimate.

Since the proposal was published, the Agency has adopted a comprehensive food safety strategy based on mandatory HACCP systems for meat and poultry establishments. The Pathogen Reduction/HACCP rule implementing this policy supersedes the July 1994 proposal. Accordingly, FSIS has limited this final rule to the codification of the zero tolerance policy for visible fecal contamination and to the removal of the "feces" nonconformance element from the poultry FPS.

Costs

As mentioned, visible fecal contamination of poultry carcasses currently is addressed at postmortem inspection by off-line reprocessing of accidentally contaminated poultry, through pre-chill FPS checks, and at other times that visible fecal contamination is detected. FSIS estimates that the frequency of corrective actions required because establishments fail an FPS test due to visible fecal contamination nonconformances is, at most, 1 time a year per establishment. Normally, the presence of visible fecal contamination found during an FPS review is at a level such that it will cause an FPS failure and trigger immediate corrective action. A typical establishment may fail a pre-chill FPS test once a month or less because nonconformances other than visible fecal contamination, such as the presence of

feathers or other dressing defects, have been observed. Such an establishment may fail a post-chill FPS test about six times a year, usually because extraneous matter is found on the carcass. Some establishments operate for 2 or 3 years without failing an FPS test.

The Agency will have to shift the allocation of Federal poultry inspection resources during the period after this rule becomes effective. Upon the effective date of this rule, FSIS inspectors will be sampling additional birds at pre-chill to examine them for visible fecal contamination, a task that will require as many as 10 staff-years to perform. This cost can be absorbed within FSIS's current resources.

As mentioned, this final rule removes the nonconformance element for "feces" from the current FPS for poultry and codifies the policy prohibiting poultry carcasses contaminated with visible feces from entering the chiller tank. As stated elsewhere in this preamble, this rule establishes a standard that is compatible with the Agency's Pathogen Reduction/HACCP regulations. It will take effect, however, before mandatory HACCP plans are implemented in most federally inspected poultry products establishments.

When this final rule becomes effective, the detection of

visible fecal contamination during the pre-chill FPS or at any other time that visible fecal contamination is detected on the carcasses before the carcasses enter the chiller will trigger corrective actions to prevent recurrence of the problem. The Agency foresees that initially, when this final rule goes into effect, there may be an increase in the frequency of corrective actions. Establishments may incur costs attributed to slowing or temporary stoppage of production lines, equipment adjustments, product rework, and the placing of additional personnel on the processing line, at a somewhat higher rate than previously.

These costs are likely to result from two primary causes. First, following the effective date, establishments will be placing increased emphasis on preventing carcasses with visible fecal contamination from entering chiller tanks. The increased vigilance of establishment personnel initially may cause some production slowdowns. Second, FSIS inspectors will be sampling birds at an increased rate to enforce the zero-tolerance policy. It is possible that a prevalence level of fecal contamination that had not been detected previously in FPS tests will now be shown to occur, and that processing lines may be slowed or stopped more often for corrective actions to be taken.

FSIS estimates that the industry-wide cost of stopping or

slowing the processing line when fecal contamination is found on dressed poultry could be as high as \$15 million during the first year this final rule is in effect. This estimate is derived from data submitted by commenters on estimated efficiency losses--including losses due to stopping or slowing the processing lines--that the proposed rule might have caused. An assumption of the commenters, which FSIS does not share, was that the efficiency reduction costs would recur annually.

FSIS sees any such cost increases as short-term. Once establishments adjust to the new inspection procedures and adopt more stringent operating standards, the need for corrective action should be reduced, and there will be greater assurance that product entering chillers is free of visible fecal contamination.

Benefits

FSIS expects the net benefits to society from this rule will be in the form of fewer outbreaks of foodborne disease attributable to poultry products. The rule will help ensure that raw poultry entering chiller tanks is free of contamination that may harbor pathogens and, thus, that there will be less cross-contamination in the chiller tanks. FSIS expects that this reduced cross-contamination will mean that raw poultry shipped in

commerce will have fewer pathogens and that the risk of illness due to improper handling of raw product after it leaves the inspected establishment will be reduced.

The Administrator, FSIS, has determined that this final rule will not have a significant impact on a substantial number of small entities. The small entities affected by this rule are the approximately 220 small poultry slaughtering establishments that meet the Small Business Administration size standard of 500 or fewer employees. This is a significant number of small entities but, for reasons given above, costs to establishments, whether they be small or large entities, should not be significantly affected by this rule. Thus, the rule will not have a significant impact on a substantial number of small entities.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule (1) preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Requirements

The July 13, 1994, proposed rule required paperwork and recordkeeping activities that would have provided FSIS with information to ensure that establishments were in compliance with the proposed regulations. As noted above, however, FSIS is withdrawing the provisions of the proposal that would have required such paperwork and recordkeeping.

List of Subjects

9 CFR Part 381

Poultry inspection, Poultry and poultry products.

For the reasons discussed in the preamble, FSIS is amending part 381 of the poultry products inspection regulations as set forth below:

PART 381--POULTRY PRODUCTS INSPECTION REGULATIONS

1. The authority citation for part 381 continues to read as follows:

AUTHORITY: 7 U.S.C. 138f, 450; 21 U.S.C. 451-470; 7 CFR 2.18, 2.53.

Subpart I--Operating Procedures

2. Section 381.65 is amended by adding a new paragraph (e) to read as follows:

§ 381.65 Operations and procedures, generally.

* * * * *

(e) Poultry carcasses contaminated with visible fecal material shall be prevented from entering the chilling tank.

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Subpart K--Post Mortem Inspection; Disposition of Carcasses and Parts

3. Section 381.76, Table 1-Definitions of Nonconformances, is amended in paragraph A-1 by removing the word "feces," by removing the end note from paragraph A-2 regarding feces, by removing paragraph A-8, "Feces $\geq 1/8$," and by renumbering paragraphs A-9 through A-20 as A-8 through A-19.

* * * * *

Done at Washington, DC, on:

Thomas J. Billy
Administrator