Approved: March 6, 1997
Date

MINUTES OF THE HOUSE COMMITTEE ON AGRICULTURE.

The meeting was called to order by Chairperson Joann Flower at 9:00 a.m. on February 20, 1997, in Room 423-S of the Capitol.

All members were present except:

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

Conferees appearing before the committee:
Allie Devine, Secretary, Kansas Department of Agriculture
Dr. Joseph Beuerlein, Division of Inspections - Meat and Poultry, Kansas Department of Agriculture
Gene Steffes, Food Bank, Olpe, Kansas

Others attending: See attached list

Chairperson Flower called the committee's attention to a memorandum from Debra Duncan, Kansas Animal Health Department, to the Budget Division, Department of Administration, concerning a fiscal note for **HB 2279**. (Attachment 1)

Hearing on HB 2425 - Certain duties of secretary of agriculture related to state compliance with certain federal regulations.

Chairperson Flower opened the hearing on **HB 2425**.

Allie Devine, Secretary, Kansas Department of Agriculture, provided an overview regarding Sanitation Standard Operating Procedures (SSOP) and Hazard Analysis and Critical Control Points (HACCP) as they relate to **HB 2425**. She said that our state meat inspection program has been designated as "equal to" by USDA. She explained that under the federal meat inspection act, federal law preempts state law. She said it would be unconstitutional for the state to act in opposition to the federal law. She explained that if the state does not conduct an "equal to" program, the federal government would take over the program and the meat processing plants would still have to continue to follow all federal rules and guidelines.

The Secretary said that requiring the Department and K-State to cease providing education and information regarding the new federal regulations as required in **HB 2425** would exclude the two leading governmental sources of information and assistance to meat processors, which would only harm the industry. She said her Department did not have an economist on staff and that one month was not sufficient time to provide credible and reliable information on the impact and ramifications of SSOP and HACCP as required in **HB 2425**. (Attachment 2)

The Secretary provided copies of the Federal Register dated July 25, 1996, containing the final regulatory impact assessment of "Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems." (Attachment 3) She also provided copies of two letters, dated June, 1995, and September, 1995, that she sent to the U. S. Department of Agriculture with the Department's comments concerning HACCP. (Attachments 4 and 5)

Dr. Joseph E. Beuerlein, Program Manager, Division of Inspections - Meat & Poultry Inspection, Kansas Department of Agriculture, provided information on the specific requirements of SSOP and HACCP and explained the benefits of having a state inspection program. He said the federal regulations now being proposed are already in effect in all establishments under federal inspection, as well as in fifteen of the twenty-six state inspection programs. Kansas is one of eleven state programs now in the process of adopting them.

He, also, emphasized that if a state inspection program declines to implement and enforce the regulations, the federal inspection system will take over. (Attachment 6)

Chairperson Flower explained that although Representative Thimesch requested introduction of a committee bill regarding HACCP, his original request was made prior to the 1997 session; therefore, **HB 2425** is sponsored by Representative Thimesch, not by the House Agriculture Committee.

Representative Daniel Thimesch testified in support of **HB 2425** to halt compliance with federal SSOP and HACCP regulations until the Secretary of the Kansas Department of Agriculture can study the impact and ramifications implementation of these regulations will have on the small meat processors and the economy in Kansas. He said that it is estimated that one-third of the small plants will go out of business, and that the remaining plants will have to spend $25,000 to $200,000 to comply with the new regulations. He explained that this bill is an attempt to get some of these questions answered. (Attachment 7)

Gene Steffes, Food Bank, Olpe, Kansas, appeared in support of the efforts expressed in **HB 2425**. He said that he did prefer state, rather than federal inspection, of small meat processing plants in Kansas. He suggested a mediator to listen to the operators' concerns and to help the small processing plants correct problems and make it easier for them to comply with inspection requirements. He assured the committee that all operators want to put out a safe and wholesome product that is good for their customers. (Attachment 8)

This concluded the hearing on **HB 2425**.

The meeting adjourned at 10:05 a.m. The next meeting is scheduled for February 21, 1997.

HOUSE AGRICULTURE COMMITTEE GUEST LIST

DATE: 2-20-97

NAME	REPRESENTING
Kate Hutchinson	Intern
Mary Jane Stattelman	KS Dept of Ag
Allie Devine	Ks Dept. of Ag
[illegible]	KS Dept of Ag.
Carole Jordan	KDA
Gene Steffes	Farber Plant
Becky Klingler	KDOC+H
Marty Vanier	KS Ag Alliance
Diane Gruver	Ks Coop Council
Mike Beam	Ks Lvstk Assn.

STATE OF KANSAS
KANSAS ANIMAL HEALTH DEPARTMENT

George Teagarden, Livestock Commissioner

712 South Kansas Avenue Suite 4-B Topeka Kansas 66603-3808
Phone 913/296-2326 FAX 913/296-1765

FAX TRANSMITTAL SHEET

Date: February 12, 1997

To: Cindy Denton, Budget Division

Fax No: 6-0231

Pages: two

From: Debra Duncan

H.B. 2279 requires the commissioner to assume control of any pseudorabies infected herd of swine from the owner. The commissioner shall develop and monitor a herd plan to eradicate the virus from the owner's premises. If, in the commissioner's opinion, sufficient progress toward pseudorabies free status has not been made, and the infected herd or herds are stopping progress toward free status, the commissioner shall order depopulation of the herd. Whenever swine are depopulated under this act, the owner of such swine shall be paid for the swine in an amount determined by the livestock commissioner from funds appropriated for such purpose by the legislature.

Agency responsibilities under this bill would not be affected. Currently, the agency quarantines pseudorabies infected herds and develops a herd plan. The agency does not, at this time, have authority to reimburse herd owners for depopulation.

There would not be any receipts generated from this bill. Expenditures, which would require an appropriation from the legislature (for the purpose of depopulation) would vary depending on the number of infected herds in the state. No funding source is specified in the bill. The agency assumes that an indemnity fund would need to be set up and funds would be appropriated from the State General Fund. Currently, only one infected herd is known to exist in the state. Depopulation of this herd is estimated to cost $36,000. This estimate is based on the following:

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3 Boars	@	$250.00	$ 750
100 Sows	@	187.50	18,750
100 Nursery	@	45.00	4,500
110 Finshers	@	75.00	8,250
30 Replacement Gilts		125.00	3,750
			$ 36,000

Herd numbers will vary from year to year. In 1993, Kansas had 3 infected herds, 1994 - 2 herds, 1995 - 2 herds and currently one herd. Herd size is unpredictable.

No additional staff will be required to implement this bill. Projections for the next three fiscal years would be approximately $50,000 per year from the State General Fund.

HOUSE AGRICULTURE COMMITTEE

HOUSE BILL 2425

FEBRUARY 20, 1997

Good morning, I am Allie Devine, Secretary of the Kansas Department of Agriculture and I want to express the following concerns regarding HB 2425.

First let me explain that our current state meat inspection program has been designated as "equal to" by the United States Department of Agriculture. Under the federal meat inspection act (21 U.S.A. 645), federal law preempts the state's. It would be unconstitutional for the state to act in opposition to the federal law. If the state does not conduct an "equal to" program, the federal government would not recognize its inspection program. The term "equal to" means the state program is in line with federal requirements to ensure uniformity of meat products across the United States. Without such designation, the state program would no longer exist; the federal government would take over the program; and the meat processing plants would still have to continue to follow all federal rules and guidelines.

HB 2425 requires the Department of Agriculture and Kansas State University to cease providing education and information regarding sanitation standard operating procedures (SSOP) and hazard analysis and critical control points (HACCP). Preventing the two leading governmental sources of information and assistance in Kansas from helping meat processors understand the requirements of SSOP and HACCP would only harm this important Kansas industry. It is critical to these individuals and their livelihood that they understand what these new food safety rules require of them whether we continue the state program or whether the federal government takes over the inspection and regulation of meat processing plants. If, as the proposed bill provides, we do not adopt the federal rules, the state program would be nullified. Federal inspectors will step in to conduct what had been the state's program. Their takeover would include implementation of all new federal food safety rules now being implemented across the nation.

The Governor's Agricultural Advisory Board met by conference call Feb. 13, 1997. Members of that board unanimously supported the implementation of federal meat inspection guidelines and the efforts of the Department of Agriculture and other entities to assist state plants through education, information and making resources available to assist with training and infrastructure upgrade costs.

HB 2425 also requires me to study the impact and ramifications of SSOP and HACCP and

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make recommendations to the legislature on or before April 1, 1997, regarding 1) how to lessen the impact of SSOP and HACCP on small processors; 2) provide alternatives which will avoid the significant cost and economic hardship associated with implementation of the regulations and 3) develop arguments and rationale to present to USDA that our current regulations are adequate to protect the health and safety of the citizens of the state of Kansas and therefore our state program should be allowed to continue.

I do not think we can provide you with credible and reliable information within one month. Furthermore, to do an impact study would require the expertise of an economist, which we do not have on staff.

The ultimate customer of the state meat inspection program, and the 150 small state-inspected plants in Kansas, is the food consumer. Food safety is a meaningful issue which must be addressed. The meat inspection program, and the new federal rules designed to modernize and improve the safety of meat and poultry products, exists to ensure consumer confidence in the products of Kansas meat processing plants.

I would now like to introduce Dr. Joe Beuerlein, the manager of the meat and poultry program, who will give you more information on the specific requirements of SOP and HACCP and explain the benefits of having a state inspection program.

Thank you for your time and attention. I would be glad to answer any questions you may have regarding this bill.

Note: The following Supplement will not appear in the Code of Federal Regulations.

Supplement—Final Regulatory Impact Assessment for Docket No. 93–016F, "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems."

Table of Contents

Appendix A to Final Regulatory Impact Assessment

I. Introduction

A. Purpose

In docket No. 93–016F, the Food Safety and Inspection Service (FSIS) is promulgating new regulations that require an estimated 9,079 inspected meat and poultry establishments to adopt a Hazard Analysis and Critical Control Points (HACCP) processing control system covering all production operations within 3½ years of final rule publication. The regulation also requires that all 9,079 establishments adopt and implement standard operating procedures (SOP's) for sanitation and establishes, for the first time, food safety performance standards for microorganisms on raw meat and poultry products. This final rule establishes pathogen reduction performance standards for *Salmonella* that are established using the current pathogen prevalence as determined by the national baseline studies. These standards are not directed at judging whether specific lots of a product are adulterated under the law. Rather, compliance with the standards will be determined by a statistical evaluation of the prevalence of bacteria in each establishment's products. FSIS will implement sampli. g programs to determine compliance with the *Salmonella* standard. The rule does not require inspected establishments to test for *Salmonella*. The pathogen reduction performance standards apply to 2,682 slaughter establishments and another estimated 2,840 establishments that produce raw ground product but do not have slaughter operations.

The final rule also requires that all slaughter establishments test for generic *E. coli* to verify process control for fecal contamination during slaughter and sanitary dressing. Results will be measured against performance criteria established from the national baseline surveys. Under this final rule, the 2,682 inspected slaughter establishments will be required to verify by microbial testing that they are controlling their slaughter and sanitary dressing processes in accordance with the performance criteria. The rule establishes testing frequencies based on production levels, but does not establish the performance criteria as enforceable regulatory standards. As the preamble points out, the criteria will be flexible and subject to change as FSIS and the industry gain experience with them and accumulate more data on establishment performance. The criteria are intended specifically to provide an initial basis upon which slaughter establishments and FSIS can begin to use microbial testing to evaluate the adequacy of establishment controls for slaughter and sanitary dressing procedures.

The objective of this regulation is to reduce the risk of foodborne illness from meat and poultry. The focus is on reducing and eventually minimizing the risk from the following four pathogens:

- *Campylobacter jejuni/coli.*
- *Escherichia coli O157:H7.*
- *Listeria monocytogenes.*
- *Salmonella.*

This document is the final Regulatory Impact Analysis (RIA) prepared in compliance with the provisions of Executive Order 12866 and analyses requirements of the Regulatory Flexibility Act (P.L. 96–354) and the Unfunded Mandates Reform Act (P.L. 104–4). The purpose of this final RIA is to evaluate alternatives to and costs and benefits associated with a mandatory HACCP-based regulatory program for all meat and poultry establishments under inspection.

B. Methodology

The methodology used to develop cost estimates for this final RIA is relatively straightforward. The costs estimates are based on data for average wages, the cost of specific processing equipment or the cost of conducting specific laboratory analyses.

The benefits analysis is less straightforward. The analysis has defined regulatory effectiveness as the percentage of pathogens eliminated at the manufacturing stage. The benefits analysis concludes that there is insufficient knowledge to predict with certainty the effectiveness of the proposed rule. Without specific predictions of effectiveness, FSIS has calculated projected health benefits for a range of effectiveness levels.

The link between regulatory effectiveness and health benefits is the assumption that a reduction in pathogens leads to a proportional reduction in foodborne illness. FSIS has presented the proportional reduction calculation as a mathematical expression that facilitates the calculation of a quantified benefit estimate for the purposes of this final RIA. FSIS has not viewed proportional reduction as a risk model that would have important underlying assumptions that merit discussion or explanation. For a mathematical expression to be a risk model, it must have some basis or credence in the scientific community. That is not the case here. FSIS has acknowledged that very little is known about the relationship between pathogen levels at the manufacturing

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stage and dose, i.e., the level of pathogens consumed.

There are many factors that play important roles in the actual link between pathogen levels at the manufacturing stage and frequency of foodborne illness. First, the effectiveness definition of "percentage of pathogens reduced" can refer to the percentage of packages that contain pathogens or the level of pathogens within packages. The pathogens-to-illness relationship is further complicated because cross-contamination in kitchens is believed to play a major role. It can not be assumed that a reduction in the number of pathogens present in a package of meat or poultry will prevent a cross-contamination related illness. On the other hand, given that the number of consumed pathogens necessary to cause illness (threshold) can be different for every possible pathogen or individual combination, a reduction in pathogen levels at the time of packaging may prevent illness for many cross-contamination scenarios.

These types of unknowns illustrate why the relationship between pathogen levels and foodborne illness levels remains unknown. As stated above, without a known relationship, FSIS has used the proportional reduction assumption to provide a quantified estimate, recognizing that the real relationship is probably different for each pathogen and category of meat and poultry product.

Risk minimization as the objective of this rule means the elimination of most foodborne illness caused by the contamination of meat and poultry products in inspected establishments by any of the four pathogens listed above. The reduction in pathogens needed to do this is unknown and would vary for individual pathogens and products.

This final RIA includes a discussion of the status of risk assessment for foodborne pathogens that responds to the new Departmental guidelines for preparing risk assessments contained in Departmental Regulation 1521–1, December 21, 1995. Although the statutory requirements for risk analysis included in the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 (P.L. 103–354) do not apply to this final rule, there were public comments on the need for additional risk assessment or risk analysis. This final RIA includes the Agency's response to those comments.

On February 3, 1995, FSIS published a preliminary RIA as part of the proposed Pathogen Reduction HACCP rule (60 F.R. 6871). The preliminary RIA announced the availability of a detailed supplemental cost analysis, titled "Costs of Controlling Pathogenic Organisms on Meat and Poultry," which was available from the FSIS Docket Clerk during the comment period. This final RIA will refer to the analysis published with the proposed rule and the supplemental cost analysis collectively as the "preliminary analysis."

During the public comment period the Department conducted a number of public hearings, technical conferences and information briefings. On May 22, 1995, the Agency conducted a special hearing in Kansas City dealing with the impacts of the proposed rule on small businesses. In July 1995, FSIS conducted a survey of the State inspection programs to collect additional information to assess the impact on State establishments.

This final RIA is based on the preliminary RIA, the supplemental cost analysis, all written public comments, the records from public hearings including the meeting on small business impacts, the survey of State programs, and any new information or data that have become available during the comment period. The analysis also refers specifically to cost estimates developed by the Research Triangle Institute (RTI) during personal interviews with nine establishments that previously participated in the FSIS HACCP Pilot Program. The RTI report, *HACCP Pilot Program Cost Findings*, August 31, 1994, which was referred to in both written and public hearing comments were developed under contract to FSIS in 1994.

C. Summary Comparison of Costs and Benefits—Proposal to Final

FSIS estimated that the proposed rule would have 20-year industry costs of $2.2 billion. Those costs are presented in Table 1, organized by the regulatory components identified in the proposal.

The estimated costs for the final rule are also presented in Table 1. For some of the regulatory components, it is easy to track the costs from the proposal to the final rule. For example, the costs for Sanitation SOP's remain essentially the same. The reduction from $175.9 to $171.9 million reflects the change in implementation period from 90 days to six months.

The costs for developing and implementing HACCP plans are also directly comparable. The estimated cost has increased for the HACCP component of plan development. FSIS has increased its estimate for this cost after reviewing the public comments and assessing the overall impact on plan development costs of the decisions to eliminate the requirements for implementing time/temperature and antimicrobial treatment requirements prior to HACCP implementation. In the preliminary analysis, the cost for developing HACCP plans was reduced because of the experience that establishments would have gained in developing their plans for implementing time/temperature and antimicrobial treatment requirements.

TABLE 1.—COMPARISON OF COSTS—PROPOSAL TO FINAL

[$ Millions—Present Value of 20-year Costs]

Regulatory component	Proposal	Final
I. Sanitation SOP's	175.9[a]	171.9
II. Time/Temperature Requirements	45.5	0.0
III. Antimicrobial Treatments	51.7	0.0
IV. Micro Testing	1,396.3[b]	174.1
V.		
Compliance with *Salmonella* standards	Not Separately Estimated[c]	55.5–243.5
Compliance with generic *E. coli* criteria	Not Applicable	Not Separately Estimated
VI. HACCP:		
Plan Development	35.7	54.8
Annual Plan Reassessment	0.0	8.9
Recordkeeping (Recording, Reviewing and Storing Data)	456.4	440.5[d]
Initial Training	24.2	22.7[d]
Recurring Training	0.0	22.1[c]
VII. Additional Overtime	20.9	17.5[d]

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TABLE 1.—COMPARISON OF COSTS—PROPOSAL TO FINAL—Continued

[$ Millions—Present Value of 20-year Costs]

Regulatory component	Proposal	Final
Subtotal—Industry Costs	2,206.6	968.0–1,156.0
VIII. FSIS Costs	28.6[f]	56.5
Total	2,235.2	1,024.5–1,212.5

[a] The preliminary analysis included a higher cost estimate for sanitation SOP's ($267.8 million) that resulted because of a programming error. The cost estimate of $175.9 million is based on an effective date of 90 days after publication.

[b] The preliminary analysis was based on the premise that microbial testing would be expanded to cover all meat and poultry processing after HACCP implementation. The proposed rule only required sampling for carcasses and raw ground product. Thus, the cost estimate of $1,396.3 million was higher than the actual cost of the proposed sampling requirements.

[c] The preliminary analysis accounted for some of the cost of complying with the new standards under the regulatory components of micro testing, antimicrobial treatments, and time and temperature requirements.

[d] These costs are slightly different from the proposal because of changes in the implementation schedule.

[e] FSIS added costs for recurring training based on the review of public comments.

[f] Based on current estimates for the cost of training, inspector upgrades, and $0.5 million for annual HACCP verification testing.

Table 1 shows that FSIS has added two categories of HACCP costs that were not included in the preliminary cost analysis. A cost for recurring annual HACCP training was added in response to comments that there would be recurring costs because of employee turnover. FSIS also added a minimal cost for annual reassessment of HACCP plans, although the Agency believes that reassessment will be negligible for establishments successfully operating under a HACCP plan.

Table 1 shows that the proposed requirements for time and temperature specifications and antimicrobial treatments have not been included in the final rule. The preliminary analysis treated these items as interim costs that were incurred prior to HACCP implementation. For the time and temperature requirements, the preliminary analysis identified both one-time capital equipment costs and recurring recordkeeping costs. The time and temperature recordkeeping costs were assumed to become part of the HACCP recordkeeping costs. The recurring costs for antimicrobials were assumed to end with HACCP implementation. The preliminary analysis indicated that at the time of HACCP implementation, the slaughter establishments would make a decision on whether to continue the antimicrobial treatments and employ other methods to reduce the microbial load on carcasses. The preliminary analysis did not, however, include a cost component for either continuing the antimicrobial treatments or adding alternative pathogen reduction methods.

Under the micro testing component, the final rule requires that all 2,682 slaughter establishments implement microbial sampling programs using generic *E. coli*. The 20-year cost of this requirement is $174.1 million. After HACCP implementation including validation that the *E. coli* performance criteria are being met, establishments may use alternate testing programs unless FSIS specifically objects. In addition, in the period prior to mandatory HACCP, FSIS will consider exemptions on a case-by-case basis for establishments that are currently using an alternative *E. coli* sampling frequency if the establishment can provide data demonstrating the adequacy of its existing program. The cost estimate of $174.1 million assumes that all slaughter establishments continue to test at the frequencies outlined in the final rule.

Up to this point, all the costs discussed have been predictable in the sense that they refer to a specific requirement directing all establishments or a specific category of establishments to take a well-defined action. FSIS has developed point estimates for all predictable costs. In contrast, the pathogen reduction performance standards for *Salmonella* do not prescribe a set of actions that establishments must take. Because the standards are set using the national prevalence estimates from the baseline studies, the Agency is also not able to predict how many establishments are already meeting the standards or how many will have to modify their current operations to comply.

The cost analysis in Section V recognizes that the performance standards create a set of potential costs for 5,522 establishments, 2,682 slaughter establishments and another estimated 2,840 establishments that produce raw ground product but do not have slaughter operations. The analysis estimates potential costs by developing two scenarios that lead to a range of possible costs depending on how the different industry sectors will respond to the new standards and depending on how many establishments will need to modify their production processes in order to comply.

Reducing pathogens for slaughter establishments involves either modifying the incoming animals or birds, improving the dressing procedures so as to reduce contamination during procedures such as hide removal and evisceration, or using interventions such as antimicrobial treatments to kill or remove the pathogens following contamination. For many establishments, the process of implementing HACCP programs may, by itself, improve the dressing procedures sufficiently to meet the new standards. Other establishments may have to choose between slowing production lines, modifying some attribute of their incoming live animals or birds, or adding post-dressing interventions such as the new steam vacuum process or antimicrobial rinses.

The 2,840 raw ground processing operations will have to control their incoming ingredients either by conducting their own testing or by requiring that suppliers meet purchase specifications. The cost analysis also recognizes that even though the rule does not require the 2,682 slaughter establishments to test for *Salmonella*, some establishments may conduct their own *Salmonella* testing programs to avoid failing a series of tests conducted by the Agency. Thus, it can be argued that the Agency's intent to implement establishment specific testing for *Salmonella* is indirectly requiring the industry to routinely monitor their *Salmonella* levels to assure they will be in compliance.

As shown in Table 1, the two scenarios developed in the cost analysis lead to a range in cost estimates of $55.5 to $243.5 million to comply with the new pathogen reduction standards. Some of these costs are contained in the

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Table 1 proposal costs of $51.7 for antimicrobial treatments and the $1,396.3 for micro testing that included the cost of having 5,522 establishments conduct daily *Salmonella* testing for each species slaughtered and each variety of raw ground product produced.

The two cost scenarios were developed to illustrate potential costs for compliance with standards established using the current pathogen prevalence as determined by the national baseline studies. These standards move the Agency's regulatory program in the direction of meeting the food safety objective of minimizing the risk of foodborne illness from pathogens that contaminate meat and poultry products. The Agency has stated its intent to establish tighter standards over time. The Agency recognizes that future tighter standards could impose a new set of compliance costs. To illustrate, where the use of hot water rinses may be adequate to assure compliance with the *Salmonella* standards as established for this rule, such rinses may not be adequate to assure compliance with future standards. Any change in the standards will, however, be implemented through additional rulemaking. At that time the Agency will have extensive data on the distribution of pathogens by establishment and better data on the cost and effectiveness of different interventions. These data enhancements will allow for improved cost analysis of future standard setting activities. Inspected establishments need to consider the Agency's overall food safety objectives when making decisions on capital investments designed to assure compliance with the food safety standards established by this rulemaking.

The cost analysis in Section V also recognizes that the performance criteria for generic *E. coli* create a set of potential costs for 2,682 slaughter establishments. A line for these costs is shown in Table 1 along with the entry that these costs were not separately quantified.

As discussed in Section V, the anticipated actions to comply with the generic *E. coli* criteria are the same as the anticipated actions to comply with the standards for *Salmonella*. FSIS has concluded that if the low cost scenario for *Salmonella* compliance proves to be more accurate, then the Agency would expect to see some compliance costs for the generic *E. coli* performance criteria. If the high cost scenario is correct, then the compliance actions taken to assure compliance with the *Salmonella* standards should also assure compliance with the generic *E. coli* criteria.

Finally, Table 1 includes a cost of $17.5 million associated with additional overtime charges for inspection. While it is recognized that final decisions on the future of the Agency's Total Quality Control (TQC) program have not been made, this analysis includes a conservative impact assumption that the existing TQC regulations will be withdrawn.

Both the preliminary and final analysis identify a maximum potential 20-year public health benefit from $7.13 to $26.59 billion that is tied to eliminating establishment-related contamination from four pathogens on meat and poultry. The contamination from these four pathogens at the manufacturing stage leads to an estimated annual cost of foodborne illness ranging from $0.99 billion to $3.69 billion. The maximum 20-year benefit results from eliminating this annual cost of foodborne illness beginning in the fifth year after publication. Although there is reason to believe significant benefits will be generated during the first four years, for analytical purposes FSIS used the conservative estimate that benefits do not begin until all establishments have HACCP systems in place and pathogen reduction standards for *Salmonella* apply to all establishments that slaughter or produce raw ground product.

There are two principle reasons why benefits will begin to accrue before the fifth year. First, the HACCP requirements and *Salmonella* standards apply to large establishments at 18 months and small establishments at 30 months. The large slaughter establishments account for over 74 percent of total carcass weight. Second, the generic *E. coli* testing requirements are effective six months after publication. The generic *E. coli* results will provide both establishment management and inspection program personnel a tool by which to assess establishments' control over slaughter and sanitary dressing procedures. Although the generic *E. coli* criteria are not being established as regulatory standards, FSIS believes their use will lead to improved control over slaughter and sanitary dressing procedures which will, in turn, lead to reductions in fecal contamination and corresponding reductions in contamination by enteric pathogens. Rather than attempt to estimate the benefits associated with reduced contamination resulting from use of generic *E. coli* testing, this analysis has assumed public health benefits begin in the fifth year. By that time all establishments have had an opportunity to adjust their *E. coli* sampling programs based on their HACCP programs.

The low and high estimates for potential benefits are due to the current uncertainty in estimates for incidence of foodborne illness and death. If the low potential benefit estimate is correct, the analysis shows that the new HACCP-based program must reduce pathogens by 15 to 17 percent for benefits to outweigh projected costs. If the high estimate is the correct estimate, the new program needs to reduce pathogens by only 4 to 5 percent to generate net societal benefits.

As discussed in Section III, there are other benefits to this rule that have not been quantified. Examples include increased public protection from physical hazards and the increased production efficiency that accompanies improved process control.

In the preliminary analysis FSIS took the position that quantified pathogen reduction benefits were related to the overall proposed HACCP-based regulatory program and that there was no way to distribute benefits among the five different components that made up the proposed rule. Under the proposed rule it was essentially impossible to determine the proportion of pathogen reduction benefits that could be attributable to the proposed pathogen reduction standards versus the proposed antimicrobial treatments or time-temperature requirements or the proposed mandatory HACCP programs. Given the revised structure of the final rule, this analysis attributes pathogen reduction benefits to the requirements that all establishments implement HACCP systems and that if those systems are implemented in slaughter establishments or establishments shipping raw ground product, they must have critical limits set to assure compliance with the new pathogen reduction standards for *Salmonella*. However, as discussed above, FSIS believes that pathogen reduction benefits will begin to occur when establishments start using the generic *E. coli* results to assess their control over slaughter and sanitary dressing procedures.

FSIS believes that the Sanitation SOP's component of this final rule has significant benefits in terms of increased productivity for inspection resources. The HACCP component also has productivity benefits in addition to public health benefits. One of the reasons FSIS has not yet achieved a program that can focus appropriate resources on the risks of microbial pathogens is that in recent years

national budget problems have provided limited increases in Agency resources compared to the increase in its responsibilities generated by industry growth, the Federal takeover of more State programs, and new food production technologies and products. For most of its history, the inspection program was able to obtain additional resources when it took on new responsibilities. Now FSIS is faced with taking on new responsibilities with the same resources.

The final rule is a necessary component of an FSIS management strategy that will raise the productivity of current resources so that the program can maintain all its consumer protection objectives. Raising productivity requires raising outputs, reducing inputs or any combination of the two that gets more done for less. Productivity can be increased in today's inspection program by: (1) focusing resource use on the basis of risk, giving the highest priority to safety objectives; (2) clarifying the respective responsibilities of government and industry to assure the best use of government resources; and (3) designing new methods of inspection that are more efficient than existing inspection but which maintain or improve consumer protection.

The Sanitation SOP's and HACCP requirements are designed to accomplish objectives in all three of the above areas. With SOP's FSIS can monitor sanitation plans with fewer resources than it takes to conduct comprehensive sanitation reviews. The benefit of the SOP's is, therefore, the capacity to reallocate inspection resources to other activities where the payoff in terms of reducing the risk of foodborne illness may be greater. With SOP's there is less likelihood that establishments will be able to substitute the inspector's sanitation review for their own sanitation program. Similarly, with HACCP there is less likelihood that firms can use inspection as a substitute for their own control programs. In both cases productivity is enhanced by clarifying responsibilities. The benefits associated with increased productivity are difficult to quantify because the precise reallocation of inspection resources is not yet clear.

Finally, with the implementation of this rule, FSIS intends to introduce new methods of inspection that are more efficient than those currently in place. As noted above, more efficient methods is the third way in which productivity can be increased in the inspection system.

II. Regulatory Alternatives

A. Market Failure

Consumers make choices about the food they purchase based upon factors such as price, appearance, convenience, texture, smell, and perceived quality. In an ideal world, people would be able to make these decisions with full information about product attributes and choose those foods which maximize their satisfaction. In the real world, however, information deficits about food safety complicate consumer buying decisions.

Since all raw meat and poultry products contain microorganisms that may include pathogens, raw food unavoidably entails some risk of pathogen exposure and foodborne illness to consumers. However, the presence and level of this risk cannot be determined by a consumer, since pathogens are not visible to the naked eye. Although they may detect unwholesomeness from obvious indications such as unpleasant odor or discoloration caused by spoilage microorganisms, consumers cannot assume products are safe in the absence of spoilage. They simply have no clear-cut way to determine whether the food they buy is safe to handle and eat.

When foodborne illness does occur, consumers often cannot correlate the symptoms they experience with a specific food because some pathogens do not cause illness until several days, weeks or even months after exposure. Thus, food safety attributes are often not apparent to consumers either before purchase or immediately after consumption of the food. This information deficit also applies to wholesalers and retailers who generally use the same sensory tests—sight and smell—to determine whether a food is safe to sell or serve.

The societal impact of this food safety information deficit is a lack of accountability for foodborne illnesses caused by preventable pathogenic microorganisms. Consumers often cannot trace a transitory illness to any particular food or even be certain it was caused by food. Thus, food retailers and restaurateurs are generally not held accountable by their customers for selling pathogen-contaminated products and they, in turn, do not hold their wholesale suppliers accountable.

This lack of information applies equally to small businesses. Some small businesses have argued for exemption from the rule because they sell most of their product to family, friends and neighbors, but they are overlooking the fact that perhaps the majority of foodborne illness victims may believe they had some type of flu virus or other illness and have no idea that their illness was foodborne and, if they do, they have no idea as to the source. Without feedback, (i.e., without a connection of product to illness), there is no market where buyers and sellers have sufficient information upon which to judge purchase decisions. Without feedback there is insufficient incentive to make substantial improvements in process control.

This lack of marketplace accountability for foodborne illness means that meat and poultry producers and processors have little incentive to incur extra costs for more than minimal pathogen controls. The widespread lack of information about pathogen sources means that businesses at every level from farm to final sale can market unsafe products and not suffer legal consequences or a reduced demand for their product. An additional complication is that raw product is often fungible at early stages of the marketing chain. For example, beef from several slaughterhouses may be combined in a batch of hamburger delivered to a fast food chain. Painstaking investigation by public health officials in cases of widespread disease often fails to identity foodborne illness causes; in half the outbreaks the etiology is unknown.

Most markets in industrialized economies operate without close regulation of production processes in spite of consumers having limited technical or scientific knowledge about goods in commerce. Branded products and producer reputations often substitute for technical or scientific information and result in repeat purchases. Thus, brand names and product reputations become valuable capital for producers.

In the U.S. food industry, nationally recognized brand names have historically provided significant motivation for manufacturers to ensure safe products. In recent years, more and more raw meat and poultry have come to be marketed under brand names. Nevertheless, not even all brand name producers produce their products under the best available safety controls. Further, a significant part of meat and poultry, particularly raw products, are not brand name products and are not produced under conditions that assure the lowest practical risk of pathogens.

The failure of meat and poultry industry manufacturers to produce products with the lowest risk of pathogens and other hazards cannot be attributed to a lack of knowledge or appropriate technologies. The science and technology required to significantly

reduce meat and poultry pathogens and other hazards is well established, readily available and commercially practical.

Explanations for why a large portion of the meat and poultry industry has not taken full advantage of available science and technology to effectively control manufacturing processes include the following:

1. Meat and poultry processing businesses are relatively easy to enter; there are no training or certification requirements for establishment operators. Consequently, the level of scientific and technical knowledge of management in many establishments is minimal.

2. The industry is very competitive and largely composed of small and medium-sized firms that have limited capital and small profits.

3. Management in many of these establishments has little incentive to make capital improvements for product safety because results from that investment are not distinguishable by customers and therefore yield no income.

In spite of these barriers, many industry establishments do produce meat or poultry products using process controls that assure the lowest practical risk of pathogens and other hazards.

FSIS has concluded that the lack of consumer information about meat and poultry product safety and the absence of adequate incentives for industry to provide more than minimal levels of processing safety represents a market failure requiring Federal regulatory intervention to protect public health.

B. General Regulatory Approaches

The problem of microbial pathogens in meat and poultry has become increasingly apparent. Documented cases of foodborne illness each year, some of which have resulted in death, represent a public health risk that FSIS judges to be unacceptable. Within existing authorities there are four broad regulatory approaches the Department could use to address this unacceptable public health risk.

- Market Incentives.
- Information and Education.
- Voluntary Industry Standards.
- Government Standards.

The final rule represents the fourth approach.

The above discussion on market failure summarizes why FSIS has concluded that the market will not address the public health risk resulting from microbial pathogens in meat and poultry.

The role and effectiveness of consumer and food service worker education in assuring food safety was raised in public comments. For example, comments suggested that since most foodborne illness involves temperature abuse or consumer/food handler mishandling, consumer education offers the most cost-effective approach. FSIS sees a clear role for education and agrees that education is essential for assuring food safety. However, experience has shown that education alone has limited effectiveness in reducing foodborne illness. The effectiveness of education for food safety, and, indeed, for improving diets and other food related behavior, has not been demonstrated. FSIS views education as a valuable adjunct to other regulatory approaches, but it has no evidence that a major increase in education expenditures will produce the behaviors required to reduce foodborne illness.

A voluntary industry standard would call for the formation of a standards setting group, such as the American National Standards Institute (ANSI) to develop and publish a voluntary standard. Compliance with such a voluntary standard would be determined by third-party testing and certification. For example, Underwriter's Laboratory (UL) tests and certifies electronic components for industry-wide standards. FSIS has not seen any evidence that the industry is prepared to undertake, or even desires a voluntary standards approach. This is understandable. Because the principles underlying the safe production of meat and poultry are the same regardless of who administers the standards, an industry administered system is likely to be more expensive and less effective than a government one. The lack of power to mandate participation reduces the value of standard setting to participants, since foodborne illness episodes attributable to non-participants tend to raise suspicion of all similar products. Further, the industry would be called upon to pay the enforcement cost which under the present rule would be paid by the government.

For these reasons, the Department concludes that mandatory process control regulations offer the best approach for addressing this unacceptable public health risk.

C. Need For Improved Process Control

FSIS has determined that effective process control is needed throughout the meat and poultry industry in order to minimize pathogen contamination and control other health hazards. Accordingly, a regulatory strategy has been formulated to mandate process control improvements to achieve immediate reductions and an eventual minimization of the risk of meat and poultry pathogens, chemical, and physical hazards in the nation's food supply. This strategy is supported by consumers, scientists, and the majority of meat and poultry industry processors who already recognize the benefits of good process control.

Process control is a proactive strategy that all segments of industry can undertake to anticipate manufacturing problems in advance and prevent unsafe foods from being produced. In practice, process control is a systematic means to:

- Identify and control production hazards.
- Determine control points in the processing system.
- Establish standard measures for each control point.
- Set procedures for establishment workers to monitor requirements.
- Provide clear instructions for appropriate corrective actions when a control point goes out of control.
- Establish record-keeping to document control point measurements.
- Provide procedures for verification tests to ensure that the system continues to operate as planned.

The process control strategy summarized in this paper is founded on three principles:

1. USDA regulatory policy should be focused on providing a solution to meat and poultry biological, chemical, and physical hazards that present the highest public health risks.

2. It is essential that the Nation's food safety system address pathogenic microorganisms which present the greatest foodborne risk to human health.

3. These pathogens and resulting risks of foodborne illness can be largely avoided by uniform meat and poultry industry efforts to attain and maintain more effective methods of control during the manufacturing process.

The focus of this strategy is explicitly on prevention; it is designed to prevent the production of defective product as opposed to more costly and less effective detect-and-condemn methods.

Process control is not a substitute for inspection any more than inspection could be a substitute for process control. This distinction is important because Federal inspection was never intended to be—and cannot be—the front-line control for food safety in meat and poultry processing establishments. Safety controls must be built into the manufacturing process and be administered continuously by industry. The objective of inspection in a process control environment is to assure that those controls are present, adequate, and properly used.

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To summarize, the process control regulatory strategy promulgated by this rule will among its other well established attributes, correct two important deficiencies in the nation's current food safety effort. It will: (1) provide industry the tools and incentive to reduce meat and poultry pathogens as a means to improve food safety, and (2) help focus Federal inspection on the highest product, process and establishment risks, and, at the same time, clarify that the industry is responsible for producing safe meat and poultry, while the Government's role is oversight.

Factors Considered in Evaluating a Process Control Strategy

The process control regulatory strategy was evaluated using five factors for effectiveness. A processing control program is effective if it:

1. Controls production safety hazards.
2. Reduces foodborne illness.
3. Makes inspection more effective.
4. Increases consumer confidence.
5. Provides the opportunity for increased productivity.

The following sections discuss these five effectiveness factors that have been applied to evaluate process control alternatives.

Controls Production Safety Hazards

Process control is a system for identifying food hazards and reducing or eliminating the risks they present. In operation, control points are established in a food production line where potential health hazards exist; management of these points has proven to be effective in reducing the probability that unsafe product will be produced. Ongoing records of each process control will enable establishment managers and quality control personnel to spot trends that could lead to problems and devise a strategy that prevents them before they occur.

Detection by end product testing is not a viable alternative to process control because it only sorts good product from bad and does not address the root cause of unacceptable foods. Additionally, keeping "bad" foods out of commerce through sorting end product is possible only when tests and standards for sampling are well established and it is practical only where the "test" is not expensive because sorting requires a huge number of samples for reliability.

Reduces Foodborne Illness

As industry improves its control over the safety aspects of meat and poultry production, foodborne illness will begin to decline. This is the principal non-negotiable goal for both USDA and industry.

The precise occurrence of human health problems attributed to pathogenic microorganisms or other potential foodborne hazards, such as chemical contaminants, animal drug residues, pesticides, extraneous materials, or other physical contaminants is not known. Foodborne illness is nevertheless recognized by both domestic and international scientists as a significant public health problem and there is wide agreement that pathogenic microorganisms are the major cause of food-related disease. The estimated annual (not discounted) cost of foodborne illness attributable to meat and poultry products from the four pathogens that are the focus of this regulation is from $1.1 to $4.1 billion. FSIS estimates that 90 percent of this annual cost, $0.99 to $3.69 billion, is attributable to contamination that occurs in establishments.

Makes Inspection More Effective

Currently, the FSIS inspectors in meat and poultry establishments that are not assigned to slaughter line positions perform selected inspection tasks that generate independent data about an establishment's production processes and environment. This activity produces "snapshots" of establishment operations at a particular moment. In contrast, process control generates records of establishment performance over time. These records and periodic verification inspections will enable FSIS inspectors to see how an establishment operates at all times, i.e., whether and where processing problems have occurred, and how problems were addressed.

The availability of more and better processing data will establish trends that set benchmarks from which deviations can be more quickly and accurately assessed. USDA inspectors will be trained to spot these deviations and take action when needed to ensure establishments bring a faulty process back into control. This type of Federal oversight is substantially more effective than a regulatory program that merely detects and condemns faulty end products. In the words of the National Advisory Committee on Microbiological Criteria for Foods, "Controlling, monitoring, and verifying processing systems are more effective than relying upon end-product testing to assure a safe product."

Increases Consumer Confidence

The number of foodborne illness outbreaks and incidents attributable to pathogens in meat or poultry raise questions about whether Federal inspection is as effective as it should be. Highly visible public controversies about meat and poultry inspection indicate an erosion of public confidence in the safety of meat and poultry products. There are growing demands that USDA improve its regulation of pathogens. The process control regulatory strategy described in this paper is USDA's response to those demands.

Many outbreaks of foodborne illness have been determined to be caused by mishandling of meat and poultry products after federally inspected processing. USDA believes that additional efforts to reduce pathogens during manufacturing will reduce these risks as well. This coupled with the improved retail regulatory controls from state adoption and enforcement of the Food Code should reduce this cause of illness. The Food Code is an FDA publication, a reference that provides guidance to retail outlets such as restaurants and grocery stores and institutions such as nursing homes on how to prepare food to prevent foodborne illness. State and local regulatory bodies use the FDA Food Code as a model to help develop or update their food safety rules and to be consistent with national food regulatory policy.

A significant portion of the meat and poultry industry do not take advantage of readily available methods to control their manufacturing processes. The Department has concluded that further regulation will bring industry standards up to what can practically be achieved in the manufacture of meat and poultry products through current scientific knowledge and available process control techniques. Raising the safety floor through regulations that mandate better process control will demonstrate to the public that USDA and industry are making a concerted effort to reduce the risk of foodborne illness from meat and poultry.

The economic benefits of increased consumer confidence can be conceptually realized as the amount consumers would be willing to pay for safer food. This "willingness to pay" reflects consumer desires to avoid foodborne illness and the expected medical and other costs associated with it. However, the data are not available to make quantitative estimates of this benefit.

Provides the Opportunity for Increased Productivity

Better process control is a sound and rational investment in the future of our

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nation's meat and poultry industry. USDA's process control strategy will educate industry management about the need and methodology for development of a consistent, preventive, problem-solving approach to safety hazards, which can be expanded to other business objectives such as product quality and production efficiency. There is considerable evidence of how process control has improved worldwide industrial productivity in the past 40 years. This proposal will extend process control principles to parts of the meat and poultry industry that have not formerly used them.

Some important non-safety benefits that will accrue from industry use of better process control methods are:

- First, better production controls will result in more efficient processing operations overall with fewer product defects. Fewer defects mean less reworking, waste and give-away, resulting in increased yields and more profit opportunities.
- Second, better controls will significantly reduce the risk to processors that product with food safety defects will slip into commerce. Expensive and embarrassing product recalls can be, for the most part, avoided or greatly reduced with proper process controls.
- Third, better control of pathogens will impact all microorganisms, including those responsible for decomposition, resulting in quality improvement and longer shelf life for products.
- Fourth, better production controls improve establishment employee productivity which improves profit opportunities.

D. Regulatory Alternatives for Process Control

1. Mandatory HACCP

Considering the five effectiveness criteria of process control discussed above, the most effective means for generating the benefits reflected in these criteria is a mandatory HACCP regulatory program. This alternative clearly meets all five criteria described above. In fact, a mandatory HACCP program was judged to be the only option that will effect adequate processing improvements in all establishments throughout the industry. Only through mandatory HACCP can pathogen risks be minimized to the fullest extent possible; thereby significantly reducing foodborne illness, improving effectiveness of inspection, increasing consumer confidence, and ensuring a more viable industry. No other alternative accomplishes as much in these five areas as mandatory HACCP.

HACCP is a process control strategy that has been scientifically proven effective in food manufacturing establishments. HACCP is widely recognized by scientific authorities such as the National Academy of Sciences and international organizations such as the Codex Alimentarius. It is used today by a number of establishments in the food industry to produce consistently safe products. This approach has been supported for years by numerous groups that have studied USDA meat and poultry regulatory activities.

In 1983 FSIS asked the National Academy of Sciences (NAS) to evaluate the scientific basis of its inspection system and recommend a modernization agenda. The resulting report, "Meat and Poultry Inspection, The Scientific Basis of the Nation's Program," National Academy Press, 1985 was the first comprehensive evaluation of a scientific basis for inspection. The 1985 NAS report provided a blueprint for change: it recommended that FSIS focus on pathogenic microorganisms and require that *all* official establishments operate under a HACCP system to control pathogens and other safety hazards.

After urging (NAS Recommendations. Page 4) the intensification of "current efforts to control and eliminate contamination with micro-organisms that cause disease in humans," NAS encouraged (Page 135) USDA to "move as vigorously as possible in the application of the HACCP concept to each and every step in establishment operations, in all types of enterprises involved in the production, processing, and storage of meat and poultry products."

The General Accounting Office (GAO) has also identified needed improvements in USDA's present inspection system. In its reports and congressional testimony, and in numerous publications, GAO has endorsed HACCP as the most scientific system available to protect consumers from foodborne illness. This sentiment is most clearly expressed in a May 1994 report, "Food Safety: Risk-Based Inspections and Microbial Monitoring Needed for Meat and Poultry," in which GAO recommended development of a mandatory HACCP program that includes microbial testing guidelines. GAO urged USDA to assist meat and poultry establishments in the development of their microbial testing programs by, among other things, disseminating information on the programs already in operation.

A third major proponent of HACCP is the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), which was established in 1988 by the Secretary of Agriculture to advise and provide recommendations to the Secretaries of Agriculture and Health and Human Services on developing microbiological criteria to assess food safety and wholesomeness. Since 1989, NACMCF has prepared a series of reports on the development and implementation of HACCP. As one of its first tasks, the Committee developed "HACCP Principles for Food Production" in November 1989. In this report, the Committee endorsed HACCP as a rational approach to ensure food safety and set forth principles to standardize the technique. In 1992, the Committee issued an updated guide, "Hazard Analysis and Critical Control Point System."

In 1993 NACMCF defined the roles of regulatory agencies and industry in implementing HACCP. "The Role of Regulatory Agencies and Industry in HACCP" proposed responsibilities for FDA, USDA, and other agencies and industry during various phases of HACCP implementation. Similar suggestions for program change have been voiced by consumers, industry, state and local government representatives, as well as other constituent groups. For example, consumers at recent public hearings and the HACCP Round Table supported implementation of mandatory HACCP throughout the meat and poultry industry.

The meat and poultry industry has itself provided broad support for HACCP as a means to control pathogens, emphasizing that HACCP-based food production, distribution, and preparation can do more to protect public health than any Federal inspection program. They have recommended that HACCP be used to anticipate microbiological hazards in food systems and to identify risks in new and traditional products. State departments of health and agriculture have also endorsed the HACCP approach.

2. Alternatives to Mandatory HACCP

FSIS examined six other approaches before determining that mandatory HACCP was the most effective means for assuring process control in the meat and poultry industries.

1. Status quo
2. Intensify present inspection
3. Voluntary HACCP regulatory program
4. Mandatory HACCP regulation with exemption for small businesses
5. Mandatory HACCP regulation only for ready-to-eat products

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6. Modified HACCP—recording deviations and responses only

These alternatives were assessed using the five effectiveness criteria presented in the previous section. The following six sections summarize the appraisal of each alternative.

Status Quo

This option would essentially continue establishment processing controls and Federal inspection as they are now. Good establishments with adequate methods for managing process lines would probably remain under control. The Agency, under its present authority, cannot shift resources out of good establishments so the situation of poor performing establishments is unlikely to change. This situation raises immediate questions about the first factor—controls production safety hazards—being met. Experience has proven that Federal inspection cannot substitute for management in establishments which have difficulty producing safe product consistently. Also, inspection cannot be as effective in the current establishment environment as in a process control establishment environment.

The status quo does not target industry and inspection resources on those hazards that lead to the greatest reduction in foodborne illness (factor two). In addition, food safety experts, consumers, and other observers have told USDA they are not satisfied with pathogen control by organoleptic methods as practiced in the present inspection program. Doing nothing new would perpetuate consumer doubts about the ability of Federal inspection to regulate pathogens which is counter to factor four. Consequently, the Department has concluded that business as usual is not an acceptable response to pathogens associated with meat and poultry products. Agency public health responsibilities alone require that more positive actions be taken.

Intensify Present Inspection

As one alternative to the proposed mandatory HACCP regulation, FSIS could intensify its present inspection system, i.e., focus new resources on suspected areas of risk in each establishment. This approach would assign to FSIS responsibility for designing, testing and mandating by specific regulation, process control systems for all meat and poultry products with potential safety hazards. A major flaw with this approach is that the burden of ensuring a safe product would be placed largely on FSIS instead of industry establishments where it belongs. Establishment management would have little motivation to become knowledgeable about process control or to implement process control systems.

The mandating of specific process controls has sometimes succeeded, as a regulatory strategy, for example, in correcting food safety problems in certain ready-to-eat products. However, these controls largely consisted of lethal heat treatments applied during final product processing. This approach is obviously inappropriate for product that is marketed raw which is most frequently associated with meat and poultry foodborne illness. The identification of processes that can be applied to raw product in every establishment would be much more difficult, if not impossible. Thus, intensified command-and-control regulation fails to meet the primary criterion for process control, i.e., control production safety hazards at all stages of meat and poultry slaughter and processing. Related to this failing, inspection would be ineffective without all establishments maintaining process control systems (factor three.) This option would not only require significant resource increases, it represents government taking on more, not less, responsibility for the production process, making it more difficult to focus on the highest risks of foodborne illness. With the burden of control and monitoring on USDA's inspection force rather than on establishment managers, industry performance in reducing foodborne illness would be unlikely to improve (factor two).

Voluntary HACCP Regulatory Program

A voluntary HACCP program would not provide reduction of pathogens uniformly across the processing spectrum because many in industry would choose not to participate. Therefore voluntary HACCP would not be sufficient to attain the necessary reduction in foodborne illness (factor two).

Voluntary HACCP would be implemented most frequently in establishments with good processing controls already, while establishments with unsophisticated controls would be less likely to participate. The explanation for this flaw is to be found in simple economics and, to a large degree, the attitudes of establishment management. Establishments with good processing controls now are most likely to adopt HACCP voluntarily because their management understands the linkage between how a product is handled during preparation and its finished quality and safety.

Conversely, establishments without good processing controls today are much less likely to participate in a voluntary HACCP program. These establishments are more often operated by management that lacks the knowledge or motivation to institute better processing controls. Nevertheless, it is precisely this group of low performing establishments that FSIS must reach to attain its public health goal. Nothing short of a mandatory HACCP regulatory program will be effective in bringing processing improvements to these marginal performers.

The Agency's regulation permitting the use of voluntary Total Quality Control (TQC) Systems provides a useful analogy to how effective a voluntary HACCP program would be. TQC focuses on establishment responsibility for meeting or exceeding the standards set by FSIS for all operations that are conducted in an establishment, including incoming raw materials, processing procedures, critical limits for product standards, and action limits for establishment quality control personnel. These systems operate under Agency oversight with an emphasis on timely and accurate recordkeeping and the necessity for appropriate action to be taken by an establishment when a limit set forth in an approved system is met or exceeded. However, over the last 10 years the number of establishments with active TQC Systems has declined from a high of around 500 (approximately 8% of all establishments) to the present 351 participating establishments (approximately 5% of all establishments). USDA experience has shown that a voluntary approach to HACCP would provide little assurance that a major portion of meat and poultry products had been produced under controls designed to minimize food safety hazards.0

Mandatory HACCP Regulation With Exemption for Small Businesses

Under this alternative, FSIS would mandate HACCP, but also provide an exemption for some category of small businesses as was done with nutrition labeling. While this final regulatory impact analysis does develop very specific definitions for small and very small establishments, the following discussion of comments uses the term "small" in a generic sense because many of the comments address small establishments or small businesses without defining these terms. There was a mix of public comments on whether or not HACCP should be mandatory for small businesses.

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Comments supporting an exemption from HACCP for small establishments noted that many owner-operators of small establishments oversee the entire operation on a daily basis and can pay closer attention to procedures than can a large establishment. Similar comments pointed out that small establishments pose a minimal potential public health hazard because of the simplicity of their operations, the slow pace of operations, and the small number of potentially affected customers. Other comments pointed out that they sell their product to family, friends and neighbors and that type of market provides the greatest incentive for producing safe product.

Some commenters opposing an exemption did not want to create a two-tiered system. Others opposing an exemption for small establishments would require HACCP for everyone while easing the burden through flexibility of implementation. Several of the commenters opposing any type of exemption from HACCP identified themselves as owners of small establishments. One commenter noted that just because small businesses produce only 2 percent of the product does not mean they are responsible for only 2 percent of the foodborne illness attributable to meat and poultry.

The Agency used the evaluative factors presented above to consider the application of the rule to small establishments. Since major goals in implementing HACCP are to improve processing controls and establishment performance across *all* of industry (factor one) as a means to achieve foodborne illness reduction (factor two), the option to exempt establishments that perform the least process control is inherently flawed. USDA inspection experience shows that some of the small establishments which would be exempted under this option have particular difficulties maintaining control over their processing system.

While it is true that small establishments produce a minimal amount of the total meat and poultry supply, they do produce a full range of products, including those most frequently associated with foodborne illness from the meat and poultry supply.

This option also fails on factor three—provide more effective inspection. Two different inspection systems would be needed: one risk-based system to inspect HACCP establishments with good processing controls; the other to provide resource intensive coverage for establishments that largely do not. If the number of small establishments were to increase, more inspection resources would be required.

For these reasons, the final rule does not include an exemption for small businesses. However, the Agency has made significant changes to ease the burden on small business, including basing microbial sampling programs on production volume and deferring implementation of mandatory HACCP for small and very small businesses as defined in Section V.

Mandatory HACCP Regulation Only for Ready-to-Eat Products

This option would mandate HACCP only for establishments that prepare ready-to-eat meat and poultry products, but not for establishments that produce raw products. However, this decision would leave the public without adequate protection from pathogenic microorganisms clearly associated with product marketed in raw form. Very little reduction in the most frequent causes of foodborne illness (factor two) could be anticipated from this approach.

Government inspection costs would continue to increase to previde traditional resource-intensive inspection for slaughtering and allied processing establishments that would not be subject to mandatory HACCP. Since most of the unsolved problems with pathogenic microorganisms are associated with raw product and not with those products that would be the subject of this HACCP option, this is an especially inappropriate regulatory approach.

Modified HACCP—Recording Deviations and Responses Only

A final alternative considered would be to mandate HACCP, modified to eliminate the record keeping burden to the inspected industry, especially small establishments. Specifically, this option would modify the HACCP record-keeping principles so that instead of demanding continuous records at critical control points, companies would need to record only deviations from critical limits and the response to them. This would mean that HACCP-controlled operations would not generate continuous monitoring data to reflect the operation at critical control points, but would only record data when deviations occurred. This arrangement eliminates the continuous picture of establishment operations which is the underpinning of factor three—make inspection more effective.

Such an approach would substantially reduce the paperwork burdens associated with mandatory HACCP as recommended by NACMCF and recognized by CODEX. However, it would also seriously compromise the usefulness of HACCP as a means to make inspection more effective and avoid program cost increases.. Regulatory officials need to have a system which can be reviewed in its entirety, so that a comprehensive picture of the process is available, not just the truncated version which grows out of recording deviations.

E. Comments on Analysis of Regulatory Alternatives

There were several general comments related to either the alternatives discussed in the proposed rule or the level of analysis conducted. There were comments noting that FSIS did not quantify the costs and benefits of the regulatory alternatives. Similar comments suggested that FSIS should have determined cost-benefit ratios for the processed food industry or for ready-to-eat products or for small businesses..

Generating quantitative benefit estimates for different types of products or different industry sectors would be very difficult. The estimates for foodborne illness attributable to meat and poultry have not been broken down by industry sector or type of product. There are no existing estimates for the portion of foodborne illness attributable to meat versus poultry or raw product versus cooked or partially cooked product.

Production volume can not be used as an indicator of potential benefits. Foodborne illness is not proportionally related to production volume because pathogen levels vary significantly by type of product. As noted above, a commenter also pointed out that just because small businesses account for only 2 percent of production does not mean that small businesses account for only 2 percent of foodborne illness.

On the cost side, the estimates are, for the most part, based on industry averages. In reality, costs will vary by industry sector based on the hazards presented and the existing presence of process control. Thus, in response to a comment that suggests that few benefits are available from changing the process for the manufacture of processed foods which are now produced under a zero pathogen standard, the Department would suggest that the costs for implementing HACCP for these products will also be low. Many ready-to-eat products such as cooked patties and roast beef are presently produced under comprehensive process control regulations.

One comment suggested that FSIS consider mandatory HACCP for only firms that produce raw meat and poultry products because that sector of the industry generates most of the problems

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and would provide the greatest pathogen reduction benefits per dollar of cost expended. The same commenter found it odd that the Agency did include an alternative for mandatory HACCP for only ready-to-eat products after acknowledging that most of the unsolved problems with pathogenic microorganisms are associated with raw meat and poultry products, rather than ready-to-eat products. In the above discussion of regulatory alternatives, it was noted that mandatory HACCP for only ready-to-eat products is an especially inappropriate regulatory approach. In contrast, a raw product option appears attractive since most of the unsolved problems with pathogenic microorganisms are associated with raw product. Most establishments handle raw product ingredients or prepare a finished raw product. Most of the cost of this rule is associated with controlling the safety hazards of raw product production. Extending the rule to cover all production adds little cost while allowing a single inspection approach, avoiding confusion where raw product production ends and ready-to-eat production begins, and assuring that the potential hazard of recontaminating ready-to-eat product by contact with raw ingredients is always covered by comprehensive HACCP programs.

Other comments noted that FSIS did not analyze an option that accounted for the savings associated with streamlining and modernizing the inspection system or that FSIS should revise the cost-benefit analysis to consider the savings from eliminating the current inspection program. The savings referred to will be used to focus on food safety risks that need more coverage.

III. Summary of Impacts

A. Introduction

This section provides a summary of the costs and benefits that will be discussed in detail in Sections IV and V. The benefits analysis in Section IV and this summary discuss benefits in terms of the reduction in the cost of foodborne illness that results from reductions in pathogen levels. There are other public health benefits beyond the reduction of foodborne illness due to pathogenic bacteria. HACCP systems will also provide increased public protection from risks posed by chemical and physical hazards. There are also benefits beyond public health benefits. As discussed in Section I, the SOP and HACCP requirements have social benefits that derive from the capacity to reallocate inspection resources to other activities where the payoff in terms of reducing the risk of foodborne illness may be greater.

The February 1995 proposal and the subsequent public comment recognized that the HACCP/Pathogen Reduction regulations would also generate benefits for meat and poultry processors. For example, a commenter at a public hearing provided confirmation that the insurance industry is aware of HACCP and has offered reduced liability insurance for firms with improved food safety controls. Other comments noted that improved production efficiency has always been associated with improved process control. Increased customer confidence can also be a benefit to the extent that it has a positive influence on demand.

The benefits analysis in the preliminary RIA noted that benefits also accrue through the reduction of operating costs like the cost of product recalls or the cost of settling product liability claims. Other operating costs include the loss of establishment production due to suspensions for sanitation problems that could be reduced by improved process control, premiums for product liability insurance, loss of product reputation, and reduced demand when a foodborne illness outbreak is publicized identifying a product or company.

The cost analysis in Section V addresses two types of costs associated with this rule. There are the predictable costs associated with requirements directing all establishments or a specific category of establishments to take a well-defined action. Examples include the requirements to develop SOP's and HACCP plans or the requirement to have access to a HACCP-trained individual. This final RIA provides point estimates for all predictable costs. There are also potential costs that may impact some establishments because of current establishment-specific situations. This analysis provides a range of potential costs developed from two different scenarios of possible establishment responses to new pathogen standards.

This summary compares both types of costs with the potential public health benefits related to pathogen reduction, recognizing that there are other potential benefits. The discussion in Section V notes how this rule will set new requirements and also improve compliance with existing requirements. Some of the potential costs discussed in Section V are costs associated with improved compliance with existing standards and should not necessarily be considered costs of this rulemaking.

Public comments demonstrate that the controversy in this rulemaking derives not from the benefit cost ratio itself, which is very favorable, but from the fact that the processors will bear most of the costs while the public, in general, will experience the benefits. The public includes both the consumers of meat and poultry and those who do not consume meat or poultry but who bear the costs of illness in the society. Another area of controversy arises from the lack of proof that the estimated benefits will result from the promulgation of the rule. These doubts are particularly troublesome to those who would have to make resource investments under the rule while benefits largely accrue to others. This is, of course, the standard controversy facing government regulators. The essence of government regulation is that there is a situation where the public undergoes unacceptable risk because the current distribution of costs and benefits is unlikely to change without government intervention. This rule represents the Department's belief that the food safety risks being borne by the public are unacceptable, that they can be reduced through the use of readily available current technologies, and that the uncertainties involved in just how much risks can be reduced should not prevent the Department from making its best effort to reduce the risks.

B. Net Benefit Analysis

Because costs and benefits accrue at different rates over different time periods, to compare costs and benefits it is necessary to examine present value estimates for both cost and benefit streams. To make these comparisons, both the preliminary analysis and this final RIA use a 20-year time period. The present values for costs and benefits are based on a discount rate of 7 percent, the current standard recommended by the Office of Management and Budget.

As discussed above, the cost analysis (Section V) addresses two types of costs. FSIS was able to develop point estimates for the direct costs of complying with the requirements outlined in the rule that all establishments must meet. These predictable costs include the costs of developing and operating HACCP plans and SOP's and the costs of required recordkeeping. There are also potential costs for establishments that may have to purchase new equipment, or modify their production practices to meet the pathogen reduction performance standards for *Salmonella*, or actually implement *Salmonella* testing programs to assure compliance with the new standards. The cost analysis develops a range of cost estimates for these potential costs.

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The estimated annual industry costs (not discounted) are summarized in Table 2. These annual costs vary over the first four years as the new HACCP-based program is undergoing its implementation phase. After the initial four years, the recurring costs are estimated at a constant $99.6 to $119.8 million per year. The present value of all industry costs summarized in Table 2 for the 20-year time period is $968 to $1,156 million as shown earlier in Table 1. This total of $968 to $1,156 million ($0.97 to $1.16 billion) is the total industry cost for the rule as shown in Table 3.

TABLE 2.—SUMMARY OF ANNUAL INDUSTRY COSTS—ALL REQUIREMENTS

[$ Thousands]

Cost Category	Year 1	Year 2	Year 3	Year 4	Year 5+
I. Sanitation SOP's:					
Plans and Training	2,992				
Observation and Recording	8,345	16,691	16,691	16,691	16,691
II. *E. coli* Sampling:					
Plans and Training	2,627				
Collection and Analysis	8,716	16,122	16,122	16,122	16,122
Record Review	406	752	752	752	752
III. Compliance with *Salmonella* Standards		5,472–16,899	5,353–25,753	5,811–25,956	5,811–26,079
Compliance with Generic *E. coli* Criteria		(1)	(1)	(1)	(1)
IV. HACCP:					
Plan Development		3,769	27,755	35,464	
Annual Plan Reassessment			69	448	1,179
Initial Training		1,270	8,284	18,435	
Recurring Training		64	542	1,877	2,799
Recordkeeping (Recording, Reviewing and Storing Data)		3,050	18,479	42,478	54,097
V. Additional Overtime		189	837	1,711	2,125
Total	23,086	47,379–58,806	94,884–115,284	139,789–159,934	99,576–119,844

[1] Not Separately Estimated.

TABLE 3.— PRESENT VALUE OF 20-YEAR COSTS AND BENEFITS

[$ Billions]

Effectiveness in reducing pathogens in the manufacturing sector (percent)	Public health benefits		Industry costs
	Low	High	
10	0.71	2.66	0.97–1.16
20	1.43	5.32	0.97–1.16
30	2.14	7.98	0.97–1.16
40	2.85	10.64	0.97–1.16
50	3.57	13.30	0.97–1.16
60	4.28	15.96	0.97–1.16
70	4.99	18.61	0.97–1.16
80	5.71	21.27	0.97–1.16
90	6.42	23.93	0.97–1.16
100	7.13	26.59	0.97–1.16

Note: Analysis assumes zero benefits until year 5. All elements of the HACCP-based program will be in place 42 months after publication of the final rule.

The public health benefits of this rule are discussed in detail in Section IV. The benefits are based on reducing the risk of foodborne illness due to *Campylobacter jejuni/coli, Escherichia coli* 0157:H7, *Listeria monocytogenes* and *Salmonella.* Section IV concludes that these four pathogens are the cause of 1.4 to 4.2 million cases of foodborne illness per year. FSIS has estimated that 90 percent of these cases are caused by contamination occurring at the manufacturing stage that can be addressed by improved process control. This addressable foodborne illness costs society from $0.99 to $3.69 billion, annually. The high and low range occurs because of the current uncertainty in the estimates of the number of cases of foodborne illness and death attributable to the four pathogens. Being without the knowledge to predict the effectiveness of the requirements in the rule to reduce foodborne illness, the Department has calculated projected health benefits for a range of effectiveness levels, where effectiveness refers to the percentage of pathogens eliminated at the manufacturing stage. The link between effectiveness and health benefits is the proportionate reduction assumption which is explained in Section IV. Because of the wide range in estimates for the cost of foodborne illness, each effectiveness level will have a low and high estimate for public health benefits. These estimates of public health benefits are shown in Table 2, as the present value of a 20-year benefit stream.

The analysis assumes that benefits will begin to accrue in year five. The five year lag leads to conservative benefit estimates since the new HACCP-based inspection program will be fully implemented in 42 months, and benefits should accrue during those 42 months as well as in the 1½ years that follow. Limiting the benefit estimates to four pathogens also leads to conservative cost estimates. To the extent that the proportionate reduction estimate may overestimate benefits, these other factors provide conservative balance.

Net benefits exist for every cost and benefit combination illustrated in Table 2 except for the case of 10 percent effectiveness using the low benefit estimate. If the low benefit estimate is correct, the new HACCP-based regulatory program would have to reduce pathogens by 14 to 17 percent to cover the projected 20-year industry costs of $968 to $1,156 million. For the high benefit estimate net benefits begin to occur at an effectiveness level of 4 to 5 percent.

The costs summarized in Tables 1 and 2 have not been reduced to account for firms that already have existing HACCP programs. FSIS does not have a good estimate of the number of such firms.

C. Impact on "Smaller" Businesses

The final rule provides regulatory flexibility for smaller firms consistent with the Regulatory Flexibility Act. For the slaughter facilities, the generic *E. coli* sampling requirements vary depending on the number of birds or animals slaughtered annually. This will significantly reduce the microbial

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testing costs for smaller establishments which, under the proposed rule, would have been required to test every species or kind they slaughter every day on which slaughter of that species or kind occurs. Under the final rule, the impact on smaller establishments is mitigated by the change to base generic *E. coli* sampling requirements on annual production and by a change to no longer require that every species or kind be sampled. The costs to small establishments are also reduced because the proposed carcass cooling and antimicrobial near term requirements have been eliminated from the final rule and training requirements are more flexible. The requirement to sample each variety of raw ground product, which caused a heavier burden on small establishments, has also been eliminated.

The regulatory burden on small establishments is eased by the provisions which extend the time small establishments have to meet the HACCP system requirements. The detailed cost analysis in Section V outlines the methodology used in developing cost estimates and varying regulatory requirements for the purpose of regulatory flexibility for small establishments.

D. Effect on Retail Price

The preliminary analysis included an estimate that the total four-year implementation costs represented only $0.0024 per pound of fresh meat and poultry. This type of estimate helps put overall cost figures into perspective in terms of the potential increase in food prices. A large number of smaller processors responded very emotionally to the low figure of $0.0024 per pound on the basis that the lack of economies of scale in their businesses means their potential unit cost increases would be far higher. This "cost-per-pound" analysis was not meant to imply that the cost impact on all business would be the same. In a competitive industry, the impact on overall retail price is, however, an important indicator of net societal benefits. The four-year implementation costs for the final rule represent $0.0011 to $0.0013 per pound based on 1993 production of 67.15 billion pounds (66.4 billion pounds federally inspected and 748 million state inspected) of meat and poultry on a carcass weight basis. The annual recurring cost of $99.6 to $119.8 million represents $0.0015 to $0.0018 per pound based on 1993 production.

E. Impact on International Trade

The final rule will have an impact on countries and the establishments in those countries that export meat and poultry products to the United States. The inspection statutes require that imported product be produced under an inspection system that is equivalent to the U.S. inspection system. The equivalence of a country's system must be established by the United States before product can be exported to the United States. The notion of equivalence has been clarified under the World Trade Organization (WTO) Agreement on Sanitary and Phytosanitary measures. Under the WTO, all members have an obligation to apply the principle of equivalence on importing countries. Equivalence determinations are based on scientific evidence and risk assessment methodologies.

In light of the WTO emphasis on the use of science to determine equivalence, a number of countries are moving toward implementation of HACCP systems. The preliminary analysis noted that a large portion of the eligible exporting establishments are in countries that are themselves in the process of implementing HACCP and complying with their own country's HACCP requirements may achieve equivalence with the requirements of this rule.

As of January 1, 1995 there were 1,395 establishments in 36 different countries certified to export meat or poultry products to the United States. Canada (599 establishments), Denmark (125 establishments), Australia (111 establishments) and New Zealand (94 establishments) accounted for two-thirds of the 1,395 establishments. These four countries were the source of 85 percent of the 2.6 billion pounds of product imported during 1994. These four countries are currently developing HACCP systems for their respective inspection programs.

Half (18) of the 36 countries have fewer than 10 establishments approved to export products to the U.S. These 18 countries represent a total of 77 establishments, 5 percent of the total. Meeting the equivalency requirements may present a problem for some of these countries in the near term. Their inspection programs will have to meet equivalency requirements for HACCP according to the implementation schedule for domestic establishments, i.e., 18 months for large establishments, 30 months for small establishments and 42 months for very small establishments. This schedule should lessen the burden on smaller establishments.

There are other factors that will affect the burden on foreign establishments. As HACCP becomes the international norm, these establishments will be required to implement changes to meet the requirements of other countries implementing HACCP. Thus, their costs may not be solely associated with U.S. requirements. Establishing impact is further complicated because the U.S. requirements apply only when they are preparing product that is to be exported to the U.S. This product may represent only a small portion of total establishment production.

Upon implementation of these regulations, FSIS will review other countries' meat and poultry systems to ensure that exporting countries have adopted comparable measures, which would entitle them to continue exporting product to the United States. As other countries improve their regulations by adopting provisions comparable to those contained in this rule, it is expected that U.S. exports will similarly be affected, i.e., the receiving countries will be closely reviewing domestic exporting establishments to assure that they are meeting the requirements of the importing country.

FSIS will continue to carry out its import inspection responsibilities with a two-stage approach. The first stage is system review, which consists of an evaluation of the laws, policies, and administration of the inspection system in each eligible country. This overall evaluation will include an assessment of the implementation of HACCP supplemented by on-site reviews of individual establishments, laboratories, and other facilities within the foreign system. The "equivalency" of foreign requirements will be determined at this stage.

The second level of review involves port-of-entry inspection by FSIS inspectors to verify the effectiveness of foreign inspection systems. Using statistical sampling plans based on the foreign establishment's history and the nature of the product, FSIS will continue to give greater scrutiny to shipments posing the highest risk. Products that do not meet U.S. requirements, which includes having been produced under a HACCP or HACCP-equivalent system, will be refused entry. FSIS has concluded that requiring HACCP systems in combination with the two-stage inspection approach will better ensure the safety of imported meat and poultry products.

All countries exporting raw products to the U.S. must develop and implement performance standards that are equivalent to the pathogen reduction performance standards for *Salmonella*. They must also be able to demonstrate that they have systems in place to assure

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compliance with the standards. As with any other type of standard, FSIS could choose to test imported product for *Salmonella* at port-of-entry to verify the effectiveness of the foreign inspection system.

With respect to the specific requirements for sampling generic *E. coli* to validate control of slaughter and sanitary dressing procedures, it will be necessary for all foreign countries to demonstrate that they have an equivalent procedure to verify that they are controlling their slaughter and sanitary dressing processes.

There were several comments related to trade issues. Most of the comments concerning the impact on exports dealt with the proposed requirement for antimicrobial treatment of U.S. product. That proposed requirement raised particular concerns because the European Union member states and Canada restrict the use of certain antimicrobials on meat and poultry carcasses. The concerns raised in the comments are no longer an issue because the final rule does not require the use of antimicrobials. The final rule will affect exports only if a company has difficulty meeting the microbial performance criteria without using an antimicrobial. One option discussed in the proposed rule was that hot water would be considered to be an acceptable antimicrobial treatment, and that would be acceptable to Canada and the members of the European Union. The public comments also indicated that Trisodium Phosphate (TSP) is approved for use in Canada and the United Kingdom and is being considered by the European Union, Australia, and New Zealand.

Comments related to imports were concerned about the procedures FSIS would use to determine equivalence with the new U.S. requirements. As a condition of the NAFTA Treaty and the GATT Treaty, the United States has agreed to allow imports from countries that have systems of inspection equivalent to that of the United States. FSIS is considering alternative methods for determining that a foreign country's system of inspection can assure that the establishments within that system are using a process control system equivalent to the HACCP-based inspection system outlined in the final rule.

F. Impact on Agency Costs

Implementation of this rule will lead to both one-time nonrecurring costs and recurring costs for FSIS. There are three categories of one-time nonrecurring costs: (1) Training, (2) in-establishment demonstration projects, and (3) laboratory renovation. In order to implement the rule, FSIS will provide training to in-establishment personnel in two segments. The first training segment will cover issues related to sanitation standard operating procedures and generic *E. coli* sampling and testing requirements. The estimated costs for this activity is $3.6 million in the first year of implementation. The second training segment will cover issues related to the implementation of HACCP and is estimated the cost $3.6 million spread over the second and third year of implementation. FSIS will utilize the train-the-trainer approach to minimize the costs of these initiatives. FSIS is also committed to working with States and industry to sponsor HACCP demonstration projects for small businesses. Pursuant to implementation of the HACCP rule, microbiological sampling and testing will increase dramatically. In the period from 1990 to 1995, FSIS averaged approximately 33,000 analyses for microbiology per year. This is estimated to increase to 125,000 analyses per year after HACCP implementation. In order to accommodate this increase, FSIS will renovate its field laboratory facilities to expand their capacity, improve ability to test for a broader range of pathogens, and purchase new equipment. FSIS estimates that the planned renovation will cost $1.5 million.

By implementing this rule, FSIS will incur recurring costs associated with increased microbiological testing and upgraded inspector salaries. FSIS estimates that microtesting costs will increase approximately $3.0 million annually. Of this amount $2.0 million is needed for equipment, supplies, and shipping costs to conduct *Salmonella* testing, $0.5 million for microtesting conducted to verify HACCP systems, and $0.5 million for personnel necessary to handle the increased workload. Under HACCP-based inspection, FSIS personnel will be required to assume greater responsbility for more complex food inspection tasks. Slaughter inspectors will be required to perform health and safety tasks, such as taking microbiological samples, and verifying HACCP systems. Processing inspectors' roles will take them out of the establishment and put them into retail and market place settings to take microbiological samples, and to ensure meat and poultry products are handled in a manner to that minimizes the growth of pathogenic organisms. FSIS estimates that compensating inspectors for assuming more complex food safety tasks will cost $1.6 million per year.

G. Impact on State Programs

Comments stated that FSIS failed to adequately consider the cost of the changes to State programs and that FSIS was increasing the resource demands for State programs without providing adequate funding. The preliminary analysis did not address the impact on State programs. However, FSIS recognizes that the 26 States operating their own meat and poultry inspection programs will likely have to substantially modify their programs after the HACCP/Pathogen Reduction regulation is finalized to remain "at least equal to" Federal inspection programs as required by the FMIA and PPIA. During the regulation's implementation period, FSIS will be using the Agency's State-Federal Program staff to assist the States in bringing the necessary changes to the State inspection programs. Although FSIS has requested some additional funds to implement this rule, FSIS has also acknowledged that implementation of this rule will require eliminating some tasks, conducting other tasks differently and streamlining the organization in order to free up resources to fully address the new requirements. FSIS believes that the same type of restructuring or reprogramming will take place within the State programs. This does guarantee, however, that all States with inspection programs will be able to implement the necessary program changes without additional funds. FSIS believes, however, that with FSIS assistance and with the flexibility provided under the "equal to" provisions, most of the States should be able to modify their programs with minimal additional funding. To the extent that there are any additional costs, the State inspection programs are eligible to receive up to 50 percent Federal matching funds.

H. Consumer Welfare Analysis

It is likely that at least some of the costs of the new HACCP-based regulatory program will be passed on to consumers in the form of higher prices. Even if costs are fully reflected in retail prices, the impact on consumers and consumption will be small. Retail costs are not expected to increase more than 0.02 percent. Retail demand for meat and poultry is inelastic. A likely range is -0.25 to -0.75. This suggests changes in quantity demanded of less than 0.02 percent. Given that annual per capita meat and poultry consumption is about 211 pounds, retail weight, the impact on individual consumption will be less than 1/10th of a pound per year. In aggregate, with a high impact

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scenario, consumption would decrease by about 50 million pounds. These impacts may be overstated if meat and poultry producers pass some costs back to livestock and poultry producers. Improved consumer confidence in the safety of meat and poultry could offset price driven decreases in consumption.

IV. Analysis of Public Health Benefits

A. Introduction

This section addresses the methodology used to develop the estimates for public health benefits that, for the purpose of this final Regulatory Impact Assessment, have been defined as the reduction in the cost of foodborne illness attributable to pathogens that contaminate meat and poultry products at the manufacturing stage. This section is organized around the Agency's responses to the public comments related to benefits. The first part of this section addresses the general comments related to risk assessment. The Agency has responded to these general requirements by providing an overall summary of the current state-of-the-art with respect to risk assessment for foodborne pathogens. The second part of the discussion (see subsection titled "Analysis of Comments on Public Health Benefits") addresses the more specific comments on the methodology used to estimate benefits in the preliminary analysis.

Several comments suggested that FSIS has not conducted an adequate risk assessment and/or should conduct a thorough risk assessment before proceeding with the current rulemaking. More focused comments assert that the relationship between pathogen reduction at the manufacturing stage and foodborne illness reduction is unknown. Those comments suggest that establishing that relationship requires a quantitative risk assessment, i.e., an estimate of the probability of adverse health effects (foodborne illness) given a particular level of a hazard (pathogens at manufacturing stage).

The preliminary analysis and this final RIA recognize that the relationship is unknown and acknowledge that there are significant data gaps regarding both likelihood and magnitude of illness and numbers of foodborne pathogens. These data gaps mean that multiple assumptions must be made in order to calculate the probabilities of risk, and FSIS is concerned with this tremendous uncertainty. However, the agency is developing quantitative assessments and believes that these will become the basis on which to make future regulatory decisions. In this rulemaking, FSIS estimates of the risk of foodborne disease linked to specific pathogens are based upon the best judgement of nationally recognized experts in infectious disease, epidemiology, microbiology, and veterinary medicine. FSIS is also relying on a qualitative estimation of risk as expressed in publications and summary reports from the CDC, other public health agencies, and special panels, such as the National Advisory Committee on Microbiological Criteria in Foods and those established by the NAS. Based on this sizable body of information and scientific judgement, FSIS is proceeding to develop benefit estimates using the assumption that a reduction in pathogens leads to a proportionate reduction in illness and death. The benefits analysis could have used a more conservative relationship estimate, e.g., a reduction in pathogens leads to a reduction in illness that is less than proportional. However, given the current level of knowledge, FSIS views the proportional assumption as most appropriate at present.

The Department has initiatives in place that will begin to relate pathogen levels at inspected establishments to incidence of human illness and support quantitative risk assessment (see Section IV–D on FSIS Data Initiatives). The present paucity of data to support a risk model for the major foodborne pathogens causing human disease limits the usefulness of quantitative risk assessment in the regulatory arena of meat and poultry inspection. It is unlikely that any single numerical constant will adequately describe the dose-response relationships for all pathogens associated with all of the products that FSIS regulates, given the complexity of possible interactions of factors associated with the host, the pathogenic strain, the diet, and the environment (CAST, 1994).

The Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 (P.L. 103–354) now requires that for each proposed major regulation (i.e. economic effects of at least $100 million a year and effects on human health, safety, or the environment) the Department publish an analysis of the risks addressed by the regulation. While this statute does not apply to this final rule, FSIS is providing a qualitative estimation of risk (Tables 4 and 5) and a recommendation to manage risk using HACCP in meat and poultry inspection programs. Concurrently, scientists from FSIS and USDA's Agricultural Research Service (ARS), Economic Research Service (ERS), and modelers from academia and industry continue to develop risk models which blend failure analysis, predictive microbiology, and other models into the framework described by the NAS (NRC, 1983). FSIS believes this approach is flexible and responsive to new data necessary to fully document risks of foodborne diseases.

B. FSIS Risk Assessment

Following the publication of the 1985 National Academy of Sciences (NAS) study on the scientific basis for meat and poultry inspection. FSIS requested that the National Research Council of NAS conduct a follow-up study that included the objective of developing a risk assessment model for the poultry production system. The subsequent report, "Poultry Inspection: The Basis for a Risk-Assessment Approach" was published by the National Academy Press in 1987. The 1987 study concluded that the present system of inspection provides little opportunity to detect or control the most significant health risks presented by microbial agents that are pathogenic to humans. The study also concluded that current databases can serve as the basis for a comprehensive, quantitative risk assessment only for certain well-characterized chemical residues.

The committee conducting the study also concluded that their report did constitute a qualitative risk assessment that could be useful for many purposes, including the evaluation of inspection strategies. That assessment found: "There is evidence linking disease in humans to the presence of pathogens on chickens. For example, epidemiological studies indicate that approximately 48% of *Campylobacter* infections are attributable to chicken. Data also suggest that chicken is probably an important source of salmonellosis in the United States." Based on these and other findings, the committee recommended that FSIS "modify the existing system so that it more directly addresses public health concerns." FSIS believes that the implementation of HACCP programs at slaughter for meat and poultry is such a "modification" of the food safety system which will address human health hazards, particularly foodborne diseases.

C. Risk Assessment Framework

The National Research Council (1983) presented a framework for risk assessment that has become a standard paradigm to organize risk assessments for chemical and microbial hazards. The framework, consisting of hazard identification, dose-response assessment, exposure assessment, and risk characterization, is flexible and can accommodate many different modeling strategies. The major distinction

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between foodborne microbial risk assessments and chemical risk assessments may be the additional uncertainties of microbial growth and survival in food prior to consumption. Survival of pathogens present in a raw food and after cooking can be modeled using predictive microbiology methods. These models can also address the growth of pathogens with time and temperature abuse of raw and cooked foods.

One of the first U.S. publications on the application of predictive microbiology to microbial risk assessment (Buchanan & Whiting, 1996) included estimations of risk of salmonellosis for several "what-if scenarios" as examples of potential time and temperature abuses of partially cooked food. The predictive microbiology model was linked to a published dose-response model for salmonellosis (Haas, 1983) to calculate a risk estimate. The dose-response model was developed by empirically fitting data from human feeding studies conducted at high-dose challenges with a number of pathogenic strains of *Salmonella* to the "beta poisson" model (Haas, 1983). The authors generated risk estimates for selected cooking and abuse scenarios, but recognized that the risk of illness is zero when the pathogen is not present in the sample even with unsafe food handling. HACCP programs at slaughter are expected to affect pathogen presence and levels before potential time and temperature abuses can occur. Therefore, changes at slaughter, in the duration of cooking, and final storage conditions of the food exert a tremendous impact upon the model outcomes.

An unpublished draft risk model is in development as a research endeavor by Agriculture and Agri-Food Canada and Health Canada. A variety of modeling approaches were organized within the 1983 NRC framework to estimate risk of human illness from *E. coli* 0157:H7 in ground beef. The draft risk model includes many stochastic variables to account for the variability and uncertainty associated with the inputs and assumptions of the model. The authors are developing the model to identify current limitations to the construction of quantitative models which accurately describe the risk of foodborne disease along the farm to fork continuum.

These recent quantitative risk assessment efforts are an encouraging beginning and serve to illustrate the tremendous uncertainties created by insufficient data describing processes throughout the farm to table continuum that contribute to risk. Additional uncertainties surround assumptions based on epidemiologic data for human illness. For example, recent data in the U.S. indicates a growing number of outbreaks of *E. coli* 0157:H7 disease linked to sources other than ground beef. The ecology of the organism on the farm, in the bovine gastrointestinal tract, and in irrigation, recreational, and drinking waters is largely unknown. Additionally, the primary sources of *E. coli* 0157:H7 causing sporadic disease may remain undercooked hamburger and may differ from vehicles causing outbreaks, as has been documented for *Campylobacter* (CDC, 1988). Outbreaks of campylobacteriosis have been caused primarily by unpasteurized milk and contaminated water, yet the overwhelming majority of infections are sporadic and have been linked to undercooked chicken. Control strategies to reduce both outbreak and sporadic case numbers for both of these pathogens may require greater understanding of vehicles of disease and more information than is currently available.

FSIS concludes that risk models for foodborne illnesses are necessarily based largely on assumptions because scientific data describing key foodborne disease processes have not been developed. The models are extremely useful to identify basic research needs that might reduce the uncertainty associated with the inputs and assumptions of the models. The agency is proposing initiatives to generate data which may reduce uncertainties associated with modeling the risk of foodborne diseases. However, application of microbial risk assessment models to regulatory decision-making appears premature at this time. The following is a summary of the availability and limitations of data supporting risk assessment for foodborne pathogens:

1. Hazard Identification

The Agency selected from the pathogens listed in Tables 4 and 5 the three most common enteric pathogens of animal origin: *Campylobacter jejuni/coli, E. coli* 0157:H7, *Salmonella* and one environmental pathogen *Listeria* monocytogenes for consideration in risk assessment. FSIS believes that these four pathogens may contaminate meat and poultry food vehicles at slaughter and can be reduced through improved process control in the manufacturing sector. Available data on estimated human disease incidence are summarized in Table 4. Data on human disease attributable to proven as well as epidemiologically linked pathogens and food vehicles are presented in Table 5. Additional and more precise information for this section regarding estimated national disease incidence and disease severity and duration is expected on these pathogens from the sentinel site surveillance initiative.

2. Exposure Assessment

Rarely can actual exposure to a specific strain of foodborne pathogen be quantified with certainty in foodborne disease outbreaks. Microbes in food are known to be non-homogeneously distributed, imposing additional uncertainty due to sampling error upon the analytical variability of the methods for detection and quantification of microbes in foods. The outbreak strain may or may not be detected in the feces of diarrheal cases or in leftovers or companion samples from suspected lots. The levels detected in leftovers or companion samples from the same lot of food may or may not be representative of the serving that was prepared and consumed since the microbial numbers vary with time and temperature conditions and the initial microbial populations. The amount of the serving consumed may not be known.

The FSIS baseline studies provide data on occurrence of pathogens (likelihood) and levels (magnitude) in uncooked meat and poultry products at slaughter and raw ground processing. Data for likelihood and magnitude of pathogens in the distribution, preparation, and consumption phases of the farm-to-fork continuum of food production are sparse. Predictive microbiology models may be the most cost-effective method to deduce possible exposure scenarios in meat and poultry beyond the slaughter phase that may result in foodborne illness. The likelihood that the selected scenarios of improper cooking and abuse actually occur among U.S. consumers may not be measurable, but the scenarios may be useful in modification of behaviors that pose increased risk to consumers.

3. Dose-Response Assessment

The relationship between the dose of a pathogen and response in the host, when known, can vary greatly for foodborne pathogens. Human feeding studies with foodborne pathogens were largely conducted several decades ago with small numbers of healthy adult males. One study reported both ill and asymptomatic volunteers who had consumed up to 1,000,000,000 pathogenic *Salmonella*. Outbreak data for other *Salmonella* serotypes in food vehicles suggest a range of infective doses from one cell to 1,000,000,000,000 cells (Blaser & Newman, 1982). Fatty food vehicles, including some meat and

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poultry products, are thought to protect enteropathogens from stomach acids and digestive enzymes that might otherwise reduce the dose to the intestinal tract and reduce the likelihood of disease. The effects of competition of the pathogen with the large indigenous microbial populations in food (ICMSF, 1980) and in the human gastrointestinal tract (Rolfe, 1991) may reduce the likelihood and/or the severity of foodborne disease.

Even carefully controlled volunteer feeding experiments at doses up to one billion organisms per volunteer have shown variability in the infectious dose of one pathogen for individuals within a group of seemingly healthy, young adults. Extrapolation of empirical models of effects at high doses to low doses typical of properly handled food may or may not be appropriate. The dose-response curve for healthy adult males may not be useful in estimating dose-response relationships for the general population or sensitive sub-populations. The data available from human feeding studies were generated from very few species and strains of bacterial pathogens, excluding *E. coli* 0157:H7. Dose-response modeling is crucial to microbial and chemical risk assessments. FSIS believes that application of dose-response models in food safety regulation requires careful examination of the validity of the assumptions and inputs of the model and of the plausibility of the model as a descriptor of foodborne disease processes.

4. Risk Characterization

The integration of exposure and dose-response models is expected in risk characterization, along with sensitivity and uncertainty analyses (Burmaster & Anderson, 1995) for the risk model. Perhaps of greater significance than the numerical estimate of risk is the uncertainty associated with the estimate. A fully developed risk characterization would include risk estimates and sensitivity/uncertainty analyses for alternative models and assumptions. FSIS is collaborating with scientists in academia, the Agricultural Research Service, the Animal & Plant Health Inspection Service, the Economic Research Service, and the Office of Risk Assessment and Cost Benefit Analysis to develop and validate a risk assessment model for a single pathogen in a single meat product. This model may be modified for other specific pathogens of concern. The expectation of a generic model for all foodborne disease agents in all products does not appear promising based on differences in pathogenesis of bacterial species and strains and in human sensitivity and pathology.

FSIS continues to evaluate new information on foodborne pathogens and on risk assessment methods and tools in accordance with the FSIS public health mission. The NAS Report, the CAST Report and the 1995 Conference recognize HACCP as a system to reduce the likelihood of foodborne illness. The CAST Task Force also concluded that "the efficacy of a HACCP system depends on the rigor and consistency with which it is designed and implemented and the use of (a) critical control point(s) that will control pathogens."

D. FSIS Data Initiatives

The 1994 report, "Foodborne Pathogens: Risks and Consequences, CAST Task Force Report No. 122, September 1994" concluded that "a comprehensive system of assessing the risks of human illness from microbial pathogens in the food supply has yet to be devised." They cited the limitations of the current food safety information database and the difficulty in accumulating dose response and minimum infective dose data. A recent multidisciplinary conference, "Tracking Foodborne Pathogens from Farm-to-Table, Data Needs to Evaluate Control Options", carefully reviewed current databases and confirmed limitations outlined in the CAST Task Force report.

FSIS has established initiatives to improve the quality and quantity of data in two major areas. First, FSIS is working with the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) to establish an active sentinel site surveillance system for the major causes of foodborne illness. This project is designed to accumulate data on the incidence of foodborne illness by pathogen and by food.

Second, the Agency has been developing baseline data for pathogen levels on major food animal species at the time of slaughter. The baseline data will allow the Agency to detect changes in the overall nation-wide pathogen levels. The National Baseline program was initiated in 1992 to provide information on the type and level of microbiological contamination on raw products under Federal inspection. Each sample collected is analyzed for nine microorganisms or groups of organisms. Microbiological baseline data are now available for steers and heifers, cows and bulls, and broiler chickens.

If sufficient data on both pathogen levels and foodborne disease epidemiology result from current and future initiatives, FSIS should be able to develop models showing how these two variables are related for different pathogens. These models should then permit/facilitate a quantitative estimate of risk. Such data are essential for FSIS to evaluate the effect of control measures on both pathogens levels and on foodborne illness.

E. ARS Food Safety Research Program

The Agricultural Research Service (ARS) administers a food safety research program that is currently funded at approximately $45 million per year. This program addresses problems in four different areas: pathogen reduction, mycotoxins, residues, and natural toxins. The reduction of microbial pathogens in food products of animal origin is the most pressing food safety problem today. Consequently, the pathogen reduction component is the largest of the four areas and is currently funded at $18.2 million annually. The ARS research in pathogen reduction addresses both preharvest and animal production, and post harvest problem areas, with approximately equal funding for each.

Ongoing ARS research will help FSIS improve its capability for performing quantitative risk assessment in the area of foodborne pathogens or improve the ability to predict the effectiveness of new pathogen reduction technologies. Ongoing projects include the modeling of bacterial growth or thermal death times which will help set standards for meat and poultry products. Ongoing projects will also provide new laboratory screening or confirmatory methods. Other projects provide and/or evaluate technology and management methods which can help producers achieve lower contamination levels in animals presented for slaughter, such as vaccines or competitive bacterial cultures to prevent pathogens in live animals. There are also technology and management methods for use in slaughter and processing establishments, such as, organic acids for use in carcass sanitation, improvements to the feather picking operation for poultry, washing of trailers to reduce microbiological contamination, and establishment of guidelines on the microbiological safety of recycling cooling solutions for ready-to-cook meat and poultry products. In many cases the research may provide the scientific basis for developing and improving technology, for example, the nature of bacterial attachment to various meat surfaces.

FSIS can and does forward very specific research requests to ARS. In preparation for this final rule, FSIS requested that ARS compare the results

from different microbial sample collection techniques, sponging versus excision at one versus three carcass sites. These studies are currently being conducted on both cow/bull and market hog carcasses. There are other specific ARS projects that will help provide the scientific basis for HACCP through risk assessment, predictive microbiology, and pathogen reduction interventions for several different bacterial pathogens which must be controlled to assure the safety of meat and poultry.

These projects include: (1) Development of models to predict the growth rates, survival times, and thermal death rates for microbial pathogens potentially present in foods, including meat and meat products. (Microbiological modeling is time consuming and expensive because it requires that the data be quantified, that is, that numbers of bacteria are obtained, rather just the knowledge of the presence or absence of a pathogen under the conditions of the test.) The microorganisms being studied include *E. coli* O157:H7, *Listeria monocytogenes,* and *Salmonella.* These models are written into personal computer software that gives FSIS a readily useable tool to help evaluate proposed meat processes and assess out-of-process events. Refining predictive models has the goal of linking an entire process from raw ingredients to distribution of finished product. A specific project is to model the survival of *E. coli* O157:H7 during the manufacture of uncooked, fermented meat products. Using the information obtained, ARS will closely collaborate with other USDA agencies to develop strategies for risk reduction using the various processing techniques, and to create risk assessment models.

(2) Modeling studies to predict the thermal inactivation of spore-forming and non-spore-forming bacterial pathogens of both cooked and ready-to-eat products. These studies will be extended to the cooling of these products to ensure that there is no potential for growth of *Clostridium botulinum* and *C. perfringens.*

(3) Determination of the long-term effects (21 days of storage at refrigerated temperatures) of organic acid treatment of red meat on some key pathogens (*E. coli* O157:H7, *Listeria,* and *Clostridium*), as well as on spoilage bacteria (mesophilic aerobes, lactic acid bacteria, and pseudomonads).

(4) Delineation of the parameters affecting the antibacterial activity of organic acids. These include tissue type (pre-rigor, post-rigor, frozen post rigor), inoculum type (pure culture or inoculated feces), inoculum level and the temperature of spray wash at meat surface. These results should clarify inconsistent reports on antibacterial activity of organic acids and also define optimum conditions to maximize the antibacterial activity of organic acids.

(5) The correlation of the *Campylobacter* levels in broilers from the chill tank with their *Campylobacter* levels during production.

F. Analysis of Comments on Public Health Benefits

There were many comments on the methodology used to estimate public health benefits in the preliminary analysis. This methodology used a series of estimates or assumptions based on incomplete data related to the six following areas:

- Incidence of foodborne illness
- Cost of foodborne illness
- Percentage of foodborne illness and cost of foodborne illness attributable to meat and poultry products
- Pathogens addressed by the rule
- Effectiveness of rule in reducing pathogens
- Estimated reduction in cost of foodborne illness related to reduction of pathogens

To facilitate discussion of the issues raised in comments, the issues are addressed organized by these six areas.

1. Incidence of Foodborne Illness

Table 4 presents the most recent estimates on the incidence of illness and death for selected pathogens along with the latest estimates on the percentage of illness and death which is foodborne. As discussed in the preliminary RIA, Table 4 includes the "best estimates" when precise data are not available. Many of these estimates are based on the landmark CDC study by Bennett, Holmberg, Rogers, and Solomon, published in 1987, which used CDC surveillance and outbreak data, published reports, and expert opinion to estimate the overall incidence and case-fatality ratio for all infectious and parasitic diseases. Estimates on the foodborne percentage of illness and death for bacteria in Table 4 are all based on CDC data. The resulting estimates for the number of foodborne cases and deaths are presented in the second and third columns of Table 5.

The benefits for the preliminary analysis and this final RIA are calculated for the three most common enteric pathogens of animal origin: *Campylobacter jejuni/coli, E. coli* O157:H7, *Salmonella* and one environmental pathogen *Listeria monocytogenes.* FSIS believes that these four pathogens can be reduced through improved process control in the manufacturing sector.

Although *Clostridium perfringens* and *Staphylococcus aureus* also cause a significant number of foodborne illnesses, they are not included in the benefits analysis because it is not clear that the HACCP-based regulatory program, which focuses on federally inspected processing, will significantly affect the incidence of disease caused by these organisms. *Staphylococcus aureus* usually enters the food chain through food handlers in restaurants and other commercial kitchens. Although *C. perfringens* may enter the food chain through the slaughter process, it is so ubiquitous in the environment that FSIS will not assume that controls at slaughter will be effective against this pathogen.

One commenter questioned why the Agency has not addressed the public health problem of toxoplasmosis given the Table 5 estimate of $2.7 billion in annual costs. FSIS believes that while process control may help decrease the spread of cysts during boning and cutting operations, most of the *Toxoplasma gondi* cysts are internal to infective muscle tissues and are not addressable by process control. Therefore, FSIS is making the more conservative assumption to exclude this pathogen in the benefits estimate of disease averted.

Many comments suggested that the large range in the illness incidence estimates demonstrates that there are insufficient data on which to base a new regulatory program. Historically, the lack of quantitative data on benefits and specific health risks have meant that health and safety regulations have required decisionmaking under uncertainty and have required the decisionmaker to balance the need to act with the need for additional or improved data. Compared to such issues as whether a chemical is a potential human carcinogen or whether low levels of air pollutants cause adverse health effects, the health effects of enteric pathogens are relatively well documented. If the pathogens enter the food supply, they do, under certain conditions, cause foodborne illness. If their presence can be prevented, no amount of temperature abuse, mishandling or undercooking can lead to foodborne illness.

The Agency believes that the existing estimates on foodborne illness are adequate to conclude that a substantial and intolerable public health problem exists. Furthermore, existing estimates are appropriate for developing estimates on the cost of foodborne illness attributable to meat and poultry. The

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Agency notes that similar estimates on the incidence of foodborne illness have been published by scientists from ERS in peer-reviewed journal articles (see footnotes to Table 5) and by the 1994 CAST Task Force.

The above statement that Table 4 includes the most recent estimates of the incidence of illness and death requires further explanation in the case of *Listeria monocytogenes*. The estimates of 1,795–1,860 cases of listeriosis and 445–510 deaths are the ones used in the latest cost of illness study conducted by ERS. ERS is in the process of publishing a comprehensive documentation for the estimates of cost of illness for 1993. In their draft document they acknowledge that the estimate for listeriosis cases originates from an extrapolation to the U.S. population of incidence data from a CDC-conducted surveillance study of six geographic regions in 1986 and 1987 (Gellin *et al.* 1987). They also note that (Tappero *et al.* 1995) found that the incidence of listeriosis has decreased since the 1960's and that projections from the surveillance data suggest that there were 1,092 listeriosis cases and 248 deaths in 1993. ERS did not modify their cost of illness estimates because Tappero *et al.*, was published after their analysis was concluded.

FSIS considered modifying the cost of illness estimates for this final analysis but decided to use the estimates in Tables 4 and 5 because (1) They are the figures that will appear in the upcoming ERS publication and, (2) updating the listeriosis estimates would have minimal impact on the overall cost of illness estimates. Considering the overall range and uncertainties involved in the cost of illness estimates, the change in listeriosis estimates has negligible impact on the regulatory analysis information conveyed through the potential benefits estimate.

The Agency also recognizes that in using the 1993 estimates for incidence of foodborne illness, the benefits analysis has not accounted for possible reductions in foodborne illness attributable to the rule that mandated safe handling statements on labeling of raw meat and poultry products. The rule mandating safe handling instructions became effective on May 27, 1994. Thus, it can be argued that the incidence of foodborne illness for 1994 through the present should reflect the effectiveness of the 1994 labeling requirement in reducing the incidence of illness.

FSIS is not aware of any quantitative evaluation of the effectiveness of safe handling labeling. Two recent surveys indicate a high level of awareness, but these surveys do not contain findings that can be translated into changes in consumer behavior. A recent Associated Press poll found that 9 in 10 Americans say they follow the safe-handling instructions. This poll, conducted in April 1996, included 1,019 randomly selected adults. This was a telephone survey conducted by ICR Survey Research Group. A November 1995 survey conducted by Wegman Food Markets in Buffalo, Rochester, and Syracuse found that 67.9 percent of respondents indicated they had read the safe handling information. The Wegman's survey found that most household meat preparers rely on color of meat or clarity of juices rather than temperature to determine when meat has been cooked thoroughly.

In this analysis, FSIS has not attempted to adjust the 1993 baseline to account for safe handling labeling. The potential effect of the 1994 regulation is one of many factors that could be affecting the current incidence or cost of illness. A May 1996 GAO study on foodborne illness notes that food safety and public health officials believe that the risk of foodborne illness is increasing. If they are correct, the 1994 labeling rule may be slowing the growth rather than reducing the absolute level.

There are many other factors that could have been incorporated into the baseline for the analysis such as population growth and increases in the cost of medical care. FSIS believes that attempts to adjust the cost of illness baseline to account for factors such as inflation, possible increases in foodborne illness due to behavior change or population increases, and possible decreases due to inventions such as safe handling labels are more likely to be misleading than informative given the level of uncertainly and wide range in existing estimates.

2. Cost of Foodborne Illness

The fourth column of Table 5 shows that the 1993 estimated cost of foodborne illness by pathogen or parasite was between $5.6 and $9.4 billion. These cost of illness estimates have been developed by ERS in conjunction with CDC over the past 15 years. As indicated in footnotes to Table 5, the results of that work have been frequently published in peer-reviewed journals.

There were only a few public comments on the proposed rule which addressed the methodology used for estimating the cost of foodborne illness. Some comments argued that the public health benefit estimates are low because of the low value-of-life factor used in the estimates for the cost of foodborne illness.

ERS intentionally used a conservative method to estimate the value of a statistical life (VOSL) acknowledging the controversy over valuing lives. ERS used Landefeld and Seskin's VOSL estimates and recognizes that the cost of illness estimates would be substantially higher if they used alternative methods. For example, Viscusi (1993) summarized the results of 24 principal labor market studies and found that the majority of the VOSL estimates lie between $3 million and $7 million per life. A survey of the wage-risk premium literature on the willingness to pay to prevent death concluded that reasonably consistent estimates of the value of a statistical life range from $1.6 million to $6.5 million dollars (1986 dollars) (Fisher et al. 1989). Updated to 1993 dollars using the change in average weekly earnings, Viscusi's range becomes $3.2 million to $7.6 million per VOSL and Fisher's range becomes $2.0 million to $10.4 million dollars for each statistical-life lost. Viscusi and the Fisher estimates are greater than the highest Landefeld-Seskin (LS) VOSL estimate of $1,584,605 in 1993 dollars (estimate for a 22 year old).

TABLE 4.—SOURCES OF DATA FOR SELECTED PATHOGENS, 1993

Pathogen	Estimated number of cases	Estimated number of deaths	Source(s) for case and death estimates	Percent foodborne	Source
Bacteria:					
Campylobacter jejuni or coli	2,500,000	200–730	Tauxe	55–70	Tauxe et al.
Clostridium perfringens	10,000	100	Bennett et al.	100	Bennett et al.
Escherichia coli O157:H7	10,000–20,000	200–500	AGA Conference	80	AGA Conf./CDC.
Listeria monocytogenes	1,795–1,860	445–510	Roberts and Pinner	85–95	Schuchat.

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TABLE 4.—SOURCES OF DATA FOR SELECTED PATHOGENS, 1993—Continued

Pathogen	Estimated number of cases	Estimated number of deaths	Source(s) for case and death estimates	Percent foodborne	Source
Salmonella	800,000–4,000,000	800–4,000	Helmick et al./Bennett et al.	87–96	Bennett et al./Tauxe & Blake.
Staphylococcus aureus	8,900,000	7,120	Bennett et al	17	Bennett et al
Parasite:					
Toxoplasma gondii	4,111	82	Roberts et al.	50	Roberts et al.

Sources: American Gastroenterological Association Consensus Conference on E. coli O157:H7, Washington, DC, July 11–13, 1994. Bennett, J.V., S.D. Holmberg, M.F. Rogers, and S.L. Solomon. 1987. "Infectious and Parasitic Diseases," In R.W. Amler and H.B. Dull (Eds.) *Closing the Gap: The Burden of Unnecessary Illness.* Oxford University Press, New York. Helmick, C.G., P.M. Griffin, D.G. Addiss, R.V. Tauxe, and D.D. Juranek. 1994. "Infectious Diarrheas." In: Everheart, JE, ed. *Digestive Diseases in the United States: Epidemiology and Impact.* USDHHS, NIH, NIDDKD, NIH Pub. No. 94–1447, pp. 85–123, Wash, DC: USGPO.

Roberts, T., K.D. Murrell, and S. Marks. 1994. "Economic Losses Caused by Foodborne Parasitic Diseases," *Parasitology Today*. vol. 10, no. 11: 419–423.

Schuchat, Anne, CDC, personal communication with T. Roberts at the FDA Science Forum on Regulatory Sciences, Washington, DC, September 29, 1994.

Tauxe, R.V., "Epidemiology of Campylobacter jejuni infections in the United States and other Industrialized Nations." In Nachamkin, Blaser, Tompkins, ed. *Campylobacter jejuni: Current Status and Future Trends*, 1994, chapter 2, pages 9–19. Tauxe, R.V. and P.A. Blake, 1992. "Salmonellosis" Chap. 12. In: Public Health & Preventative Medicine, 13th ed. (Eds: Last JM: Wallace RB; Barrett-Conner E) Appleton & Lange, Norwalk, Connecticut, 266–268.

Tauxe, R.V., N. Hargrett-Bean, C.M. Patton, and I.K. Wachsmuth. 1988. "Campylobacter Isolates in the United States, 1982–1986," *Morbidity and Mortality Weekly Report*, vol 31, no. SS–2: pages 1–14.

TABLE 5.—MEDICAL COSTS AND PRODUCTIVITY LOSSES ESTIMATED FOR SELECTED FOODBORNE PATHOGENS, 1993

Pathogen	Foodborne illness		Foodborne * costs (bil $)	Percent from meat/poultry (%)	Meat/poultry related		Total costs * meat/poultry (bil $)
	Est. No. of cases	Est. No. deaths			Est. No. of cases	Est. No. deaths	
Bacteria:							
Campylobacter jejuni or coli	1,375,000–1,750,000	110–511	0.6–1.0	75	1,031,250–1,312,500	83–383	0.5–0.8
Clostridium perfringens **	10,000	100	0.1	50	5,000	50	0.1
Escherichia coli 0157:H7	8,000–16,000	160–400	0.2–0.6	75	6,000–12,000	120–300	0.2–0.5
Listeria monocytogenes	1,526–1,767	378–485	0.2–0.3	50	763–884	189–243	0.1–0.2
Salmonella	696,000–3,840,000	696–3,840	0.6–3.5	50–75	348,000–2,880,000	348–2,880	0.3–2.6
Staphylococcus aureus **	1,513,000	1,210	1.2	50	756,500	605	0.6
Subtotal	3,603,526–7,130,767	2,654–6,546	2.9–6.7	N/A	2,147,513–4,966,884	1,395–4,461	1.8–4.8
Parasite:							
Toxoplasma gondii	2,056	41	2.7	100	2,056	41	2.7
Total	3,605,582–7,132,823	2,695–6,587	5.6–9.4	N/A	2,149,569–4,968,940	1,436–4,502	4.5–7.5

Source: ERS, 1993

* Column rounded to one decimal place.

** Roberts' rough approximation of costs in "Human Illness Costs of Foodborne Bacteria", *Amer. J. of Agricultural Economics*, vol. 71, no. 2 (May 1989) pp. 468–474 were updated to 1993 dollars using the Consumer Price Index (all items, annual average). Cost estimates for other pathogens are more detailed, see the following for a discussion of the methodology:

listeriosis—Roberts, Tanya and Robert Pinner, "Economic Impact of Disease Caused by *Listeria monocytogenes*" in *Foodborne Listeriosis* ed. by A.J. Miller, J.L. Smith, and G.A. Somkuti. Elsevier Science: Amsterdam, The Netherlands, 1990, pp. 137–149,

E. coli O157:H7—Roberts, T. and Marks, S., "*E. coli* O157:H7 Ranks as the Fourth Most Costly Foodborne Disease," *FoodReview*, USDA/ERS, Sept-Dec 1993, pp. 51–59.

salmonellosis—Roberts, Tanya, "Salmonellosis Control: Estimated Economic Costs," *Poultry Science*. Vol. 67 (June 1988) pp. 936–943,

campylobacteriosis—Morrison, Rosanna Mentzer, Tanya Roberts, and Lawrence Witucki, "Irradiation of U.S. Poultry—Benefits, Costs, and Export Potential, *FoodReview*, Vol. 15, No. 3, October-December 1992, pp. 16–21, congenital toxoplasmosis—Roberts, T., K.D. Murrell, and S. Marks. 1944. "Economic Losses Caused by Foodborne Parasitic Diseases," *Parasitology Today*. vol. 10, no. 11: 419–423; and Roberts, Tanya and J.K. Frenkel, "Estimating Income Losses and Other Preventable Costs Caused by Congenital Toxoplasmosis in People in the United States," *J. of the Amer. Veterinary Medical Assoc.*, vol. 196, no. 2 (January 15, 1990) pages 249–256.

N/A indicates item is not-applicable.

ERS is currently working on a sensitivity analysis for their cost of illness estimates for foodborne illness. The sensitivity analysis replaces the LS VOSL estimates with estimates found in the literature on wage-risk studies. Preliminary findings show that the estimates of the total cost of foodborne illness will increase greatly when these higher VOSL estimates are used.

FSIS considers that the existing conservative estimates are appropriate considering the controversy and uncertainty. The conservative estimates are more than sufficient to justify the

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final rule implementing a new HACCP-based regulatory program for meat and poultry. This final RIA uses the cost of illness estimates shown in Table 5.

Another comment stated that the cost of illness estimates are low because they do not account for increases in productivity. In response, the Agency notes that ERS used Landefeld and Seskin's estimates for the value of a statistical life, and those estimates do include an estimated 1% annual increase in productivity.

One commenter suggested that a methodology based on earning power may overestimate the value of life where many deaths from foodborne illness are the very elderly, the immunocompromised and the terminally ill. This commenter also noted that while all deaths are tragic, from a strictly economic standpoint many of these tragic cases have little or no productivity left and in fact are utilizing resources at the rate of $3,000 to $12,000 or more dollars per month of maintenance.

The cost of illness methodology used by ERS does account for the fact that older individuals have lower remaining earning power than younger individuals. This difference was taken into account when estimating the costs of lost productivity for *salmonellosis* patients. Different Landefeld and Seskin estimates of the values of statistical life were used for the different age categories. The methodology used U.S. death certificate data to estimate that the average age for patients who die from salmonellosis is over 65 years. The concept of a statistical value of life accounts for the fact that older individuals may continue to work or be retired or be patients under long term health care.

3. Percentage of Foodborne Illness and Cost of Foodborne Illness Attributable to Meat and Poultry

The fifth column of Table 5 includes estimates on the percentage of foodborne illness attributable to meat and poultry products. A separate estimate has been developed for each pathogen. These estimates are based on outbreak data reported under the CDC Foodborne Disease Outbreak Surveillance System and on data from community-based and other epidemiologic studies. Major data sources are cited in the preamble to the final rule. An assumption is made in this analysis that the source of foodborne pathogens, i.e., meat and poultry versus dairy products, seafood, vegetable, etc., has no effect on the cost of illness. The Department is not aware of any data indicating that the severity of foodborne illness cases varies by source of pathogens.

Comments noted that the Department had increased the percentage of foodborne illness attributable to meat and poultry from the earlier rulemaking for safe handling labels. One commenter stated that the Department has not revealed any new information which would support such an increase.

At this time, data on incidence of foodborne illnesses and the percentage of cases attributable to different food items are limited. Estimates by pathogen have been made by experts at CDC and USDA, based on a variety of studies. However, these are, indeed, estimates: FSIS does not have exact numbers. The estimates in the 1993 **Federal Register** document were relatively crude, assuming that 100% of *Campylobacter* and *E. coli* O157:H7 cases, 96% of *Salmonella* cases, and 85% of *Listeria* cases were foodborne, and that, for all bacterial pathogens, a flat 50% of foodborne cases were attributable to meat and poultry. The 1995 document looked at the numbers in a somewhat more sophisticated way, evaluating each pathogen individually and, where appropriate, giving ranges for, first, percentage of cases which were foodborne, and, secondly, percentage of cases which were attributable to meat and poultry. Nonetheless, when all of the various percentages are multiplied out, estimates of total cases attributable to meat and poultry were remarkably similar, as shown below in Table 6.

TABLE 6.—PERCENTAGE OF FOODBORNE ILLNESS ATTRIBUTABLE TO MEAT AND POULTRY

Pathogen	Percentage of total cases attributed to meat and poultry [a] 1993 (percent)	Percentage of total cases attributed to meat and poultry, 1995 (percent)	Estimated total cases, 1993	Estimated total cases, 1995
Campylobacter	50	41–53	1,050,000	1,031,250–1,312,500
Salmonella	48	43–72	921,600	348,000–2,880,000
E. coli O157:H7	50	60	3,834–10,22	46,000–12,000
Listeria	43	43–48	649–672	763–884

[a] Reflects percentage of foodborne multiplied by percentage attributable to meat and poultry.

Most other comments related to the estimates on the percentage of foodborne illness attributable to poultry. Comments questioned the high incidence of poultry-related foodborne illness when even, as a commenter asserted, public health authorities tell consumers that the problem with poultry meat is not due to consumption because poultry is cooked. Comments questioned whether cross-contamination in the kitchens could possibly generate such high levels of foodborne illness. Related comments suggested that if cross-contamination was such a serious problem, the data would show more outbreaks and fewer single cases. Other comments suggested that the cost of salmonellosis attributed to poultry was high because of the high incidence of *Salmonella enteritidis* in eggs and requested that the Agency exclude any foodborne illness costs associated with eggs, because those issues are outside the scope of this rulemaking. Another comment cited an Australian finding that the *Campylobacter* strains that infect chickens are not the strains that primarily infect humans.

The Department agrees that undercooked poultry is not a primary cause of foodborne illness. The preamble to the proposal stated that the majority of salmonellosis results from cross-contamination. The best available estimates for foodborne illness do suggest that a high incidence of illness is attributable to cross-contamination in kitchens—both household kitchens and food-service establishments.

The comment suggesting that cross-contamination would have led to more outbreaks makes sense, if the available estimates on incidence were heavily

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based on outbreak data. However, as mentioned in the proposal, it is widely recognized that CDC outbreak data do not provide accurate estimates of foodborne disease incidence. The outbreak data are more useful in identifying factors that lead to illness and have been used to estimate proportions of illness attributable to specific food groups. They do not play a major role in the overall incidence estimates. The existing incidence estimates are for total cases including both individual cases and multiple cases. The methodology used does not distinguish between outbreaks and single cases. Just as there are unreported individual cases of foodborne illness, there are unreported cases where entire households or portions of households experience foodborne illness due to cross-contamination in household kitchens. As discussed above, the estimates of foodborne illness were derived from both CDC outbreak data and community-based epidemiologic studies.

The outbreak data (two or more individuals ill from the same source) are compiled by CDC from reports that are voluntarily submitted from state and local health authorities. The laboratory reporting system for *Salmonella* only captures information on those cases where a patient sees a doctor, the doctor collects a stool culture and sends the culture to a participating laboratory and the laboratory can perform the specific diagnostic test. The estimates for overall disease incidence are derived using both databases plus data collected from population-based studies in specific geographic areas. The current (initiative) collaborative surveillance project should improve the estimates in the future.

The comment referring to the Australian finding is referring to an article by Korolik, et al, published in the May 1995 issue of the Journal of Clinical Microbiology, entitled, "Differentiation of *Campylobacter jejuni* and *Campylobacter coli* strains by Using Restriction Endonuclease DNA Profiles and DNA Fragment Polymorphisms." The study was undertaken to determine if DNA fingerprinting technologies could identify strains of *Campylobacter* in chickens that cause disease in humans.

FSIS reviewed the article and concluded that the study did not refute U.S. epidemiologic studies showing that approximately 50% of human *Campylobacter* infections are due to poultry. To confirm FSIS's interpretation of the study, a staff member contacted the author, Dr. Victoria Korolik, in Australia. She confirmed that her study does not shed doubt on the role of poultry in human *Campylobacter* infections.

4. Pathogens Addressed by the Rule

While the proposed rule indicated that HACCP systems will be designed to control all public health hazards, the preliminary benefits analysis assumed that the primary benefits will come from controlling the three most common enteric pathogens of animal origin: *Campylobacter jejuni/coli, E. coli* O157:H7, *Salmonella* and one environmental pathogen *Listeria monocytogenes*. Two other pathogens—*Clostridium perfringens* and *Staphylococcus aureus* primarily become or create hazards in meat and poultry products as prepared in restaurants, other commercial kitchens, and in homes. Consequently, the proposed regulatory program, which focuses on the manufacturing sector, will not significantly affect the presence of these organisms on meat and poultry products.

The public comments did not address the assumption that the proposed rule would have the most impact on the four pathogens identified above and that benefits would be most appropriately discussed in terms of reducing the level of these pathogens. This final RIA will continue to assume that the HACCP-based regulatory program will have the most impact on the four pathogens identified in the preliminary analysis.

The preliminary benefits analysis also included an assumption concerning the percentage of the four pathogens that contaminate the meat and poultry supply at inspected establishments or grow from contamination that occurs at inspected locations. Based on the expert judgment of FSIS microbiologists, the preliminary benefit analysis assumed that 90 percent of the four pathogens result from contamination that occurs at inspected establishments.

The public comments did not directly address the estimate that slaughter and processing establishments are the source of 90 percent of enteric pathogen contamination. There were, however, a large number of comments that cited studies or estimates that show or indicate that the majority of foodborne illness can be attributed to improper cooking, recontamination and other mishandling and abuse in the food service and home environment. Many comments cited data presented in the 1994 CAST Report which "demonstrated" that only 6.9 percent of outbreaks were "attributable" to the food processing establishments. Other comments referred to "a well-recognized fact that 97 percent of the problems with foodborne illness occur outside the realm of state and federal inspection." Other comments attributed the 97 percent figure to a Special Report by the American Association of Meat Processors. These types of comments were presented in a manner indicating that the commenters believe that the data attributing "cause" to the food service or home environment directly contradicts the Agency's estimate that inspected establishments are the source of 90 percent of the four pathogens addressed by this rule.

In response, the Agency points out that the studies cited by commenters concluding that high percentages of foodborne illness are attributable to factors such as temperature abuse and mishandling do not conflict with either the assumption that slaughter and processing establishments are the source of 90 percent of enteric pathogen contamination or the assumption discussed later concerning the effectiveness of HACCP in reducing that contamination. Occurrence of foodborne disease is a multi-step process. The first, and critical, step is the introduction of a pathogen into or onto the raw product. If a pathogen is present, then subsequent temperature abuse or mishandling may permit bacterial counts to increase to levels which increase the likelihood that illness will occur; mishandling may result in cross-contamination of other foods which are not cooked before being eaten; or improper cooking may not kill all pathogenic bacteria present in the product. In these instances, it may be said that the illness was "caused" by improper handling. However, disease would not have occurred if the pathogen had not been present on the raw product in the first place.

The CAST study included a table showing factors contributing to the occurrence of 1,080 outbreaks occurring from 1973 to 1982. That table consisted of data from the CDC national foodborne disease surveillance system that was published in an article in the Journal of Food Protection by Frank L. Bryan in 1988. The CAST study and journal articles use terminology like "factors that contribute" and address the location or type of employee/consumer where any mishandling or mistreatment of food occurred. The focus of these studies is to enhance our understanding of the sequences of events and behaviors that lead to foodborne illness since behavioral modification for the food preparer and consumer at the end of the food chain may have the greatest impact on the incidence of foodborne disease. Many of the comments are written in a manner that blurs the distinction

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between factors in the kitchen that may permit an outbreak to occur from slaughter-origin contamination and those that would have caused an outbreak despite the absence of contamination of the raw ingredients.

The comments referring to the CAST study or directly to CDC estimates have not interpreted the Foodborne Disease Outbreak Surveillance Data correctly. The standard CDC foodborne disease outbreak report form does not include a question about whether the food processing industry was involved, and while many foodborne outbreaks have a chain of causation, investigators may differ in their assessment of the point or points in the chain to which primary responsibility for occurrence of the outbreak should be assigned.

The Bryan article used for the CAST study had the following summary concerning the role of food processing establishments: "Many of the animals that enter abattoirs are either infected or contaminated with foodborne pathogens and further spread occurs during processing. Hence, abattoirs and raw-product processing establishments must accept some of the blame of spreading salmonellae and other pathogens to many carcasses and pieces of meat. These products are major sources of pathogens for food-service establishments and homes where further abuse (e.g., inadequate cooking or cross contamination) leads to outbreaks of foodborne illness."

The comments have not provided any basis for changing the expert judgment of FSIS microbiologists that inspected establishments are the source of 90 percent of the four pathogens addressed by the final rule. This final benefits analysis is based on this assumption.

5. Effectiveness of the Rule in Reducing Pathogens

In accordance with the assumption that meat and poultry establishments are the source of 90 percent of the four pathogens addressed by the rule, the preliminary analysis calculated the benefits under a scenario where the proposed rule would eliminate essentially 100 percent of those pathogens that enter the meat and poultry supply at inspected processing establishments. In other words, for the preliminary analysis, FSIS calculated an estimate of maximum benefits by assuming the rule would eliminate 100 percent of the 90 percent.

By assuming this scenario, FSIS was not predicting that it believed that the rule would result in elimination of 100 percent of those pathogens in the manufacturing sector. Rather, the Agency was acknowledging that it has responsibility for having a food safety objective that recognizes the scope of the problem and attempts to reduce pathogens in that sector as much as possible, since without pathogens, no amount of subsequent abuse would result in foodborne illness.

By presenting a sensitivity analysis in the proposal, FSIS intended to clarify that the benefit estimates were a maximum and not a prediction of what is likely to happen. The distinction was unclear to many commenters who expressed doubt that the proposed HACCP program would result in a 90 percent reduction in pathogens. A large number of comments on the potential effectiveness of HACCP programs contrasted the FSIS estimates with those contained in the recent study by the Institute of Food Science and Engineering, Texas A&M University, titled "Reforming Meat and Poultry Inspection: Impacts of Policy Options," (hereafter referred to as the IFSE study). Both FSIS and IFSE estimates are useful as assumptions rather than as quantitative predictions of potential effectiveness of HACCP.

The ISFE study examined four policy options for addressing pathogens in the meat and poultry supply. One option called for mandatory HACCP for inspected slaughter and processing establishments and estimated that mandatory HACCP in inspected establishments would produce a 20 percent reduction in pathogens. The difference in the FSIS and IFSE estimates is not based on data but on assumptions for different "HACCP" scenarios.

The HACCP program scenario considered in the IFSE study did not assume a mandatory pathogen reduction performance standard. Requiring process control without a standard could lead to processes that are well controlled at unacceptable pathogen levels. The Agency would agree that such a situation would result in less pathogen reduction. FSIS believes that a standard is necessary to encourage innovation and provide the impetus for continuing improvement and increasing effectiveness. In estimating effectiveness, the IFSE study noted that "with experience and additional research, it is possible that higher levels of reduction in pathogens could be achieved * * *".

Another major difference between the two program scenarios is that the IFSE program does not include a prerequisite requirement for SOP's. SOP's could cover potential sources of enteric and environmental pathogens that are not be covered under a HACCP plan. However, as discussed in Section I, this analysis discusses benefits of SOP's in terms of increased productivity for inspection resources and clarity of responsibilities.

Several comments refer to the IFSE estimates as being more objective or "scientific" than those in the Agency's analysis. The IFSE authors characterize their own effectiveness estimates as "the consensus judgment of the task force" or "the most reasonable expectation." The IFSE estimates are judgments, as are the Agency's estimates.

A general comment related to the effectiveness issue stated that while HACCP remains an interesting theoretical concept, it is still only a concept that has never been tested on a meaningful scale under actual meat establishment conditions, and never proven to significantly improve the microbial quality of the finished product. Although HACCP has been tested in food processing establishments to the satisfaction of scientists, food technologists, and industry management to produce safe food, the Agency recognizes that the potential effectiveness of HACCP in reducing pathogens within a regulatory framework is unknown at the present time. FSIS conducted a pilot HACCP study in nine establishments from 1991 to 1993. Findings regarding pathogen reduction effectiveness were inconclusive. FSIS did not receive any data during the comment period from establishments currently operating HACCP systems. Rather than select an arbitrary effectiveness estimate, or use the maximum potential 100 percent estimate from the preliminary analysis, this RIA will present a range of effectiveness estimates and show the minimum level necessary to generate net benefits.

6. Estimated Reduction in Cost of Foodborne Illness

Several comments focused on the issue that the relationship between pathogen reductions at the manufacturing stage and foodborne illness reductions is unknown. The comments recognize that the proposal did acknowledge that little data exist on the relationship between pathogen levels and incidence of illness. One comment pointed out that FSIS recognized that the pathogen testing requirements that are part of the proposal will help to elucidate the relationship between pathogen contamination and foodborne disease. The commenter concluded that it did not seem reasonable for the Agency to rely on an assumption, whose very validity can only be tested by the implementation of the proposal under examination, to justify the proposal.

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Other commenters concluded that the Agency needed to develop better data or complete a thorough risk assessment that would establish the public health benefits of pathogen reduction before proceeding.

The comments asking for better data or requesting a thorough risk assessment are not comments on the cost-benefits analysis. These comments imply there is insufficient evidence to support new pathogen reduction efforts. This issue is addressed in the preamble to the final rule. The comments have made a policy judgment with which the Department does not agree.

For the benefits analysis included with the proposed rule, FSIS assumed that a reduction in pathogens will lead to a corresponding proportional reduction in foodborne illness. The Department notes that the IFSE study referred to favorably by many commenters used the same method for estimating public health benefits as did FSIS, i.e., a reduction in pathogens leads to a proportionate reduction in illness and death. The Agency is aware that the proportionate reduction method is an assumption that has not been tested or validated. However, the Agency also recognizes that research methodology for relating pathogen levels at establishments to incidence of illness is in its early developmental stages. Risk models for foodborne pathogens are likely to develop as the basis for regulatory decision-making in the future. The Agency believes the implementation of mandatory HACCP will improve food safety and protect public health while research in modeling risk associated with foodborne pathogens continues.

The Agency has and continues to support any effort to improve the quality of data and methodology available for risk assessment of illness caused by foodborne biological agents. FSIS, FDA, CDC, and local public health departments are collaborating with state health departments and local investigators at five locations nationwide to identify more accurately the incidence of foodborne illness, especially illness caused by *Salmonella* and *E. coli* O157:H7.

G. Summary

The final rule addresses four pathogens that are estimated to cause from $1.1 to $4.1 billion in annual illness and death costs attributable to meat and poultry products. The rule addresses 90 percent of that cost of illness or from $0.99 to $3.69 billion annually. FSIS recognizes that the actual effectiveness of the final requirements in reducing pathogens is unknown, and presents a range of benefits based on reducing varying percentages of the $0.99 to $3.69 billion in annual cost of foodborne illness addressed by this rule.

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V. Cost Analysis

A. Introduction

The final HACCP rule includes several regulatory components all directed at improving process control in meat and poultry operations in order to reduce the risk of foodborne illness associated with meat and poultry products. The requirements of the final rule are organized around the following three sections:

- Requirements that all inspected establishments develop and implement sanitation Standard Operating Procedures (SOP's) within 6 months.
- Requirements that all inspected establishments develop and implement HACCP programs within the 18 to 42 month time period following publication. Scheduling will be based on establishment size.
- Requirements that (1) all establishments slaughtering cattle, swine, chickens, or turkeys, or producing a raw ground product from beef, pork, chicken or turkey comply with new pathogen reduction performance standards for *Salmonella* and (2) all establishments slaughtering cattle, swine, chicken or turkeys implement microbial testing programs using generic *E. coli* within 6 months. Compliance with the pathogen reduction performance standards for *Salmonella* will be required at the time the establishment is required to implement HACCP.

This cost analysis is presented in three sections. The first section describes the methodology used in generating cost estimates. The next section addresses the regulatory flexibility designed to reduce the burden on small business. The last section presents the cost estimates for each regulatory requirement. For each broad requirement, the discussion of the cost estimates is organized using the following five topics:

- Summary of the requirements in the final rule identifying any changes from the proposal.
- Review of the cost estimates from the preliminary RIA.
- Summary of the comments related to the preliminary cost estimates.
- Response to the comments.
- Final cost estimates.

B. Methodology for Cost Analysis

The final pathogen reduction/HACCP rule includes regulatory requirements that are directed at improving the control over food processing operations. In general, compliance with these requirements requires expenditures of time, i.e., employee hours to develop plans, monitor critical control points, record findings and collect and analyze samples. This final RIA is based on time required by four categories of employees that were defined in the supplemental cost analysis. These include the following:

- Quality Control manager earning $25.60 per hour.
- Supervisors or QC technicians that review findings and records at $18.13 per hour.

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- Laboratory technicians earning $18.13 per hour.
- Establishment employees/ production workers that would monitor sanitation and HACCP programs or collect samples at $12.87 per hour.

The four categories of wages are based on 1993 data adjusted for 1994 dollar inflation from the Bureau of Labor Statistics and *Meat and Poultry Magazine* and include a 33 percent overhead requirement for benefits such as health insurance and retirement contributions. Unless otherwise noted, the analysis assumes that all establishments and employees work a standard 52 week, 260 day, 2080 hour work year.

This final cost discussion is based on retracing the steps and/or calculations of the preliminary analysis and discussing related public comments in the appropriate sections. Other comments that are related to the analysis but do not reflect directly on the methodology are summarized at the end of the analysis in Appendix A.

This analysis makes frequent references to the Enhanced Economic Database. In 1994, the Research Triangle Institute (RTI) took a compilation of existing FSIS databases containing establishment production or inspection data and added data on annual sales and employment from sources that incl. led Dun and Bradstreet and American Business List databases. Actual estimates for annual sales and number of employees were available for approximately 80 percent of the establishments. In other cases, estimates for sales and number of employees were developed using the employment/sales data for establishments producing the same type and volume of product.

The enhanced database includes production data (number of head slaughtered, pounds of product produced) from 1993 for all federally-inspected establishments in operation as of August 1994. The preliminary analysis and this final RIA combine 1993 production data with the population of federally and state-inspected establishments that were in operation as of August 1994. As of August 1994, there were 6,186 federally inspected and 2,893 state inspected establishments. These 9,079 establishments include a total of 11,719 "operations"—2,597 red meat slaughter operations, 364 poultry slaughter operations and 8,758 further processing operations.

This final analysis assumes a constant level of 9,079 inspected establishments. The analysis does not attempt to account for costs associated with exits from or entries into the marketplace. For operations that are entirely new, or include a new processing operation, the requirements for HACCP plans and sanitation SOPs will increase the one-time, up-front cost of entering the market. If marketplace entry involves the purchase of an existing business, the business will already have an existing HACCP plan and sanitation SOP. In these cases, the acquisition cost of the business would include the value of the existing HACCP plan and SOP.

There should be minimal additional cost for HACCP and SOP plan development for new construction that expands a firm by replicating an existing operation in a new location. This type of new establishment can apply HACCP and SOP plans that have been developed for a similar existing establishment. This analysis has assumed that each establishment is independent and has not reduced cost estimates to account for firms that operate several similar establishments.

The preliminary analysis developed cost estimates for three sizes of manufacturing establishments. Most of the costs that involve employee time are influenced by a number of factors including the physical size of the establishment, the volume of production, the type of production practices and the number or production lines. The preliminary analysis used the data on annual sales developed by RTI because the sales data correlated reasonably well with size and production volume data and the Agency had an estimate of sales for 6,186 federally inspected establishments.

For the preliminary analysis the Agency defined a large establishment as one with over $50 million in annual sales, a medium establishment as one with between $2.5 and $50 million and a small establishment as one with less than $2.5 million in annual sales. For calculating costs, the Agency collected data from the field based on these three size categories. Public comments provided good reason to change size definitions for implementation (regulatory flexibility) purposes and the Agency has done so for the final rule. This does not affect the accuracy of proposed or current cost estimates based on previously collected data. The final analysis uses the old categories for presenting cost data to facilitate comparisons and minimize confusion. To summarize, this cost analysis uses the terms high, medium and low volume producers for cost presentation that involves average establishment costs and uses the terms large, small and very small business for discussing regulatory flexibility. The cost and flexibility principles do not overlap in this analysis.

Commenters pointed out that in comparing total costs with the value of current production, the preliminary analysis did not address impacts on producers, i.e., the costs that would be passed back to livestock producers. FSIS recognizes that some costs will be passed back to producers in terms of lower prices for live animals and other costs will be passed forward in terms of higher consumer prices. Other costs may have to be absorbed by slaughter and processing establishments. Because the necessary knowledge of empirical cost structures and supply and demand elasticities is inadequate, FSIS does not offer any quantitative estimates of the distribution of costs of this rule on various sectors of the production and marketing chain. The aggregate cost estimate establishes an upper bound on the costs any sector might ultimately bear.

There are two types of potential costs that were not addressed in the preliminary cost analysis. The first type of cost is the cost of taking corrective action when routine monitoring of a CCP finds a deviation from a critical limit. The critical limit could be associated with assuring compliance with existing regulatory requirements or it could be a limit set to assure compliance with the new pathogen reduction standards for *Salmonella* or the criteria established for generic *E. coli*. Corrective action would also occur when FSIS would find a problem with either a HACCP plan or a sanitation SOP.

The second type of potential cost is related to the question of whether existing processing methods are adequate to meet the pathogen reduction performance standards for *Salmonella* and the criteria for generic *E. coli*. It is expected that some establishments will have to make permanent changes to their existing production practices to have a HACCP-based program that assures compliance with the new standards and criteria. The final rule raises a third type of potential cost when it outlines the Agency's plans for using the results of its own *Salmonella* testing program for regulatory purposes. Whether or not this testing leads to industry testing costs depends on whether the government testing indirectly forces an establishment to regularly conduct its own testing.

The preliminary analysis did address a fourth category of potential costs that includes the cost of necessary materials, such as thermometers and test kits, that establishments will need to

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systematically monitor their processes. Recognizing that the rule does not make any equipment obsolete, the preliminary analysis suggested costs of from $10 to $20 per establishment. These costs were not included in the overall cost summary.

Potential costs are addressed in this final analysis under Section V.D.2., Costs of Meeting Pathogen Reduction and Microbial Sampling Requirements.

C. Regulatory Flexibility

The Regulatory Flexibility Act (P.L. 96–354) requires analyzing options for regulatory relief for small businesses. This section reviews the regulatory relief provided in the proposal, responds to comments related to the definition of small business used in the proposal and summarizes the regulatory relief for small business provided for in the final rule. In Section II, this analysis addressed the option of providing an exemption for small business noting that comments on an exemption were mixed with a substantial number of comments from small businesses strongly opposing an exemption.

The proposed rule intended to spread the implementation of HACCP over a three year period. To minimize the burden on small establishments, they would be given a maximum time of 36 months to develop and implement their HACCP plans. A small establishment was defined as one with annual sales of less than $2.5 million.

The decision to use the above definition generated a large number of comments. "Very small" establishments commented that they could not compete with a relatively "large" business with annual sales of $2.5 million. For example one commenter stated that: "calling an establishment, small, that produces $2,500,000 worth of product annually is not fair to those establishments producing far less." Other comments suggested that by defining small at the $2.5 million level, the Agency demonstrated that it does not understand what a small business is. Comments from businesses with annual sales of $2.5 to $10.0 million or even $25.0 million stated that they should also be considered small businesses. Commenters also pointed out that other Federal agencies use different definitions. For example, one commenter noted that OSHA uses 50 employees as their criterion for a "small business." Others commented that FSIS should or must use the existing definition of fewer than 500 employees published by the Small Business Administration (SBA).

Several comments promoted a set of requirements distinguishing "small" from "very small" establishments. "Very small" establishments would only be required to implement the proposed provisions on sanitation standard operating procedures, antimicrobial treatment of carcasses, and time and temperature provisions. They would be exempt from routine microbial testing and long-term provisions of HACCP as long as annual sales do not exceed $1 million (not counting "pass through"). The establishments would still be subject to incidental sampling for microbial testing as determined by the Administrator. Required implementation of the three near-term initiatives would be 12 months after publication of the final rule.

The "small" establishments (between $1.0 and $2.5 million) would be required to implement SOPs, antimicrobial treatment, time and temperature provisions, and limited routine sampling, in proportion to the number of slaughtered animals and/or poundage of processed products. The establishments would still be subject to incidental sampling for microbial testing as determined by the Administrator. They would be exempt from long-term provisions of HACCP as long as annual sales, as defined above, do not exceed $2.5 million. The required implementation of all near-term initiatives would be six months.

There were other comments that suggested variations on the above definitions and requirements for "small" and "very small" establishments. For example, one State department of agriculture recommended the same requirements for "small" and "very small" establishments but suggested that size criteria based on head slaughtered or pounds produced would be more practical. Another State department of agriculture recommended that a "every small" plant be defined based on the number of employees (no more than 20 full-time), slaughter volume (no more than 2,500 animals per year), or processing volume (100,000 pounds of meat and/or poultry products per year). The recommendation suggested that a plant in this category would be required to implement the provisions of the proposed rule pertaining to sanitation SOP's and time-temperature requirements. Antimicrobial treatment of carcasses would be voluntary, and such a plant would be exempted from microbial testing as proposed. Implementation of a HACCP program would be initially voluntary, and phased in with considerations in the areas of documentation and record-keeping for the limited work force.

FSIS has considered the above regulatory framework for "small" and "very small" establishments. Some of the suggestions are no longer applicable because major provisions of the proposed rule have been dropped. FSIS believes it has addressed the other concerns in more appropriate ways.

FSIS was aware of SBA Size Standards during the development of the proposed rule. If FSIS used the size standard for meat and poultry "manufacturing" firms, over 94 percent of the federally inspected establishments would meet the criterion of having fewer than 500 employees. FSIS is also aware that there are six different SBA size standards that apply to the 6,415 FSIS official establishments. FSIS determined the SBA size standards by themselves are not appropriate for meeting FSIS's need to sequence HACCP implementation.

Table 7 shows the distribution of 6,415 official establishments by Standard Industrial Classification (SIC) code. The SIC codes were developed to promote the comparability of statistics describing various facets of the Nation's economy. The SIC codes were used as part of the Enhanced Economic Analysis Database developed by Research Triangle Institute to represent all FSIS inspected establishments. As can be seen from Table 7, a significant portion of official establishments are not in an SIC Code for manufacturing. Food manufacturing establishments have a 4-digit SIC Code beginning with 20. The Census of Manufacturers published by the Department of Commerce characterizes the meat and poultry manufacturing industry by summarizing data for SIC Code 2011—Meat Packing Establishments, SIC Code 2013—Sausages and Other Prepared Meats, and SIC Code 2015—Poultry Slaughtering and Processing. The SBA Size Standards in Table 7 are published in the Code of Federal Regulations—13 CFR, Chapter 1, Section 121.601.

In a written comment, the Office of Advocacy, Small Business Administration claimed that FSIS was wrong in concluding that one-third of federally inspected establishments would have the maximum time for compliance with HACCP requirements using the criterion of $2.5 million in annual sales. In supporting their claim, they cited U.S. Census Bureau data. However, Census data do not accurately describe the federally inspected meat and poultry industry. As shown in Table 7, the problem is that less than half of the firms are classified in the three 4-digit SIC Codes identified above that define meat and poultry manufacturing. FSIS addressed this data

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problem by contracting with RTI to develop a more accurate economic profile of federally inspected meat and poultry establishments.

TABLE 7.—ESTABLISHMENTS STANDARD INDUSTRIAL CLASSIFICATION

SIC code	Standard industrial classification	Number of establishments	Cumulative number of establishments	SBA size standard
2011 ...	Meat packing establishments	1,503	1,503	500 employees.
5147 ...	Meats and meat products	1,312	2,815	100 employees.
2013 ...	Sausages and other prepared meats	939	3,754	500 employees.
2015 ...	Poultry slaughtering and processing	438	4,192	500 employees.
4222 ...	Refrigerated warehousing and storage	356	4,548	$18,500,000.
5421 ...	Meat and fish markets	309	4,857	$5,000,000.
5144 ...	Poultry and poultry products	268	5,125	100 employees.
5141 ...	Groceries, general line	238	5,363	100 employees.
5812 ...	Eating places	156	5,519	$5,000,000.
2038 ...	Frozen specialities, nec	139	5,658	500 employees.
5142 ...	Packaged frozen foods	130	5,788	100 employees.
5411 ...	Grocery stores	95	5,883	$20,000,000.
5149 ...	Groceries and related products, nec	65	5,948	100 employees.
9999 ...	Not applicable	63	6,011	
2032 ...	Canned specialities	61	6,072	1,000 employees.
2099 ...	Food preparations, nec	55	6,127	500 employees.
Other	All other SIC codes	288	6,415	

Note: The Enhanced Economic Analysis Database uses the number of active establishments as of August, 1994 and identified 6,415 establishments as active official establishments. Of these 6,415, a total of 229 were identified as cold storage/ID warehouses, universities or churches. From the 6,415 total, 6,186 federal establishments were classified as processing, slaughter or combination operations. nec—(Not Elsewhere Classified).

The final rule provides for sequencing HACCP implementation by establishment size, using the SBA definition of a small manufacturing business, i.e., a small business is an establishment with fewer than 500 employees. Those establishments with 500 or more employees will be referred to as large establishments. In addition, in response to comments that there are hundreds of "very small" or "micro" establishments, the Agency will classify an establishment as "very small" if it has either fewer than 10 employees or annual sales of less than $2.5 million.

This sequencing of HACCP responds to a large number of comments requesting that small businesses be given a longer period of time to implement HACCP requirements. Many small businesses stated they did not want to be exempt, but asked for more flexibility in implementing HACCP. Some commenters specifically requested five, eight or 10 years to implement HACCP.

While the final rule does not provide for longer periods of five, eight or 10 years, it does substantially extend the implementation period for hundreds of small and very small establishments.

To illustrate, the proposed rule would have required HACCP plans in over 2,100 establishments producing raw ground product within 12 months. Under the final rule, over 1,800 of those establishments will have either 30 or 42 months to implement HACCP. The smallest 5,127 establishments (2,893 state and 2,234 federal) will have an additional six months. The proposed rule called for implementation of a HACCP system in all "small" establishments by 36 months; the final rule allows 42 months for the newly defined "very small" category.

Table 8 illustrates the distribution of 6,186 federally-inspected slaughter, processing, and combination establishments used for the sequencing of HACCP implementation in the proposed rule and in the final rule. There are 496 more establishments in the two smaller categories than there were in the proposal. As shown in Table 8, there are 353 large, 2,941 small and 2,892 very small federally-inspected establishments.

TABLE 8.—SIZE CATEGORIES FOR FEDERALLY INSPECTED ESTABLISHMENTS

Establishment category	Definition	No. of establishments
Proposed Rule		
High volume	>$50 million	849
Medium volume	$2.5–$50 million.	3,103
Low volume	<$2.5 million.	2,234
Total		6,186

TABLE 8.—SIZE CATEGORIES FOR FEDERALLY INSPECTED ESTABLISHMENTS—Continued

Establishment category	Definition	No. of establishments
Final Rule (Sequencing of HACCP)		
Large	≥500 Employees.	353
Small[a]	10–499 Employees.	2,941
Very small[b]	<10 Employees or <$2.5 Million.	2,892
Total		6,186

[a] New definition of small includes 2,445 establishments that were medium volume establishments plus 496 that were high volume for the preliminary analysis.

[b] New definition of very small includes the 2,234 establishments that were low volume establishments plus 658 that were medium volume establishments for the preliminary analysis.

D. Final Cost Estimates

1. Sanitation Standard Operating Procedures

a. Summary of Requirements. The final rule requires that all inspected establishments develop and implement Sanitation SOP's within 6 months after publication of the final rule. The proposed rule would have required the implementation of SOP's within 90

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days. To facilitate the development of SOP's and to provide maximum flexibility, the Agency will not prescribe any specific format or content but will provide guidelines to assist inspected establishments in developing written SOP's. There will not be any FSIS approval of the written documents. With the exception of the implementation schedule, the requirements for SOP's in the final rule are the same as those in the proposed rule.

b. Review of Preliminary Cost Estimates. The preliminary cost analysis identified separate costs for SOP plan development and SOP recordkeeping where recordkeeping was defined as observing or verifying procedures, recording findings, reviewing records and maintaining files. FSIS assumed that the Sanitation SOP's would be developed by a quality control manager at a cost of $25.60 per hour. FSIS estimated that it would cost an average of $128, $256 and $640 for low, medium and high volume establishments to develop Sanitation SOP's.

The preliminary cost analysis assumed that Sanitation SOP's observation and recording for low, medium and high volume establishments would take 15, 25 and 45 minutes per day by an employee earning $12.87 per hour and that supervisory review of records would take 5, 10, and 20 minutes by an employee earning $18.13 per hour. In developing these time estimates for recording and reviewing records, FSIS recognized that the time required would be influenced by a number of factors including the physical size of the establishment, the volume of production, the type of production practices and the number of production lines. The estimates are based on program judgement of the time required to conduct two sets of sanitation observations per day, one for preoperational sanitation procedures and one for operational sanitation.

Using the above inputs, the annual costs for recording and reviewing Sanitation SOP's records for low, medium and high volume establishments would be approximately $1,230, $2,180 and $4,080, respectively, based on a 260-day, 2,080 hour work year. These costs were adjusted upward to approximately $1,242, $2,204 and $4,104 to account for the cost of maintaining records.

The preliminary analysis also included training costs of $62, $155 and $372 for low, medium and high volume establishments. Instructing an employee in verification and recording procedures was assumed to take 2, 5 and 12 hours, respectively involving both a QC technician ($18.13 per hour) and a production worker ($12.87 per hour). Total training cost was, therefore, $31 per hour. Total per establishment Sanitation SOP's costs, as estimated in the preliminary analysis, are summarized in Table 9.

TABLE 9.—SUMMARY OF SANITATION SOP COSTS PER ESTABLISHMENT

[Dollars]

Establishment category	Plan development cost	Annual recordkeeping cost	Training cost	Total first year cost	Recurring annual cost
Low	128	1,242	62	1,432	1,242
Medium	256	2,204	155	2,615	2,204
High	640	4,104	372	5,116	4,104

Using the per establishment costs from Table 9, total aggregate costs were calculated for all inspected establishments as shown in Table 10. Establishments with an existing written sanitation program were assumed to have only 50 percent of the plan development costs because these establishments would have to modify an existing plan rather than start from the beginning. Establishments with existing sanitation plans include the 287 establishments with TQC programs and 46 slaughter establishments with PQC sanitation programs. It was also assumed that these 333 establishments would not require training to implement a sanitation SOP.

TABLE 10.—COSTS OF SANITATION SOP'S

[Dollars in thousands]

Establishment category	No. of establishments	First year costs	Recurring costs
High	849	$4,276	$3,484
Medium	3,103	8,079	6,839

TABLE 10.—COSTS OF SANITATION SOP'S—Continued

[Dollars in thousands]

Establishment category	No. of establishments	First year costs	Recurring costs
Low	2,234	3,185	2,775
Subtotal	6,186	15,540	13,098
State	2,893	4,143	3,593
Total	9,079	19,683	16,691

Note: For preliminary RIA, all State establishments were assumed to be low volume establishments.

c. Comments on Preliminary RIA. Comments on proposed requirements for sanitation Standard Operating Procedures (Sanitation SOP's) focused on the cost of recordkeeping. In the preliminary cost analysis, recordkeeping included observation (i.e., verifying the procedures), recording findings, supervisory review of records and maintenance of files. One commenter stated that the cost of recordkeeping for their company would be approximately $10,000 annually.

A state inspected establishment, currently participating as a pilot establishment for HACCP/sanitation plans in their state program, indicated that they spend several hours each week verifying procedures and have weekly costs of at least $50 to keep the paperwork for their sanitation plan current. Their annual cost for keeping paperwork current would, therefore, be at least $2,600. This state establishment also stated that they had used an estimated $3,000 to $4,000 designing an SOP and that was with the assistance of two universities, several suppliers and their state inspection program. It took nine months to put the plan together.

Comments at public hearings indicate that there is a lot of uncertainty as to what FSIS expects in Sanitation SOP's. At one of the public hearings the owner of a "small" establishment stressed the importance of guidance and training with respect to what is expected in terms of recordkeeping.

d. Response to Comments.

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The Agency recognizes that the costs reported by the state establishment participating in a pilot program are substantially higher than the costs used in the preliminary analysis. The reported development time of nine months is also longer than the allowed implementation period. FSIS believes that the reported pilot project involving two universities, several suppliers and a state program has far exceeded the expectations of the rule. The same is true for the comment suggesting recordkeeping costs of $10,000 per year.

FSIS has now developed model Sanitation SOP's and a guideline for developing Sanitation SOP's. These documents should clarify FSIS expectations. FSIS believes that these documents are consistent with the cost estimates used in the preliminary analysis.

There is some reason to believe that the estimated cost for Sanitation SOP's in the preliminary analysis is conservative, that is, a possible overstatement of costs. Whether the costs associated with Sanitation SOP's are totally new or just how they may be modified over time can only be determined in individual establishment situations. For example, task verification and recordkeeping are costs that can be reduced through efficient management and allocation of resources and should decrease with experience. In many cases the tasks can be integrated with current duties.

For many establishments, the cost of Sanitation SOP's should be offset by changes in the approach to sanitation. Under current procedures, slaughter operations can not begin until inspection personnel have given their approval. Under the new procedures all establishments will be able to commence daily operations without USDA approval upon successful completion of the preoperational portion of their Sanitation SOP. When operational sanitation problems are identified, corrected and documented as they occur by the establishment, establishment officials will spend less time interacting with inspectors or responding to inspection findings. For example, federally inspected establishments currently provide written responses to approximately 700,000 to 800,000 Processing Deficiency Records (PDRs) per year. Over 70 percent of these PDRs are for sanitation deficiencies.

Finally, while FSIS recognizes that keeping sanitation records will be a new task, FSIS does not necessarily view the time spent verifying sanitation procedures as a new regulatory cost. FSIS is not changing any sanitation requirements. It is also true that FSIS has had an ongoing problem getting all establishments to comply with existing sanitation requirements. It can, therefore, be argued that some establishments have not conducted the necessary verification to assure compliance with existing regulations or have used FSIS employees to conduct sanitation verification.

e. Final Cost Estimates. After considering the comments, FSIS does not see a need to adjust the cost estimates shown in Tables 9 and 10. The final aggregate cost estimates for SOP's are those shown in Table 10. The costs in Table 10 assume that the requirement for SOP's does not lead to new compliance costs associated with new regulatory obligations apart from paperwork and recordkeeping. The analysis assumes that satisfactory sanitation is achieved one way or another under current procedures and that the changes that will occur with SOP's have more to do with issues of responsibility and efficient use of inspection resources. It follows that, for the most part, this provision of the rule will have no direct effect on the rate, extent or severity of pathogenic contamination, and thus will also have no effect on the rate, extent, or severity of foodborne illness. This is not saying there will be no change in establishment or employee conduct. In fact, FSIS expects to see more sanitation activities conducted at the firm's initiative rather than following inspection findings.

2. Costs of Meeting Pathogen Reduction and Microbial Sampling Requirements

a. Summary of Requirements. The final rule implementing HACCP-based programs establishes pathogen reduction performance standards for *Salmonella*. The rule both establishes the standards and defines the procedures the Agency will use to measure and assure compliance with the standards. The rule does not specify a minimum testing requirement for *Salmonella*. The pathogen reduction performance standards apply to an estimated 5,522 inspected establishments, 2,682 establishments that slaughter cattle, hogs, chicken or turkeys and another 2,840 establishments that do not slaughter, but produce raw ground product from beef, pork, chicken or turkey. If an establishment slaughters two species, e.g. cattle and hogs, the establishment would be subject to the standards for both cattle and hogs. The Agency's testing program would, however, be directed at the predominant species. If an establishment both slaughters and processes a raw ground product from that same species, the Agency will test the ground product. If an establishment produces more than one variety of ground product, the Agency intends to sample each.

The proposed rule included the same standards but contained a different approach for enforcement. The proposed rule included the requirement that each of the 5,522 affected establishments would collect and analyze one sample for each species or variety of raw ground product for *Salmonella* on a daily basis. The establishments would maintain records from these tests that would be reviewed by inspection program personnel to determine compliance. The proposed rule did not include a discussion of how the Agency would use the test results in a program for regulatory enforcement.

Under the proposal, the results from each establishment's *Salmonella* testing program were also to be used as a measure of process control. This final rule requires that all 2,682 slaughter establishments implement sampling programs using generic *E. coli* as a measure of process control for slaughter and sanitary dressing procedures.

b. Review of Preliminary Cost Estimates. As discussed earlier under methodology, the preliminary RIA did not attempt to analyze the overall impact of complying with the new pathogen reduction standards. The preliminary RIA did include a detailed analysis of the costs associated with the requirement that slaughter and raw ground processing establishments collect and analyze samples for *Salmonella* on a daily basis. The laboratory analysis required only a positive-negative finding, i.e., the proposed rule did not require the analysis necessary to determine the number of bacteria present in the sample. The cost of meeting the proposed requirement would vary depending on whether or not the establishment had an inhouse laboratory. It was assumed that approximately 20 percent of samples would be collected in establishments with in-house laboratories. For an establishment without a laboratory the total cost for each sample was estimated as shown in Table 11.

TABLE 11.—COST OF A SALMONELLA SAMPLE ANALYSIS FOR ESTABLISHMENTS WITH NO IN-HOUSE LABORATORY

(Dollars)

Component	Cost
Average Private Laboratory Cost	22.50
Shipping	7.00

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TABLE 11.—COST OF A SALMONELLA SAMPLE ANALYSIS FOR ESTABLISHMENTS WITH NO IN-HOUSE LABORATORY—Continued

(Dollars)

Component	Cost
Collecting and Packaging	3.75
Total	33.35

The establishment without an in-house laboratory would also be required to train an individual to perform aseptic sampling. The cost components for a *Salmonella* test at an in-house laboratory were estimated for the preliminary RIA as shown in Table 12.

TABLE 12.—COST OF A SALMONELLA SAMPLE ANALYSIS FOR ESTABLISHMENTS WITH AN IN-HOUSE LABORATORY

[Dollars]

Component	Cost
Laboratory Supplies	5.90
Collecting and Preparing Sample	5.28
Laboratory Analysis (0.5 hours at $18.13 per hour)	9.07
Total	20.25

Since the requirements in the final rule have changed substantially, this section will present only a brief summary of what was a relatively complex analysis to estimate the total industry sampling costs associated with the proposed requirements. The costs associated with the proposed *Salmonella* testing requirement are summarized in Tables 13 and 14. Table 13 shows the different cost components.

TABLE 13.—COMPONENT COSTS FOR MICROBIAL SAMPLING AS PROPOSED

[$ Thousands]

Establishment category	Training for aseptic sampling	Sampling plan development	Sample collection and analysis	Recording and review time
High	10	508	5,267	242
Medium	514	1,473	20,555	887
Low	604	959	18,624	606
Subtotal	1,128	2,939	44,446	1,735
State	998	1,588	21,150	688
Total	2,126	4,527	65,597	2,423

TABLE 14.—AGGREGATE COSTS OF MICROBIAL SAMPLING AS PROPOSED

[$ Thousands]

Establishment category	Number of raw product operations	First year costs	Recurring costs
High	793	6,027	5,509
Medium	2,301	23,429	21,443
Low	1,498	20,792	19,230
Subtotal	4,592	50,248	46,181
State	2,481	24,424	21,838
Total	7,073	74,672	68,020

Note: All state establishments were assumed to be low volume producers. Columns may not add to totals due to rounding.

Table 14 summarizes the first year and annual recurring costs. Training and sampling plan development costs are one-time first year costs. Sample analysis and recording costs are both recurring annual costs. The following notations help characterize the estimated costs from the preliminary analysis:

- Training and plan development costs were based on a total of 7,073 raw product operations. This total is based on a count of meat slaughter, poultry slaughter and raw ground processing operations. Sample collection and analysis and recording and record review costs were based on a count of 8,329 species-specific operations, i.e., the total of beef slaughter, pork slaughter, raw ground processing, etc. Thus, an establishment with beef slaughter, pork slaughter and raw ground processing would count as two operations for training and plan development, but three operations for sampling and recordkeeping.
- The proposed requirement of one sample per day per species resulted in low volume federal establishments and state establishments accounting for over 60 percent of the estimated first year costs (See Table 14).
- The analysis underestimated costs in that with existing data it was necessary to assume that the 3,029 establishments with raw ground product operations produced only one product. The proposal would have required 2 samples per day if an establishment produced both raw ground beef and raw ground pork on a daily basis.
- The analysis overestimated costs in that it counted operations for minor species or kind (e.g. sheep and goats). The proposal did not cover sheep, goats, equine, ducks, geese, etc.
- The analysis overestimated costs in that it assumed that every establishment

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with multiple operations was running each operation every day (260 days per year).

• Each of the 7,073 operations would require a sampling plan—25 hours for a QC manager at $25.60 per hour for a total of $640 per plan. At $640 per plan, 7,073 plans totaled $4.53 million as shown in Table 13.

• The analysis assumed that 5,275 (approximately 75 percent) of the 7,073 operations would have to train an individual to perform aseptic sampling. The total of 5,275 includes all 1,498 low volume raw operations, 1,275 (55.4%) of the 2,301 medium volume raw operations, 25 (3.2%) of the 793 high volume operations and 2,477 (99.8%) of the State inspected raw product operations. Training was estimated at $403 per operation—8 hours with a trainer at $37.50 per hour and a trainee at $12.87 per hour. Training for 5,275 operations at $403 per operation would cost $2.13 million as shown in Table 13.

• Recording and review time was estimated at 5 minutes per day for each of the 8,329 species-specific operations. Five minutes per day equals approximately 21.7 hours per year or an average of approximately $291 per year per operation based on wages of $18.13 and $12.87 per year (average of $13.43). The total is $2.42 million as shown in Table 13. Since the requirement was one sample per day per species, the cost estimates could also be viewed as 5 minutes per sample.

c. Comments on the Preliminary RIA. Similar to the preliminary analysis, the public comments focused on the cost of required *Salmonella* sampling and did not address the overall impact of meeting the proposed pathogen reduction performance standards for *Salmonella*. The proposed regulation would have required daily sampling for each species or kind slaughtered and each type (meat or poultry) of raw ground product per establishment per day. Comments from individual establishments indicated that some small establishments could be required to take 5 or more samples per day. A "small" establishment currently slaughtering three different species (beef, swine and lamb) and producing multiple raw ground products estimated they would need approximately 2,200 samples per year at a cost of approximately $77,000 per year. That is over eight per day based on a 260 day work year. A "small" ground meat processing establishment estimated they would need over 500 samples from approximately 350,000 pounds of annual production.

Several comments from "small" establishments pointed out that the proposed sampling program placed a disproportionate burden on small establishments from two perspectives. First, "small" establishments have less production over which to spread the cost of sampling. Second, smaller establishments tend to be the ones that slaughter more species or kind and produce more varieties of raw ground product. Other comments pointed out that the proposed *Salmonella* testing would not provide a good procedure to validate process control.

There were also comments that referred to the cost of the product that is lost or damaged during sample collection. A turkey processor noted that the value of a 40 pound tom is $63.60 at wholesale price. The same comment pointed out that shipping costs could be very high, especially if next day service is required.

Several comments noted that the IFSE study estimated costs for microbiological testing that were far higher than the cost estimates provided by FSIS. Another commenter noted that microbiological testing is being proposed to correct a deficiency of an inspection system that is currently unable to detect microbial contamination of meat. If mandatory inspection is a federally funded program, why not the "correction" of the system?

Most of the comments referred to the cost of the proposed requirement and were not comments on the methodology used to determine costs in the preliminary analysis. One comment that did address the cost methodology had calculated the cost of a *Salmonella* test at $38.00 to $44.50 per test where FSIS used a cost of approximately $33.00 to $34.00. There was some confusion concerning the proposed requirements. Some comments indicated the establishments believed that they would have to test every product line. Other comments based estimates on a far costlier test for *Salmonella* indicating they assumed the test would require information concerning the number of bacteria present, not just a positive-negative result.

There were also comments that suggested that FSIS has overestimated the cost of microbial sampling because, as the amount of laboratory analysis increases, the cost per sample will probably decrease. Other commenters pointed out that demand will lead to simpler and less costly new methods development.

d. Response to Comments. The changes in the final rule eliminate the issues raised by most of the comments. The comments concerning the burden on "small" establishments made a convincing argument that "small" establishments could not afford to implement the microbial sampling program as proposed. The final rule does not include a minimum testing requirement for *Salmonella*. Each individual establishment can conduct the level of testing they deem necessary to provide assurance that they are meeting the pathogen reduction performance standards for *Salmonella*.

The Agency agrees with public comments and conclusions reached at technical conferences that the proposed *Salmonella* testing would not have provided a good measure of process control. The final rule requires that all slaughter establishments implement testing programs using generic *E. coli* to validate control of slaughter and sanitary dressing procedures. After reviewing all public comments and other materials made available during the comment period, FSIS concluded that using generic *E. coli* is more practical. Generic *E. coli* is generally present in the feces of mammals and birds and is, therefore, an excellent indicator of fecal contamination. It has a higher frequency than *Salmonella* and can be tested and quantified relatively less expensively and, therefore, provides a more efficient measure of control of slaughter and sanitary dressing procedures. Testing for generic *E. coli* is also easier for in-house establishment laboratories.

By basing *E. coli* sampling programs on production volume, the Agency is responding to small establishment concerns over equity of the regulatory burden. In addition, establishments with very low production will be required to conduct sampling for only a limited time period each year. Sampling will only be required for slaughter establishments. Establishments slaughtering more than one kind of poultry or species of livestock will be required to sample only the kind or species representing the most production. There will also be provisions for decreasing the number of samples after implementation of HACCP plans and provisions for using alternative generic *E. coli* sampling programs in cases where the establishment can present data demonstrating control of slaughter and sanitary dressing procedures.

The comments referring to the value of lost product identified a cost that was not addressed in the preliminary analysis. Such costs will not be a factor for the final rule because beef and pork samples collected by FSIS will use the wet sponge swab technique and poultry samples will be collected using a whole

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bird rinse. In both cases, no product will be damaged or lost.

With respect to comments referring to high microbial sampling costs identified by the IFSE study, FSIS notes that the Agency's preliminary cost estimates were based on the proposed regulatory requirement of one test per species (carcass or raw ground product) per day for *Salmonella*. The IFSE study based their per establishment costs on a microbiological testing program currently being used in a beef slaughter establishment. The cost estimates generated by the IFSE study were not related to the testing program outlined in the proposed rule.

The comments were correct that FSIS based the preliminary cost analysis on existing laboratory methods and on current laboratory cost estimates. The comments suggesting less expensive methods are only speculative. There is no way to estimate potential new methods. While there is no way to predict the effect of increased demand on costs, it seems reasonable to expect that, in the long run, laboratory analysis costs per sample will go down as more firms implement microbial sampling programs. FSIS notes that short run costs could actually increase as demand goes up faster than the supply of laboratory capability. In the long run, however, establishments should benefit from quantity discounts and lower fixed costs per sample as the total number of analyses increases.

e. Final Cost Estimates. The final rule requires that all establishments slaughtering cattle, hogs, chickens or turkeys or producing a raw ground product from these species or kind meet a new pathogen reduction performance standard for *Salmonella*. This requirement applies to an estimated 5,522 establishments as shown in Table 15. Because the standard has been established using the baseline studies that estimate a national prevalence by carcass, the Agency does not have an estimate for the number of establishments that are currently meeting the standard. The baseline studies do not provide data on how pathogen levels vary between establishments and include data from only the larger establishments that represent most of the production.

TABLE 15.—ESTABLISHMENTS AFFECTED BY THE PATHOGEN REDUCTION PERFORMANCE STANDARD

Category	Very small	Small	Large	Total
Cattle and hog slaughter	1,876	376	66	2,318
Poultry slaughter	100	121	143	364
Raw ground processing	1,413	1,358	69	2,840
Total	3,389	1,855	278	5,522

This analysis of how the *Salmonella* standards will impact the 5,522 establishments will, by necessity, be primarily a qualitative discussion. The analysis will, however, develop two scenarios that can be used to present a range of potential impacts.

Since the focus of this rule is about reducing pathogens in or on raw meat and poultry products, it is anticipated that the potential costs are greatest for those slaughter establishments that are currently not meeting the new pathogen reduction performance standards. For slaughter establishments, the potential costs take one of two forms.

First, even though the rule does not require establishments to test for *Salmonella*, the Agency recognizes that some establishments may conduct their own *Salmonella* testing programs to avoid failing a series of tests conducted by the Agency. Thus, it can be argued that the Agency's intent to implement establishment specific testing for *Salmonella* is indirectly requiring the industry to routinely monitor their *Salmonella* levels to assure they will be in compliance.

The manner in which FSIS will implement its *Salmonella* testing program should help keep establishment costs down. During the first phase, referred to as pre-implementation testing, FSIS will test product from each slaughter or raw ground operation and share those results with the establishment. Thus, before FSIS begins the actual enforcement of the *Salmonella* performance standards, the Agency will provide each establishment with a status report on *Salmonella* incidence. This pre-implementation testing will precede HACCP implementation, which occurs from 18 to 42 months after publication of the final rule. The pre-implementation results will assist the establishments in preparing for implementation of HACCP and the pathogen reduction performance standards. Establishments with low incidence of *Salmonella* will have some level of assurance that they are already meeting the new *Salmonella* standards.

The second type of potential cost relates to the question of whether firms will have to make permanent changes in their processing or production practices in order to comply with the pathogen reduction performance standards for *Salmonella*. Reducing pathogens for slaughter establishments involves either modifying the incoming animals or birds, improving the dressing procedures so as to reduce contamination during procedures such as hide removal and evisceration, or using interventions such as antimicrobial treatments to kill or remove the pathogens following contamination. For many establishments, the process of implementing HACCP programs may, by itself, improve the dressing procedures sufficiently to meet the new standard. Other establishments may have to choose between slowing production lines, modifying some attribute of their incoming live animals or birds, or adding post-dressing interventions such as the new steam vacuum process or antimicrobial rinses.

This analysis will examine the two types of costs for the three industry segments of poultry slaughter, meat slaughter and raw ground processing. The analysis develops two cost scenarios to estimate the impact of the new pathogen reduction standards for *Salmonella*. As discussed earlier, the Agency does not have an estimate for the number of establishments that are currently meeting the standards.

The two cost scenarios are based on three general premises. The first premise is that a certain portion of large establishments will take whatever action is necessary to provide assurance that they are meeting all regulatory requirements. The second premise is that the establishments that are typically having problems controlling operations today will also have problems meeting the *Salmonella* standards. The low cost scenario is based on these first two premises. FSIS has historically found serious control problems in from 5 to 10

percent of establishments. The recent 1,000 establishment review found serious control problems in 8.9 percent of 358 randomly selected establishments. The 1993 review of establishments with the New Turkey Inspection System found 3 of 26 establishments with problems with product ready for shipment. A 1991–1992 survey of poultry reprocessing found that while only 2 percent of poultry is reprocessed off-line, from 5 to 10 percent of the establishments had very high reprocessing rates.

The high cost scenario is based on a third premise that (1) approximately half of the affected establishments are currently not meeting the standards and that (2) most large establishments and the majority of smaller establishments will take some action to assure compliance with the *Salmonella* standards.

As shown in Table 15, there are 2,318 cattle or swine slaughter establishments that must meet the pathogen reduction performance standards for *Salmonella*. The Agency does not have information that would indicate that *Salmonella* testing is routinely conducted by a major segment of the beef or pork industry. The baseline studies have shown a one percent positive rate for steers and heifers and a 2.7 percent positive rate for cows and bulls. In addition, the Agency does not know how, or if, beef and pork establishments would respond to the Agency's *Salmonella* testing initiative. Given the relatively low levels of *Salmonella*, most establishments will probably choose to depend on the assurance provided by a validated, well functioning HACCP program.

To develop a low cost scenario, the Agency assumes that the 66 large establishments would initiate daily testing using in-house laboratories ($20.25 per analysis—$347,490 per year) and that half of the 376 small establishments would conduct weekly testing at outside laboratories ($33.35 per analysis—$326,030 per year). Under a high cost scenario, the large establishments would conduct 8 tests per day ($2.78 million per year), the small establishments would all conduct one test per week ($652,059 per year) and half (938) of the very small establishments would conduct a test each month ($375,388 per year). The low and high *Salmonella* sampling costs for cattle and hog slaughter operations are summarized in Tables 16 and 17, respectively.

Beyond testing, there is the issue of whether the required actions of developing and implementing process control procedures will, by themselves, be sufficient to meet the *Salmonella* standards or whether changes in processing methods will also be required. FSIS recognizes that beef and pork dressing procedures involve a lot of manual steps and, therefore, it is reasonable to assume that substantial pathogen reduction can be accomplished through training and careful monitoring of the dressing procedures. This is especially true for the low volume establishments that do not have automated lines and use what is known as the "bed kill" dressing process.

For slaughter establishments that do have to make process modifications, there are several options available. First, FSIS is aware of establishments that are testing live animal washing systems. Second, the preliminary analysis included estimates for the cost of using different antimicrobial treatments for varying sizes of cattle or hog slaughter establishments. The lowest cost option was a hot water spray system with no cabinet. The cost for that system was estimated at $.08 per carcass or approximately $8.78 million annually for all cattle and hog establishments. In contrast, a pre-evisceration acid spray system with both a pre-wash spray cabinet and a sanitizing cabinet was estimated at $.79 per carcass for a low volume establishment. A TSP system for cattle was estimated at $.85 per carcass for a low volume establishment.

The preliminary analysis noted that 23 establishments were already using acetic or lactic acid sprays on carcasses either before or after evisceration. Other establishments had requested approval for citric acid, TSP, or hot water.

Third, FSIS has now approved the new steam vacuum systems for beef and pork operations. The installation of a steam vacuum system is estimated at $10,000 per establishment, with expectations that increased use will result in lower prices. Annual increased utility costs to run a steam vacuum system are estimated at $4,000. Maintenance cost is estimated at 5 percent or $500 per year.

For a low cost option, it is assumed that 10 percent of the large establishments must install a steam vacuum system to meet the new requirements and that half of 376 small establishments must use a hot water rinse at $.08 per carcass. The initial costs for the steam systems would be $70,000. Annual operating costs would be $31,500. Annual operating costs for hot water rinses on half the small establishment production would be $915,000.

Under a high cost option, it is assumed that half (33) of the large establishments would have to install steam systems and that all small and very small establishments would use hot water rinses. The initial cost for steam systems would be $330,000. Annual operating costs would be $148,500. Annual costs for hot water rinses would be $2,075,387. The low and high process modification costs for cattle and hog slaughter operations are summarized in Tables 16 and 17, respectively.

As shown in Table 15, there are an estimated 2,840 establishments that produce raw ground products using ingredients from other establishments. These establishments do not have the same opportunities to reduce *Salmonella* levels as do slaughter establishments. They can control growth by avoiding temperature abuse and can limit cross-contamination, but basically they must depend on the *Salmonella* levels of their incoming product in order to meet the performance standards. These establishments may choose to test incoming product in order to eliminate suppliers whose product is found to be positive. Larger establishments that are important customers of other suppliers may choose to include pathogen requirements in their purchase specifications.

For a low cost scenario, this analysis assumes that the 69 large firms would analyze one sample per day using in-house laboratories ($20.25 per analysis) and that 10 percent (136) of the small firms would test one sample per week using an outside laboratory ($33.35 per analysis). Under a high cost scenario, this analysis assumes that half (679) of the small firms would test one sample per week and that the large firms would double their sampling. Under each scenario, it is assumed that the large establishments would begin testing 12 months after publication and the small establishments 24 months after publication. These starting dates correspond with the end of the Agency's pre-implementation testing. The low and high *Salmonella* sampling costs for raw ground processors are summarized in Tables 16 and 17, respectively.

As shown in Table 15, there are 364 poultry slaughter operations that will be required to meet the new pathogen reduction performance standards for *Salmonella*. FSIS believes that almost all of the larger establishments in the poultry industry currently conduct routine or periodic analyses for *Salmonella* and will use their ongoing testing programs to (1) establish and validate their HACCP controls to assure they will initially comply with the new pathogen reduction performance

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standard, and (2) periodically verify continuing compliance. Therefore, the costs for additional *Salmonella* testing in the poultry industry will be minimal.

For cattle and hog operations, this analysis used the cost of antimicrobials from the preliminary analysis in estimating possible process modification costs. In contrast, for the poultry industry, meeting the pathogen reduction performance standards is clearly not analogous to meeting the proposed antimicrobial requirement. The preliminary analysis assumed that 90 percent of all high volume poultry processors and 70 percent of all low or medium volume processors already meet that proposed requirement.

FSIS recognizes that many poultry establishments may have to modify existing procedures to meet the new standards for *Salmonella*. Where cattle and hog dressing operations still include many manual procedures that can be easily controlled by improved training and monitoring, the poultry slaughter industry is highly automated, increasing the probability that process control may require modifications of equipment, facilities, or incoming product. However, because there is extensive vertical integration in the poultry industry, many firms have the added option of controlling *Salmonella* in the live birds. There is evidence that controlling *Salmonella* in feed and controlling rodents in poultry houses can have a substantial impact on the level of *Salmonella* in birds entering the slaughter facility.

In the late 1980's, FSIS tested some alternative processing methods at an establishment in Puerto Rico. Two methods included a counterflow scalder and a hot rinse immediately following the scald tank. At the time, FSIS recognized that it may be expensive to retrofit an existing establishment with a counterflow scalder because of the physical space and plumbing required.

Recognizing that other options are available, this analysis develops potential cost estimates based on the addition of TSP rinses. TSP rinse systems for the poultry industry are relatively expensive. It is currently estimated that a TSP installation would cost $40,000 per line with an operating cost of $0.003 per broiler or $0.014 per turkey.

As a low cost option, FSIS assumes that 36 large poultry establishments (27 broiler and 9 turkey establishments) will add TSP systems. Average broiler production is estimated at 35 million and average turkey production at 6 million. Annual average operating cost are, therefore, $105,000 for a chicken slaughter operation and $84,000 for a turkey slaughter operation. Each large poultry establishment is assumed to have 2 lines. Small establishments were assumed to average 1.5 lines.

As a high cost option, FSIS assumes that 182 (100 large and 82 small) poultry establishments will have to add TSP systems to meet the new requirements. The 182 establishments include 136 chicken and 46 turkey slaughter establishments. The total low cost scenario for poultry slaughter operations is summarized in Table 16. The high cost scenario is summarized in Table 17.

TABLE 16.—SALMONELLA TESTING AND PROCESS MODIFICATION COSTS

[Low Cost Scenario—$000]

Industry sector cost category	Year 1	Year 2	Year 3	Year 4	Year 5+
Sampling by Raw Ground Processors	0	363	599	599	599
Process Changes for Cattle and Hog Slaughter Operations	0	86	489	947	947
Sampling by Cattle and Hog Slaughter Operations	0	347	674	674	674
Process changes for poultry slaughter operations	0	4,676	3,591	3,591	3,591
Total	0	5,472	5,353	5,811	5,811

TABLE 17.— SALMONELLA TESTING AND PROCESS MODIFICATION COSTS

[High Cost Scenario—$000]

Industry sector cost category	Year 1	Year 2	Year 3	Year 4	Year 5+
Sampling by raw ground processors	0	$727	$1,904	$1,904	$1,904
Process changes for cattle and hog slaughter operations	0	404	1,063	2,101	2,224
Sampling by cattle and hog slaughter operations	0	2,780	3,807	3,807	3,807
Process Changes for Poultry Slaughter Operations	0	12,988	18,979	18,144	18,144
Total	0	16,899	25,753	25,956	26,079

After the initial implementation years, the annual cost for all three industry sectors is approximately $5.8 million for the low cost scenario. Under the high cost scenario, the total recurring industry cost of meeting the new performance standards is $26.1 million per year.

The high and low cost scenarios have addressed the potential costs of process modification when establishments find they are not meeting critical limits set to assure compliance with the new pathogen reduction standards for *Salmonella*. While the scenarios have addressed permanent process modifications, it is also reasonable to assume that meeting the *Salmonella* standards would involve some day-to-day process adjustments, i.e., corrective actions that do not involve adding new procedures or new equipment. One example would be the decision to reduce line speeds on a day when the incoming live animals are particularly dirty. The Agency believes that many establishments already take this type of precautionary action.

Under HACCP, there will presumably also be some costs associated with corrective actions related to critical limits set for the purpose of meeting existing regulatory limits. As discussed earlier under methodology, the preliminary analysis did not include any costs for taking corrective actions when such deviations from critical limits occur. If this rulemaking were implementing a new regulatory program where none had previously existed, one might expect to see establishments experiencing considerable additional costs due to temporary production down-time, the need to rework or condemn product or the need to

investigate the causes of deviations and develop corrective action plans. Meat and poultry inspection is, however, an existing regulatory program with a broad range of requirements that are well understood by the regulated industry and enforced by the daily presence of an inspector. The system already includes procedures whereby establishments are (1) implementing corrective actions for almost a million written Processing Deficiency Records (PDRs) annually, (2) developing written Establishment Improvement Programs (PIPs) when continuing problems with facility maintenance are observed, and (3) developing Corrective Action Plans when establishments experience serious ongoing problems in complying with existing sanitation or other regulatory requirements. In addition, the regulations already include a wide array of time and/or temperature requirements for cooking and chilling processed products. Many of the existing regulations have been developed with the standards of food safety in mind that are represented by critical limits under HACCP.

Within this existing regulatory framework establishments already experience down-time and expend considerable resources discussing causes of problems and plans for preventing future occurrences. Thus, from the perspective of looking at the existing system, FSIS does not envision that establishments will experience a significant increase in the costs of corrective action and believes the new system can help establishments avoid situations that currently cost them resources to correct. FSIS views the new program as a more effective way of assuring that establishments meet already established health and safety related requirements. For example, the requirement that establishments develop and implement sanitation SOPs does not include any change in existing sanitation standards. Under the existing system, FSIS takes responsibility for determining when establishments meet the standard and when they can operate. Under the new program, establishments will have to document their procedures and take responsibility for implementing those procedures before they begin operations. FSIS recognizes that some establishments will have to spend more time cleaning facilities and equipment. Today, many establishments conduct sanitation procedures only after inspection has identified a problem. FSIS does not, however, view such increased costs of sanitation as a cost of this rulemaking. If this rule imposes such additional costs, it is because the HACCP-based program will inherently provide improved enforcement procedures in situations where firms have been substituting the inspector's sanitation review for their own production control.

In summary, under the broader cost category of process modification and corrective action, FSIS has concluded that the cost of this rule is most appropriately addressed under the subject of potential costs associated with meeting the new pathogen reduction standards. The low and high cost scenarios provide the estimates for these potential costs. As will be discussed under the next topic of generic *E. coli* testing, these low and high cost scenarios include the types of actions establishments would take if they were also experiencing continuing difficulty in meeting criteria established for generic *E. coli*.

The final rule also requires that all establishments that slaughter cattle, swine, chickens or turkeys implement testing programs for generic *E. coli* to validate control of slaughter and sanitary dressing procedures. All samples will be analyzed for quantity, i.e., number of bacteria present. These testing programs will use production volume as the basis for determining the frequency at which establishments will conduct testing for generic *E. coli*. The frequencies for *E. coli* testing for each slaughter species are as follows:

cattle—1 test per 300 carcasses
swine—1 test per 1,000 carcasses
chickens—1 test per 22,000 carcasses
turkeys—1 test per 3,000 carcasses

These frequencies were selected so that, in the subgroup of establishments accounting for 99 percent of total production for each species, the 5 percent of establishments with the highest production volume would each have to conduct a minimum of 13 *E. coli* tests, or one test window, each day. With these frequencies, 90 percent of all cattle, 94 percent of all swine, 99 percent of all chicken, and 99 percent of all turkeys will be slaughtered in establishments conducting a minimum of one *E. coli* test per day.

The above frequencies notwithstanding, all slaughter establishments must conduct sampling at a minimum frequency of once per week. Establishments with very low volumes, slaughtering at or below 6,000 cattle, 20,000 swine (or a combination of such livestock not to exceed a total of 20,000, with a minimum of 6,000 cattle), 440,000 chickens, or 60,000 turkeys annually, will only be required to sample once per week until a sampling window has been completed where the results indicate that the slaughter and dressing process is under control. Once these criteria have been met, these establishments will be required to complete a new sampling window once each year, or when a change has been made in the slaughter process or personnel. This cost analysis assumes that the average low volume establishment will have to complete two windows (26 samples) each year before they meet the established criteria, recognizing that some establishments will meet the criteria on their first window and others may require three or more.

The final rule also provides that slaughter establishments operating under a validated HACCP system may use a sampling frequency other than that provided for in the regulation if the alternative sampling frequency is an integral part of the establishment's HACCP verification procedures and if FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishmen's slaughter and sanitary dressing controls. In addition, the final rule allows an establishment to use an existing generic *E. coli* sampling program if it can provide the data necessary to show that the existing plan is assuring adequate control. This analysis has not attempted to account for alternative sampling frequencies. It is likely that any reduction in generic *E. coli* sampling would be offset by alternative verification procedures.

The estimated component costs for collecting, shipping and analyzing a generic *E. coli* sample at a commercial laboratory are shown in Table 18.

TABLE 18.—COST OF A GENERIC E. COLI SAMPLE ANALYSIS COMMERCIAL LABORATORY

[Dollars]

Component	Cost
Average private laboratory cost	13.00
Shipping	7.00
Collecting and packaging	3.75
Total	23.75

The component costs for collecting and analyzing a generic *E. coli* sample at an FSIS field laboratory are shown in Table 19.

TABLE 19.— COST OF A GENERIC E. COLI SAMPLE ANALYSIS FSIS FIELD LABORATORY

[Dollars]

Component	Cost
Sample collection supplies	1.45
Sample collection (0.5 hrs/$18.60 per hr)	9.30
Laboratory supplies	2.90
Laboratory analysis (0.5 hrs/$18.60 per hr)	9.30
Total	22.95

Based on the above average cost estimates, this final RIA uses a per sample cost of $24 per analysis, recognizing that establishments with in-house laboratories will be able to conduct sample analysis at lower costs. In using the average cost of $24 per sample, FSIS is providing an upper bound estimate. The corresponding cost per sample for *Salmonella* was $33.35 at a commercial laboratory. Thus, using generic *E. coli* instead of *Salmonella* for process control validation has reduced the per sample cost by approximately 30 percent.

Aggregate annual sampling costs were estimated by applying the sampling frequencies to annual production data recorded by the Animal Disposition Reporting System (ADRS), an existing Agency database. The ADRS includes the total annual production in terms of number of livestock or poultry slaughtered for each federally inspected establishment. Table 20 summarizes estimates for the number of samples that will need to be collected and analyzed each year by the 364 inspected poultry slaughter operations. As shown in Table 20, the 364 establishments will be required to analyze 419,123 samples annually. Table 21 summarizes estimates for the number of samples that will need to be collected and analyzed each year by the 2,318 inspected cattle and swine slaughter operations. As shown in Table 21, the 2,318 establishments will be required to analyze 252,640 samples annually.

The smallest 2,098 slaughter operations (less than 6,000 cattle, 20,000 swine, 60,000 turkeys and 440,000 chickens) will be required to analyze one sample per week until they demonstrate compliance with established criteria. This analysis assumes an average of 26 samples per establishment per year; recognizing that some may need more and others less. These 2,098 smaller slaughter operations (over 78 percent of the total 2,682) will not be required to conduct any further analyses within a given year unless major changes to facilities, equipment or personnel occur.

Tables 20 and 21 were constructed assuming that all establishments operate on a 52 week, 260 day, 40 hours per week, 2,080-hour work-year. As discussed above, this final RIA does not attempt to account for possible reductions in sampling frequency in establishments where the establishment can demonstrate an existing acceptable alternative program or where alternative frequencies are an integral part of successful HACCP verification procedures.

Tables 20 and 21 incorporate data from the preliminary analysis showing that there are 1,328 state-inspected slaughter establishments, with an estimated 1,270 slaughtering cattle or swine and 58 slaughtering poultry. Based on additional data collected in July 1995, FSIS anticipates that 50 of the state-inspected cattle or swine slaughtering establishments will exceed the limits of 6,000 cattle or 20,000 hogs and will be required to conduct a minimum of one sample per week on an ongoing basis. It is further assumed that none of these establishments will have to conduct more than one per week, i.e., cattle slaughter is under 15,600 (300×52) and swine slaughter is under 52,000 (52×1,000). The other 1,220 state-inspected cattle or swine establishments would average 26 samples per year (2 windows). The July 1995 data indicate that all 58 state-inspected establishments slaughtering poultry process fewer than 60,000 turkeys and 440,000 chickens annually.

TABLE 20.—REQUIRED E. COLI SAMPLING FOR POULTRY SLAUGHTER ESTABLISHMENTS

Annual slaughter production category	Number establishments	Sampling range per day	Average sampling rate per establishment	Annual samples
Chickens over 45.8 million	60	Over 8 per day	10.9 Per Day	170,300
Chickens 5.72 to 45.8 million	125	1–8 per day	4.7 per day	152,230
Chickens 440,000 to 5,720,000	23	1 per week-1 per day	1.9 per week	2,215
Turkeys over 6.24 million	18	Over 8 per day	12.7 per day	59,540
Turkeys 780,000 to 6,240,000	25	1–8 per day	4.8 per day	31,330
Turkeys 60,000 to 780,000	5	1 per week-1 per day	2.7 per week	700
Chickens under 440,000 and Turkeys under 60,000	108	NA	One per week (26 weeks)	2,808
Total	364	NA	NA	419,123

NA—Not applicable.

TABLE 21.— REQUIRED GENERIC E. COLI SAMPLING FOR SWINE AND CATTLE SLAUGHTER ESTABLISHMENTS

Annual slaughter production category	Number of establishments	Sampling range	Average sampling rate per establishment	Annual samples
Cattle over 780,000	16	10 or more per day	14.8 per day	61,750
Cattle between 78,000 and 780,000	50	1–10 per day	3.2 Per Day	41,340
Hogs over 2,080,000	17	8 or more per day	11.6 per day	51,090
Hogs between 260,000 and 2,080,000	29	1–8 per day	4.0 Per Day	30,290
Cattle between 6,000 and 78,000 and/or hogs between 20,000 and 260,000.	216	One per week—one per day.	1.5 per week	16,430
Under 6,000 cattle and under 20,000 Hogs	1,990	NA	One per week (26 weeks)	51,740
Total	2,318	NA	NA	252,640

NA—Not applicable.

The total costs for meeting the final requirements for generic *E. coli* sampling in poultry and livestock slaughter establishments are summarized in Tables 22 and 23. These tables use the same cost estimates as the preliminary analysis for requirements such as plan development, training and recording and reviewing analytical results. Plan development is $640 per plan. The preliminary analysis assumed that 75 percent of operations will require training for aseptic sampling at $403 per operation. Recording and reviewing laboratory results averages 5 minutes per sample at an average wage of $13.43.

As shown in Table 22, implementation costs (training and sampling plan development) for generic *E. coli* sampling in poultry establishments will be $286 thousand. For cattle and swine establishments, the implementation costs are $2.34 million as shown in Table 23. Annual recurring costs total $10.5 million for for the 364 poultry establishments and $6.35 million for the 2,318 cattle and swine establishments. The total implementation costs for all 2,682 slaughter establishments are $2.63 million. The total recurring costs are $16.85 million.

In addition to the required sampling costs, there is the question of whether there will be additional compliance costs for establishments where test results indicate the performance criteria generic *E. coli* are not being met. In addressing this question, FSIS considered several factors. First, FSIS acknowledges that some establishments will find they are in compliance with the pathogen reduction standards for *Salmonella*, but are not meeting the performance criteria for generic *E. coli*. Second, the fact that the performance criteria are not established as enforceable regulatory standards does not mean that there will not be compliance costs. Third, the compliance actions identified for meeting the *Salmonella* standards (steam vacuum system, TSP systems and hot water rinses), are the same actions establishments would likely employ to achieve compliance with the performance criteria.

TABLE 22.—COSTS FOR IMPLEMENTING GENERIC E. COLI SAMPLING PROGRAMS IN POULTRY SLAUGHTER ESTABLISHMENTS

[Dollars in Thousands]

Production Category	Number of establishments (number of annual samples)	Training for aseptic sampling	Sampling plan development	Samples collection and analysis (recurring)	Recording and review (recurring)
Turkeys Under 60,000; Chickens Under 440,000	108 (2,808)	44	69	67	3
Turkeys Between 60,000 and 780,000; Chickens Between 440,000 and 5,720,000	28 (2,915)	6	18	70	3
Turkeys over 780,000; Chickens over 5,720,000	228 (413,400)	3	146	9,992	463
Total	364 (419,123)	53	233	10,059	469

TABLE 23.—COSTS FOR IMPLEMENTING GENERIC E. COLI SAMPLING PROGRAMS FOR CATTLE AND SWINE SLAUGHTER ESTABLISHMENTS

[Dollars in Thousands]

Production category	Number of establishments (number of annual samples)	Training for aseptic sampling	Sampling plan development	Samples collection and analysis (recurring)	Recording and review (recurring)
Cattle Under 6,000; Hogs Under 20,000	1,990 (51,740)	802	1,274	1,242	58
Cattle Between 6,000 and 78,000; Hogs Between 20,000 and 260,000	216 (16,430)	54	138	394	18
Cattle over 78,000; Hogs over 260,000	112 (184,470)	1	72	4,427	206
Total	2,318 (252,640)	857	1,484	6,063	283

After considering the above factors, FSIS concluded that if the low cost scenario for compliance with *Salmonella* standards proves to be more accurate, there will likely be more separate compliance costs for generic *E. coli*. As the costs for *Salmonella* compliance go up, the likelihood of separate generic *E. coli* costs goes down. It is important to note that under the high cost scenario, all cattle and swine slaughter establishments are using the steam vacuum system or a hot water rinse and half of all poultry slaughter establishments are using TSP systems. Under this scenario, it is difficult to imagine that any establishments would

still be failing to meet the performance criteria for generic *E. coli*.

FSIS considered the possibility that the smaller establishments conducting only seasonal testing would increase testing to cover the whole year to provide better assurance of control over sanitary dressing procedures. However, FSIS rejected this possibility after considering the cost pressures on small businesses. FSIS would certainly not expect to see these establishments use both expanded testing and hot water rinses.

3. HACCP Programs—Plan Development and Annual Reassessment Costs

a. Summary of Requirements. The proposed rule included a requirement that each inspected establishment develop a written HACCP plan for each distinct "process" conducted on the premises. The proposed rule identified nine process categories that would require separate HACCP plans. Each plan would include: identification of the processing steps which present hazards; identification and description of the CCP for each identified hazard; specification of the critical limit which may not be exceeded at the CCP (and if appropriate a target limit); a description of the establishment monitoring procedures; a description of the corrective action to be taken if the limit is exceeded; a description of the records which would be generated and maintained regarding this CCP; and a description of the establishment verification activities and the frequency at which they are to be conducted.

The requirements in the final rule for HACCP plans are essentially the same. The final rule requires that each establishment conduct a hazard analysis and then develop a comprehensive HACCP plan that covers each hazard identified. The final rule has eliminated the nine process categories because the sequencing of HACCP implementation will be based on establishment size and not on process categories. The final rule also includes the provision that each plan be reassessed on an annual basis.

b. Review of Preliminary Cost Estimates. Using existing databases (PBIS and ADRS) FSIS estimated that the 6,186 federally inspected establishments would require 16,899 HACCP plans, an average of 2.73 plans per establishment. It was assumed that each of the 2,893 state inspected establishments would have 2.1 plans per establishment for a total of 6,120 plans. The total number of plans for all establishments is, therefore, 23,019. The Agency requested specific comments on the assumptions used to estimate the number of state plans, but received none. In estimating the cost of HACCP plan development for federally inspected establishments, FSIS used the following cost estimates as shown in Table 24.

TABLE 24.—HACCP PLAN DEVELOPMENT COSTS

Plan difficulty	Plan sequence		
	First	Second	Third
Easy	4,000	2,000	1,000
Moderate	8,000	4,000	2,000
Difficult	12,500	6,250	3,125

Table 24 accounts for both the complexity or difficulty of the plan and the experience gained by developing previous plans. The table was developed from several sources including discussions with a number of private sector food consultants and the results of the *HACCP Pilot Program Cost Findings* study which was conducted by RTI and completed in August 1994. The RTI Study found that the nine pilot establishments reported plan development costs ranging from $607 to $15,750.

For state establishments, FSIS assumed an average cost of $2,000 for 6,120 plans. For the federally-inspected establishments, the above table generated an average cost of approximately $2,020 per plan. The resulting average cost is relatively low because the preliminary analysis credited each establishment with having developed one plan prior to HACCP because of the need to develop plans for sanitation SOPs, microbial sampling and time-temperature controls. It was assumed that the experience gained in developing plans for these three near-term interventions could be applied to their first HACCP plan.

- The total cost for developing 23,019 plans was estimated at approximated $46.4 million ($34.14 million federal and $12.24 million state) spread over a 3 year implementation period.

c. Comments on the Preliminary RIA. There were several specific comments on the cost of developing a HACCP plan. Examples include:

- To write each plan would cost around $9,000.
- Average time to draft a plan is 300 hours.
- Average time of 300 hours at $125 per hour ($37,500).
- An average of $5,000 per establishment.
- Approximately $1,000 to $1,500 per establishment.

More general comments stated that FSIS had underestimated or overestimated the cost of plan development or that FSIS should develop or pay for the cost of developing plans. There were also comments that indicate that some establishments believed that they would be required to have a separate plan for each product they produce.

d. Response to Comments. The comments that suggested FSIS had overestimated costs or had developed an upper limit on implementation costs, pointed out that a market driven response to the rule would likely cut costs. The market would increase the number of consultants which would be available at reduced costs, especially for small establishments that are most likely to employ outside consultants. While FSIS agrees that the number of available consultants will increase and that the hourly cost for outside assistance will likely decrease, the Agency notes that Table 24 was developed with those factors in mind. The discussions with private sector food consultants focused on projected costs, recognizing that costs would decrease as more consultants became available and the overall level of industry expertise and experience increased.

The comments included a wide range of estimates for the cost of developing a HACCP plan. Most of the specific cost estimates contained in the comments were within the ranges presented in Table 24. The comments do not provide a compelling reason to modify Table 24, especially since FSIS has an ongoing effort to develop implementation aids for establishments that will help keep plan development costs down. In addition to generic models that will be available at least six months before any mandatory requirement, FSIS is developing or considering: (1) Information publications, such as a HACCP Handbook that explains how a establishment can effectively and economically incorporate the seven principles into its operations; (2) training videos and computer programs that present HACCP implementation guidance in alternative formats; (3) models for onsite HACCP training of establishment employees; and (4) a catalog of hazards with examples of control measures and generic plans for each slaughter and processing category described in the proposed rule. FSIS is also planning to sponsor in-establishment demonstration projects to generate real-world information and guidance about near-term and HACCP implementation issues in small businesses.

FSIS will also continue its technical assistance to state programs by including states' training officials in

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Federal training efforts, by facilitating state access to and use of federal computer support systems, and by expansion of state/federal cooperative efforts through the Conference for Food Protection, the National Association of State Departments of Agriculture, the Association of Food and Drug officials, and the Meat and Poultry Inspection Advisory Committee. Also, FSIS' plans for in-establishment demonstration projects referenced above will focus on small establishments under State regulation as well as those under Federal regulation.

The findings from the nine pilot establishments reported in the RTI study were based on conditions existing in the 1991–1992 time period. Many factors have changed since then including the number of available HACCP consultants, the number of trained individuals, the number of courses available and the general level of knowledge concerning the implementation of HACCP principles in food processing establishments. These factors should help drive plan development cost down.

The 1994 RTI study noted that: "Several participants commented that there is a lot more discussion and information about HACCP in the trade press and elsewhere today than there was even three years ago. Without exception, participants felt that USDA could reduce the costs of HACCP—especially training and HACCP plan development costs—by making as much information about HACCP available as possible."

In response to comments that FSIS should develop or pay for the development of plans, FSIS believes that these suggestions would diminish the principle of having industry take ownership and responsibility for the production process. This principle is a key factor in HACCP. If FSIS developed or paid for the plans, it would detract from the establishment's assuming ownership and responsibility for the HACCP plans. FSIS also believes that government funding of the plans would set a bad precedent. If the government assumes the cost of compliance with regulatory actions which ultimately benefit the regulated industry, establishments will campaign for additional actions leading to greater government outlays. Government funded plans would also require an increase in the FSIS budget requiring a corresponding increase in taxes and also likely lead to more expensive plans. By bearing the costs, establishments will have a stronger incentive to control plan development costs than FSIS. Finally, FSIS expects that market forces will permit establishments to shift some of the costs to producers and consumers which is a more equitable allocation of costs than placing the burden on taxpayers in general.

In response to comments expressing concern that each product would require a HACCP plan, FSIS notes that there is a major distinction between requiring that "each product must be covered by the establishment's HACCP plan" and requiring that "each product have a unique HACCP plan." The final complexity of an establishment's HACCP plan is related to the number of distinct processes used by the establishment and not the number of products produced.

e. Final Cost Estimates. Although the final rule has eliminated the process categories and requires a single, comprehensive HACCP plan for each establishment with hazards, the final cost estimates are based on the earlier estimates of 16,889 plans for federally inspected establishments and 6,120 plans for state inspected establishments. Since final cost is still a function of the number and complexity of processes, FSIS sees no reason to change the methodology for estimating HACCP plan development costs. Furthermore, it is reasonable to assume that establishments may develop their plans in segments beginning with relatively simple processes and then proceeding to more complex processes.

The final cost estimates for 23,019 HACCP plans are shown in Table 25. The final cost estimate for federally inspected establishments is based on Table 24 which presents different costs, depending on the sequence, for easy, moderate and difficult plans. The final cost estimate does not, however, assume that the first HACCP plan is actually the second plan because of experience gained in developing sanitation SOP plans and microbial sampling plans. The result is that the average cost for the 16,899 plans for federally inspected establishments is now $3,240, up from the preliminary analysis average of $2,020 per plan. The average cost for 6,120 plans in state inspected establishments is $2,000, the same per plan cost used in the preliminary analysis.

It is assumed that HACCP validation is an integral part of HACCP plan development and that the requirement for annual reassessment will be a minimal cost for establishments that do not modify their products or processes and are not experiencing difficulty in meeting all critical limits. The analysis assumes that the average annual reassessment will take two hours per plan at a quality control manager's salary of $25.60 per hour. Thus, the average annual reassessment will cost $51.20 per plan.

TABLE 25.—COST OF HACCP PLAN DEVELOPMENT AND ANNUAL REASSESSMENT

Establishment category	Number establishments	Number plans	Total cost ($000)	Average cost per plan (dollars)	Annual reassessment ($000)
Low	2,234	5,106	17,762	3,479	261
Medium	3,103	8,712	28,075	3,223	446
High	849	3,081	8,911	2,892	158
Subtotal	6,186	16,899	54,748	3,240	865
State	2,893	6,120	12,240	2,000	313
Total	9,079	23,019	66,988	2,910	1,179

As discussed above under methodology, this cost analysis assumes a static number of establishments and processes while recognizing that the rule will add to the cost of new establishments or processes. One such

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cost would be the annual reassessment for establishments that add new processes or substantially modify existing production practices.

4. HACCP Programs—Recordkeeping Costs

a. Summary of Requirements. The final rule requires that all establishments record observations when monitoring critical control points and document any deviations and corrective actions taken. The rule also requires a certification review of records by an employee not involved in recording observations. Such recording and certification review of observations at critical control points is a fundamental HACCP principle.

FSIS is requiring that the records involving measurements during slaughter and processing, corrective actions, verification check results, and related activities contain the identity of the product, the product code or slaughter production lot, and the date the record was made. The purpose of this requirement is to assure that both the company and the regulator can readily link a record to a product and the timeframe in which it was processed. FSIS is also requiring that the information be recorded at the time that it is observed and that the record be signed by the operator or observer.

FSIS is also requiring that the HACCP records be certified by a company employee other than the one who produced the record, before the product is distributed in commerce. The purpose of this review is to verify that the HACCP system has been in operation during the production of the product, that it has functioned as designed and that the company is taking full responsibility for the product's meeting applicable regulatory requirements. The employee conducting the certification review must sign the records.

FSIS is also requiring that HACCP plans and records be available for review by program personnel. Records access is necessary to permit verification of all aspects of a HACCP system.

b. Review of Preliminary Cost Estimates. In the preliminary cost analysis, recordkeeping cost was defined to include the time it takes to make observations and record the results of those observations plus the cost of certifying and maintaining records. Several key variables were involved in the estimates for HACCP recordkeeping costs for the preliminary RIA. First, it was established that recordkeeping costs are related to the number of processing lines operating simultaneously and not the number of HACCP plans. That is, an establishment may have several HACCP plans but never have more than one operating at any given time. To estimate recordkeeping costs it was necessary to collect data on the average number of production lines operating per shift. To estimate product lines, data was collected for a sample of low, medium and high volume establishments from each of the FSIS Regional Offices. The data on average number of simultaneous operating lines was collected for processing operations, red meat slaughter operations and poultry slaughter operations for both first and second shifts. Costs were then estimated based on 7,639 federal and 4,080 state inspected operations as shown in Table 26.

TABLE 26.—OPERATIONS IN FEDERAL AND STATE INSPECTED ESTABLISHMENTS

Manufacturing operation	Federal inspected establishments	State inspected establishments	Total
Processing	6,006	2,752	8,758
Meat slaughter	1,327	1,270	2,597
Poultry slaughter	306	58	364
Total	7,639	4,080	11,719

It was further assumed that each State establishment was a single shift establishment and that State establishments would have the same number of production lines as the first shift of a low volume federal establishment.

Other variables included the average number of CCP's per plan and the average amount of time for recording and reviewing records per CCP. For federally inspected establishments, the analysis assumed that processing HACCP plans have an average of 7.4 CCP's and slaughter plans have an average of 5 CCP's. It was assumed that State inspected establishments will average 5 CCP's per HACCP plan. Recording time was estimated at an average of 5 minutes per CCP per shift. Review time for certification was estimated at an average of 2 minutes per CCP per shift. Recording cost was estimated based on an employee earning $12.87 per hour. Certification cost was based on a supervisor or QC technician earning $18.13 per hour. All storage costs were based on a national survey of storage costs showing an average annual cost of $8.40 per square foot.

Total recordkeeping costs are the sum of the costs for three components: Monitoring CCP's and recording findings, certifying records, and storing records. The following calculation for the annual costs of recording the findings from monitoring CCP's in State processing operations illustrates how the above estimates were used in estimating total recordkeeping costs:

Recording Costs For State Processing Operations =
(2,752 operations) × (1.1 average production lines)
× (5 minutes per CCP per day ÷ 60 minutes per hour)
× (5 CCP's per line)
× ($12.87 per hour) × (260 days per year)
= $4.22 million

The total costs per establishment for recordkeeping, as estimated in the preliminary analysis, are summarized in Table 27. The total aggregate costs are shown in Table 28. The average cost per establishment and the total aggregate costs were reduced to account for the recordkeeping that already occurs in TQC, NELS and SIS establishments.

TABLE 27.—SUMMARY OF RECORDKEEPING COSTS PER ESTABLISHMENT

[Dollars]

Establishment category	Recording observations	Certifying records	Maintaining records	Recurring annual cost
Low	2,560	1,442	28	4,030
Medium	4,202	2,368	52	6,621
High	10,994	6,195	90	17,279
State	2,163	1,219	33	3,415

TABLE 28.—HACCP RECORDKEEPING COSTS

[$ Thousands]

Establishment category	Number of establishments	Annual costs
Low	2,234	9,003
Medium	3,103	20,545
High	849	14,669
Subtotal	6,186	44,217
State	2,893	9,880
Total	9,079	54,097

With the methodology used for estimating recordkeeping costs, it is also possible to look at annual recording and certification cost per operating line. Assuming a line runs 52 weeks, 40 hours per week, 2,080 hours per year,

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the average annual recordkeeping cost (excluding any storage costs) for a processing line in a federally inspected establishment would be $3,226.23 ($2,063.40 recording plus $1,162.74 certification). The average annual cost for a federally inspected slaughter line would be $2,179.88 ($1,394.25 recording plus $785.63 certification). All lines in State inspected establishments were assumed to have an annual cost of $2,179.88.

c. Comments on the Preliminary RIA. Most of the comments referring to HACCP recordkeeping costs were general comments that the costs would be extremely burdensome. The comments did not question the methodology used in the preliminary analysis to estimate either recording, reviewing or storage costs. The comments included at least two proposed modifications that would substantially reduce costs. One comment suggested that small establishments record only deviations from the HACCP plan and responses to them. At one of the public hearings a representative from a consumer organization suggested that inspectors could conduct the recordkeeping in small establishments.

d. Response to Comments. FSIS believes that while both of the above suggestions would reduce cost, they both do damage to the concept of HACCP. Having the industry take ownership and responsibility of the production process is a key component of HACCP. Having inspectors conduct the recordkeeping would severely detract from ownership. Furthermore, a fundamental HACCP principle requires that observations be recorded and reviewed at critical points in the manufacturing process on an ongoing basis. Recording only deviations does not meet this principle.

The discussion of sanitation SOP recordkeeping costs identified three factors that affect how one views such costs. At least two of those factors apply here. HACCP recordkeeping is a cost that can be reduced through good management and efficiency and should also decrease with experience. If recordkeeping can be conducted by employees working at a CCP location, the additional cost should be minimal. HACCP should also substantially reduce the time establishment officials currently spend interacting with or responding to inspection findings. In addition to responding to the approximately 700,000 to 800,000 Processing Deficiency Records (PDRs) per year, establishments have thousands of meetings with program officials following reviews conducted by area and regional officials or reviewers from the Program Review Division in Lawrence, Kansas. FSIS believes strongly that establishment officials will find some recordkeeping time from reducing inspection interaction time.

e. Final Cost Estimates. After considering the comments, FSIS does not see a need to adjust the costs estimates shown in Tables 27 and 28. The final aggregate cost estimates for recordkeeping are those shown in Table 28.

5. HACCP Programs-Training Costs

a. Summary of Requirements. The final rule requiring that each establishment have access to a HACCP-trained individual remains identical to the training requirement as proposed. The final rule does not, however, include the proposed requirement that the name and resume of the HACCP-trained individual be on file at the establishment.

b. Review of Preliminary Cost Estimates. The proposed rule included the requirement that each establishment have access to a HACCP-trained individual. In the preliminary cost analysis FSIS pointed out that establishments would have options for meeting that requirement. For example, establishments could train an existing employee or use a consultant on an as-needed basis. To provide a cost estimate, FSIS assumed that each slaughter or processing operation would send one employee to a recognized HACCP course for approximately three days.

The preliminary analysis assumed a combination establishment would require training for both slaughter and processing operations. The preliminary analysis identified 11,719 separate meat slaughter, poultry slaughter and processing operations. The analysis assumed that 5 percent of these operations currently have a trained individual and 11,133 would require training.

Training would be a one-time, up-front expense. The cost of training 11,133 establishment employees at $2,514 each would be approximately $28 million. The $2,514 included tuition for a three-day course, travel expenses and wages. In estimating these costs, FSIS used a listing of 1994 HACCP courses compiled by the USDA Extension Service.

c. Comments on the Preliminary RIA. Most of the comments relating to the cost of training industry personnel were of a general nature (e.g., FSIS underestimated the cost of training) or suggested that all training be funded by USDA. Many small processors lumped training with other requirements and indicated that the cost of implementing HACCP would force them to close. A couple of comments indicated that the commenter believed they would have to hire an additional HACCP-trained employee. Several comments noted that the training costs estimated in the IFSE study were far higher than the costs estimated by FSIS.

d. Response to Comments. With respect to the comments that referred to the higher training costs estimated in the IFSE study, FSIS notes that the IFSE study assumed that training was both an up-front and a continuing annual expense. They also assumed that HACCP training was necessary for top management, supervisors and relevant hourly employees. Since the IFSE study was written with a beef slaughter establishment in mind, it is assumed that the authors believed it is necessary to train some or all of the employees working the dressing line. Under their assumptions, a high turnover would require substantial recurring annual costs.

The FSIS cost estimate was tied to meeting the proposed regulatory requirements. The IFSE estimates are the authors' judgment of what would be required to "successfully" implement an effective HACCP program. The IFSE study did not provide any rationale for the cost estimates used. For example, the authors assumed that annual training costs for 5,127 small businesses would be $10,000 each for a total annual cost of $50 million. That estimate would appear high considering the large number of establishments with fewer than five employees.

The IFSE study does raise the issue of whether a single three-day course for one employee is adequate to ensure an effective HACCP program. A low cost ongoing training program may be better. FSIS now plans on having training videos and/or correspondence courses available for each establishment. This will present an easier burden for very small establishments because it will not require having an employee leave on travel to receive training. As the number of available courses and locations increases, travel costs will also decrease. Trade associations can help provide local training for all establishments near large metropolitan areas.

FSIS also recognizes that employee turnover will require some level of recurring cost. The necessity of training new hires should, however, decrease over time as the available pool of HACCP-trained individuals increases. FSIS will, however, include a 10 percent recurring cost in the final cost estimate.

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e. Final Cost Estimates. The final training cost estimates are shown in Table 29. The one-time cost of $27,988 thousand is the same cost as estimated for the preliminary analysis. In response to comments, an annual recurring cost of $2.8 million has been added.

TABLE 29.—HACCP—TRAINING COSTS

[$ Thousands]

Establishment category	Number of employees	One-time cost	Recurring costs (10%)
Low	2,610	6,562	656
Medium	3,593	9,033	903
High	1,054	2,650	265
Subtotal	7,257	18,244	1,824
State	3,876	9,744	974
Total	11,133	27,988	2,799

6. HACCP Programs—Impact on Total Quality Control/Overtime Issues

a. Summary of Requirements. The proposed rule did not include proposed revisions to existing Total Quality Control (TQC) regulations. However, the preamble stated that FSIS is considering having HACCP be the only Agency recognized health and safety related process control system. The preliminary RIA published with the proposed rule stated that: "With the publication of the rule, TQC establishments could lose their authority to produce and ship product after their normal shift production time. As a result, 287 active TQC establishments could begin to incur annual overtime charges."

The final decisions on TQC regulations have not been made. This final analysis uses the impact on overtime as a conservative estimate of the potential impact of pending decisions.

b. Review of Preliminary Cost Estimates. The Agency's supplemental cost analysis recognized that there are 287 TQC establishments that would incur overtime costs to continue their current operating schedules if the TQC regulations were eliminated. The total cost for these 287 establishments was estimated at $2.1 million per year. The preliminary analysis estimated that the total of 287 included 112 low, 124 medium and 51 high volume producers.

c. Comments on the Preliminary RIA. A TQC establishment commented that under the proposed rule they would have to pay an additional $32,308.80 per year in overtime charges. The establishment commented that these additional overtime charges would equate to a substantial portion of their annual net profit.

d. Response to Comments. The comment from the TQC establishment is consistent with the preliminary analysis that was based on the premise that TQC establishments would lose their authority to produce and ship products after their normal shift production time. If such authority is withdrawn establishments would have to incur overtime charges if they want to continue their present operating schedules.

The establishment estimated its potential overtime cost based on an assumption of 100 percent coverage. If the establishment's overtime hours were covered by a patrol assignment, they would be subject to the provisions of proportional coverage and the actual level of overtime charges could be substantially lower.

Inspection assignments cover 8 hours of regular time and may also include scheduled overtime inspection. An assignment may specify 8 hours in one establishment or direct the inspector to cover multiple establishments, i.e., a patrol assignment where the inspector would spend a portion of each day in each establishment. In cases where an inspector spends 8 hours in a single establishment and that establishment decides to operate for 2 hours of overtime on a routine basis, inspection coverage may be provided by having the assigned inspector work 2 hours of overtime. This type of coverage would be likely if the establishment was located in an isolated area. In this type of case, the establishment would be charged for 2 hours of overtime inspection each day. This type of overtime situation would lead to maximum costs as suggested by the commenter.

If the establishment was part of a patrol assignment and there were two establishments working 2 hours of overtime, the overtime production could be covered by having the inspector work 2 hours of patrol overtime, but each establishment would only be billed for one hour, i.e., proportional overtime coverage.

Because the majority of establishments are covered by patrol assignments, proportional coverage is employed frequently. Thus, the establishments' estimate of $32,308.80 is a maximum level. The actual level of charges could probably be substantially lower.

e. Final Cost Estimates. This final analysis has included a cost of $2.1 million for annual overtime charge. The analysis has assumed that the additional overtime charges will occur on the same timeframe as the sequencing of HACCP implementation.

E. Summary of Costs for Low Volume Producers

Because there has been particular interest in the impact of this rule on small business, this final section summarizes the overall costs for low volume producers. Table 30 illustrates the costs faced by a typical low volume producer over the four-year implementation period. Because there are less than 100 low volume poultry slaughter establishments, the costs for generic *E. coli* sampling was not included in Table 30. The costs illustrated in Table 30 apply to the majority of inspected establishments, an estimated 2,234 federally inspected establishments and all but a few of the 2,893 state inspected establishments. These 5,000-plus establishments all meet the regulatory flexibility definition for a very small establishment and have the full 42 months to implement mandatory HACCP systems. There are another 658 establishments (medium volume production) that will have slightly higher costs, but will also have 42 months to implement HACCP because they meet the regulatory flexibility criteria for a very small establishment. All establishments meeting the regulatory flexibility criteria for small establishments will have 30 months to implement HACCP. The 353 large establishments (more than 500 employees) will be required to implement HACCP 18 months after publication.

TABLE 30.—SUMMARY OF COSTS FOR A TYPICAL LOW VOLUME ESTABLISHMENT

[Dollars]

Cost category	Year 1	Year 2	Year 3	Year 4	Year 5+
I. Sanitation SOPs Plans and Training	[a] 190	.....	.....	.....	
Observation and Recording	1,242	1,242	1,242	1,242	1,242
II. Compliance With *Salmonella* Standards	.....	.....	.....	[b] 0–1,200	[b] 0–1,200

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TABLE 30.—SUMMARY OF COSTS FOR A TYPICAL LOW VOLUME ESTABLISHMENT—Continued

[Dollars]

Cost category	Year 1	Year 2	Year 3	Year 4	Year 5+
III. HACCP Plan Development				4,231–7,952	
Annual Plan Reassessment					177
Initial Training				[d]2,937–3,368	
Recurring Training					294–337
Recordkeeping				2,015	4,030
IV. Additional Overtime				[e]0–3,702	[e]0–7,404
Total	1,432	1,242	1,242	10,425–11,625	5,743–6,986

[a] This cost for the 112 low volume TQC establishments would be $64.

[b] The estimate of $1,200 is based on monthly testing for two products and an antimicrobial rinse for one.

[c] The Cost Analysis is based on estimates that low volume federally inspected establishments will require an average of 2.29 plans each, at a cost of $3,479 per plan (see Table 25) for a total average plan development cost of $7,952. The number of plans for federally inspected establishments is based on data from existing FSIS data bases. It was assumed that state plans have an average of 2.12 plans each for a total cost of $4,231 per establishment ($2,000 per plan).

[d] Average training costs for state establishments ($3,368 per establishment) were estimated to be slightly higher than the average federally inspected low volume establishments ($2,937 per establishment) because the state programs have a higher percentage of combination slaughter and processing establishments. The cost analysis assumed that plans would train one individual for each processing, red meat slaughter and poultry slaughter operation.

[e] The preliminary analysis estimated that 112 of 287 active TQC establishments are low volume producers. The average TQC establishment avoids an annual overtime charge of $7,404. The cost estimates in Table 30 for additional overtime costs apply only to those 112 establishments and assume that TQC provisions will be phased out as HACCP is phased in—42 months after publication for the low volume establishments. Because the overtime costs apply to only 112 establishments, they are not included in the Table 30 totals.

The average costs shown in Table 30 will be a burden for many of the low volume producers. However, there are factors that should help diminish the burden. Most of the costs and essentially all of the recurring costs are labor costs for monitoring sanitation procedures, monitoring HACCP critical control points and keeping both HACCP and sanitation records. As the above analysis points out, these are costs that can be reduced through efficient management and allocation of resources and should decrease with experience. The Agency also views a portion of these costs as a shift in resources, i.e., establishment management should spend more resources monitoring establishment operations and less time interacting with program personnel.

Another way of illustrating costs to small businesses is to look at the costs for one or more specific examples. Table 31 illustrates the costs for a small, single-shift, processing establishment (no TQC or sanitation PQC program) with two distinct production operations other than raw ground product (overall average was estimated at 2.29 based on data shown in Table 25).

TABLE 31.—COSTS FOR TYPICAL SINGLE-SHIFT PROCESSING ESTABLISHMENT

[Dollars]

Requirement	Development and Implementation costs	Recurring Annual Costs
Sanitation SOP's ...	190	1,242

TABLE 31.—COSTS FOR TYPICAL SINGLE-SHIFT PROCESSING ESTABLISHMENT—Continued

[Dollars]

Requirement	Development and Implementation costs	Recurring Annual Costs
HACCP Plan Development	6,958	0
Annual Plan Reassessment	0	102
Training	2,514	251
Recordkeeping	0	6,480
Total	9,662	8,075

If one of the two production operations produced a raw ground product, the establishment would have to meet the pathogen reduction performance standard for that product. As noted earlier in the development of the low and high cost scenarios for meeting the new *Salmonella* standards, raw ground operations do not have the same opportunities to reduce *Salmonella* levels as do slaughter establishments. They can control growth by avoiding temperature abuse and can limit cross-contamination, but basically they must depend on the Salmonella levels of their incoming product in order to meet the performance standards. These establishments may choose to test incoming product in order to eliminate suppliers whose product is found to be positive. The final analysis has assumed that the low volume producers would not test incoming ingredients.

Table 32 illustrates the costs for a small, single-shift, combination (slaughter and further processing) establishment that slaughters cattle or swine, but not both, and has a single further processing operation other than raw ground product. The establishment is not under TQC inspection.

TABLE 32.—COSTS FOR TYPICAL SINGLE-SHIFT COMBINATION ESTABLISHMENT

[Dollars]

Requirement	Development and implementation costs	Recurring annual costs
Sanitation SOP's ...	190	1,242
Compliance with *Salmonella* Standards	0	800
E. coli Sampling	1,043	653
HACCP Plan Development	6,958	0
Annual Plan Reassessment	0	102
Training	5,028	503
Recordkeeping	0	5,434
Total	13,219	8,734

The cost of meeting the pathogen reduction performance standards assumes that the establishment will use a hot water antimicrobial rinse and have one sample per month analyzed at an outside laboratory ($33.35 per sample-$400 per year). The average number of head slaughtered in a low volume establishment is approximately 5,000

annually. The annual cost for the rinse is $400.

The development costs for *E. coli* sampling in the small establishment includes $640 for developing a sampling plan and $403 to train an individual to conduct aseptic sampling. The recurring costs are based on the assumption that an average low volume slaughter establishment will have to complete two sampling windows (26 samples) before they demonstrate compliance with established criteria.

The cost of HACCP training has doubled for the combination establishment because the FRIA assumed that slaughter and processing operations are significantly different, so that the establishment must either train two employees or send one employee to two separate training courses.

The HACCP recordkeeping costs (monitoring CCP's and recording findings, reviewing records and storing records) in the above two examples assume that the establishments are operating each process continuously over a standard 52-week, 260-day, 2,080-hour work year. Data collected during the preliminary analysis indicates that many low volume establishments frequently have only a single production line operating at a given time. As shown in Tables 27 and 30, the final analysis estimates an average annual cost for HACCP recordkeeping of $4,030 for low volume establishments.

Appendix A to Final Regulatory Impact Assessment

Response to Comments Related to the Preliminary Regulatory Impact Analysis But Not Addressed Directly in the Text of the Final Analysis

1. A comment noting that the "data in Tables 1 and 2, (60 FR 6781) for *Toxoplasma gondii* are confusing or in error" is correct. The tables as published contained typographical errors that have been corrected for this analysis. The number of cases of foodborne illness from toxoplasmosis should be 2,056 cases, not 3,056 cases. The total number of cases from the foodborne illnesses considered also needs to be adjusted to correct for the above typographical error. Specifically, the total number of cases should be 3,605,582 to 7,132,823, and not 3,606,582 to 7,133,823.

2. The same comment questioned whether it is true that the "estimated medical costs for the 2,056 cases (toxoplasmosis) and 41 deaths is $2,7000,000,000?" This estimate is correct but these costs include the estimated costs of lost productivity and costs of residential care as well as the estimated medical costs of toxoplasmosis.

3. There were several comments that indicated that while attempting to reduce the overall public health risk, the Agency could be increasing the risk to farmers and small producers that now have livestock custom-slaughtered at inspected establishments. If a large number of these small diverse businesses go under, the comments predicted an increase in at- home slaughter under very marginal conditions. These comments imply at-home slaughter is a high risk practice using terms such as barn yard butchering or shade tree butchering or back shed butchering.

Changes in the final rule should allow most small businesses to continue to operate successfully under inspection. There are some small businesses that are currently primarily custom-exempt/ retail exempt operations that may choose to withdraw from inspection. These types of facilities will still be available for their custom slaughtering services.

4. A comment referred to the FSIS assertion that consideration of the costs of the various alternatives under examination is not relevant because the alternatives do not meet the Agency's goal of achieving the maximum pathogen reduction possible. The commenter concluded that this is an entirely inappropriate analytical framework for the examination of regulatory alternatives. By starting from the assumption that only the maximum benefit attainable will suffice, FSIS effectively renders its consideration of available regulatory alternatives a complete sham. The purpose of a regulatory impact assessment should be to examine both the benefits and the costs attributable to each available alternative, and to consider whether there is an alternative to the Agency proposal that is a more cost-effective means of addressing the problem at hand.

5. One commenter stated that the Agency must include the costs attributable to the retained requirements as well. These retained costs will significantly increase the operational costs of the combined, layered system. FSIS does not agree that the RIA needs to include the cost of existing requirements.

6. Comments expressed concern that the proposed rule was an experiment to collect the data needed to determine whether it was a good idea. These comments stated that industry should not bear the cost of a government research project. FSIS has clearly stated the public health objective of this rule.

7. There are several comments that referred to a study conducted by the Research Triangle Institute for FSIS. In that study, *HACCP Pilot Programs Cost Findings*, August 31, 1994, RTI collected cost information during personal interviews at all nine establishments that had participated in USDA's HACCP Model Pilot Program.

One comment noted that the pilot establishments used for the study are establishments that are larger than most of the establishments that are going to be affected. The RTI study noted that none of the voluntary participants have annual sales under $3 million. The RTI study was one source of information for the FSIS cost analysis. The Agency did not use the information in a way that suggested it was representative of all establishments or in any way imply that it was.

Another comment stated that USDA relied very heavily on the nine pilot establishment studies. The data collected by RTI was one source of information used for the preliminary cost analysis. The analysis clearly cites the RTI study as one of several data sources.

A comment during the public hearing attributed a cost of $23,000 or $27,000 to the RTI study for a hazard analysis, plan development and validation for a small business that doesn't need any equipment or establishment upgrade. The RTI study reported costs for plan development ranging from $607 to $15,750. FSIS assumes that the hazard analysis is part of plan development. The RTI study did not address a separate cost component for validation.

8. One comment indicated that the source of the estimates for total cases and deaths for *E. coli* O157:H7 does not support the number used in the benefit estimates. The preliminary analysis was based on 10,000–20,000 total cases and an estimate of from 200–500 total deaths. Sources identified were the AGA conference and CDC communications. The "CDC comm." citation mentioned in the FSIS proposal refers to both the Ostroff et al. (1989) and the McDonald et al. (1988) articles as described in the comment. These references provide an incidence rate for *E. coli* O157:H7 of 2.1/100,000 to 8/ 100,000. The AGA conference suggests there are 10,000 to 20,000 cases of *E. coli* O157:H7 each year in the United States. This translates to a rate of approximately 4/100,000 to 8/100,000, which is higher on the lower estimate. ERS chose to use the consensus numbers because they reflect the current thinking of a nonadvocate panel of experts. FSIS agrees with the commenter that better data on

foodborne disease incidence is needed but believe that the preliminary analysis used the best estimates available.

9. Commenter stated FSIS relied on faulty data. FSIS responds that there is a difference between saying data are limited and saying data are faulty. Existing food safety data are limited and more thorough data may not be available for a long time.

10. A commenter noted that FSIS did not address the "cost" of the development of a highly susceptible population because some exposure is necessary to establish immunity. The same commenter suggested there might be a "nutritional health" cost penalty, i.e., the rule would increase the cost of food so much that consumers would not be able to afford nutritional food. FSIS notes that the commenter did not provide support for these "costs."

11. A commenter noted that their low annual insurance premium of $150 strongly suggests that the insurance industry considers their existing safety record commendable and worthy of a low liability rate. FSIS notes that another comment has suggested that lower rates are being offered in conjunction with improved process control systems.

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KANSAS DEPARTMENT OF AGRICULTURE

June 30, 1995

Ms. Diane Moore, Docket Clerk
Room 3171, South Building
Food Safety and Inspection Service
U.S. Department of Agriculture
Washington, D.C. 20250

Subject: Docket No. 93-016P: Proposed Rule: Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems

Dear Ms. Moore:

In response to the USDA, FSIS proposed rule published on February 3, 1995 in the Federal Register, the following comments are presented by the Kansas Department of Agriculture and its Meat and Poultry Inspection program. These comments have been developed after consideration of the four "Transition to HACCP" near-term initiatives contained in the Pathogen Reduction Act, after a thorough academic introduction to and orientation in the seven principles of HACCP, and after extensive surveying of the targeted industry and our inspection personnel.

1. All inspected establishments develop and adhere to written standard operating procedures (SOP's) specifically relating to direct contamination or adulteration of product.

This initiative places the responsibility for maintaining sanitary conditions and compliance with sanitation requirements firmly on the shoulders of the inspected establishment. There exists a small percentage of plants that do not have the best of attitudes toward sanitation, and will wait for inspection personnel to point out deficiencies before taking action to improve sanitation. As such, this first initiative is long overdue, and is strongly supported.

Ideally, the SOP's should be developed by those who understand the operation of the individual establishment, i.e., plant management. However, due to the various levels of formal training in sanitation and food safety among plant management, it is more prudent that minimum requirements should be addressed that each plant must abide by. Smaller plants that lack the personnel dedicated exclusively to sanitation would be better served with a generic sanitation guideline provided to them. This could serve as a template to customize for their own unique plant characteristics and operations.

House Agriculture Committee
February 20, 1997
Attachment 4

Oversight by inspection personnel during the development of the SOP's would ensure that all criteria for maintaining sanitary conditions are addressed by plant management. Review and adjustment of the SOP's would be needed as plant operations changed with time and purpose, and cooperative efforts between the extremely small plants and inspection personnel would engender a less antagonistic relationship between the two parties.

2. All slaughter establishments use an antimicrobial treatment on all carcasses prior to chilling or cooling.

An active step in the slaughter process to reduce the bacterial load on a carcass appears to be a sensible requirement, at the outset. Among the various treatments initially approved is hot water, organic acid rinses, chlorine solutions, and Trisodium Phosphate. Each of these treatments has advantages and disadvantages for the small plant.

When introducing a new technology or technique into a small slaughter operation, one needs to remember the limitations involved in terms of physical plant limitations as well as capital outlays. Requiring an expensive system that is not engineered for confined operations is not in the plant's best interest. The introduction of additional water vapor and sprays through the use of these systems may lead to additional condensation and contamination problems.

There are indications that some pathogens, such as E. coli O157:H7, are not as susceptible to acid environments as previously thought. The use of the recognized organic acid rinses may not be effective in reducing the level of pathogens, as planned. In fact, if these pathogens survive the treatment, the lack of the normal competitive bacterial flora may allow the pathogenic bacteria to flourish in their absence.

Today's consumer is assailed from all sides by consumer advocates decrying the use and abuse of chemicals in food. This initiative takes a stand requiring the use of more chemicals. Consumer acceptance of such a product, or at least the controversy that may be raised about the product, should be thoroughly evaluated before implementing this initiative.

An organic acid rinse system, in addition to the consumer acceptance question, will also present other challenges and requirements to the plant operator. OSHA and EPA view the organic acids and Sodium Hypochlorite as regulated compounds. An EPA Hazardous Waste Permit is required for the use of these compounds. For plants utilizing these compounds, additional regulations and inspections will accompany their storage, use, and disposal at the plant level. This will add another layer of inspection by another federal agency onto the small plant.

The hot water alternative, although not a chemical problem, does present some concerns from a safety standpoint, and would increase the work involved in cooling the carcass to a safe temperature in the required time frame. Without the use of an automated system to ensure complete coverage, the application of hot water to the carcass may be less than effective in controlling pathogen

loads. Requiring an automated hot water delivery system may put this option out of the reach of the very small plant.

The actual efficacy and practicality of the utilization of these systems in the very small slaughter establishment should, therefore, be thoroughly studied and evaluated prior to the enforcement of this initiative. Research on different carcass treatment procedures is ongoing at various universities, and these results should be taken into consideration, when completed.

3. All finished carcasses and parts must meet specific time-temperature requirements for chilling and cooling.

Requiring specific time-temperature standards for meat and poultry products will help to retard the growth of spoilage micro-organisms, as well as pathogens. This creates a situation that benefits all parties involved. Product shipped from inspected establishments will have been held at temperatures that minimize bacterial growth, resulting in greater safety for the consumer. Producers will have a reduced incidence of spoilage, or "souring", of meat and poultry items, resulting in a higher-quality product with a longer shelf life, and greater consumer acceptability.

Utilizing the same set of guidelines for all species, however, fails to take into account the variation in carcass size. Smaller species, such as sheep, swine, and poultry , may be cooled within the required time frame, due to their smaller mass. Beef carcasses, with their greater mass, will be much more difficult to cool with the time limitations. Extending the time limit for beef carcasses to eight to reach 50 F should be implemented.

Refrigeration systems in many plants will need upgrading to consistently meet the limits, keeping in mind Kansas ambient temperatures that annually range from sub-zero to above one hundred degrees. Limited cooler facilities and older refrigeration units may also hamper cooling rates, and sufficient time should be allowed for smaller plants to renovate facilities, as needed. More stringent EPA regulations on the repair of refrigeration systems, as well as more costly refrigerants, have increased the overhead associated with refrigeration in a plant. This represents an additional source of concern to many plant operators who must deal with the fiscal impact of such regulatory control.

Requiring a 40 F internal temperature for handling, holding, and shipping is acceptable and will benefit all parties. However, some practical situations must be addressed. For example, what is the accepted method of taking an internal temperature for a vacuum-packed meat item?

We recommend a measured response for products found above the proposed temperature limits. Accepting product at 39 F, but rejecting product at 41 F is extremely harsh. A measured response would accept product at 40-45 F if the internal temperature can be reduced to 40 F within 2 hours. Product at 45-50 F would be accepted for further cooking purposes only, and product over 50 F would be condemned.

4. Certain raw product must be tested for Salmonella, and establishment must achieve targeted reductions in the incidence of Salmonella in 2 years.

This initiative, requiring microbial testing, is strongly opposed as described and interpreted in the proposed rule. If implemented, one sample would be required to be collected by the plant for each day of slaughter and from each slaughter class, as well as from each species of raw ground meat.

This requires a very small plant that slaughters multiple species, or a very small number of animals each day, to bear a disproportionately higher cost of sampling per head or pound than a fully-automated, multiple-shift large plant. In fact, utilizing the proposed sampling frequency, a very small plant that slaughters 2 head of cattle and 3 hogs three days each week, and produces 150 pounds of ground beef each day of the week, would actually have to take more samples for their 15 animals slaughtered and 750 pounds of ground beef than a large plant that slaughters nearly 3,000 head of cattle and produces thousands of pounds of ground beef each day of the week.

FSIS officials have stated that "statistically, volume does not matter" when considering sampling frequency. This statement fails to consider the actual operations in a very small plant, and the difference in automation, number of individuals touching a carcass, time spent ensuring that proper dressing procedures are followed, and the attitude and ability of both plant personnel and inspection personnel to control the process.

From a food safety standpoint, any high volume plant generates a greater risk of contaminated product due to the sheer volume of product involved. Product from very small plants typically reach a relatively small number of people each day, in a confined geographical area. A deviation in operations would not affect a notable segment of the population. However, a single error in the operations of a large plant results in dangerous product reaching millions of consumers over significantly wide regions of the country, and potentially world-wide, on any given day. As proof of this, consider any product recalls in the past several years. These have typically involved product from large plants, shipped to several states in the country, and reaching a tremendous number of consumers.

It is recommended, therefore, that this initiative be withdrawn in its entirety, or accommodation be made for the very small plants that would be severely impacted by its implementation. This accommodation would base a sampling frequency on the number of head slaughtered or pounds of ground meat produced. This would place less of a burden on those plants that contribute less to the overall problem, and more of the testing responsibility on those plants generally associated with the production of contaminated product. A sampling frequency of one sample per 100 head of each species, and one sample per 10,000 pounds of ground product is proposed as a reasonable accommodation for these plants.

It is also recommended that the implementation of this initiative be temporarily suspended in those plants that do not have on-site laboratory

facilities. With technological advances occurring in the areas of microbiological testing procedures, a relatively simple and inexpensive test should be commercially available in the near future. When a reliable, self-contained test is developed that allows rapid, in-house testing for the small plant, the sampling requirement can be reintroduced.

5. Hazard Analysis and Critical Control Point (HACCP) System

Developing a system that results in a safer product for the consumer is the ultimate goal of this proposed rule, and this department fully supports that goal. The concept of HACCP is currently recognized by many as the proper approach to a science-based food safety system. It has been implemented in several different segments of the food industry. A cautionary note: Its implementation in the meat and poultry industry has yet to be attempted on any meaningful scale. The two-year pilot project conducted by FSIS in nine selected plants produced indeterminate results. In some cases, the incidence of pathogens actually increased after HACCP was implemented in the plant.

At this time, there is a considerable lack of practical knowledge regarding the application of HACCP in the meat industry. Many small plant operators do not fully understand what HACCP entails. With the estimated costs involved, based upon FSIS's own study, mandating such a program without full knowledge of its ability to achieve the desired results exhibits poor judgement. Despite the best of intentions of FSIS, a mandated HACCP system with an accelerated phase-in time frame will force many plants out of business due to economic constraints. If HACCP is determined to be unsuccessful in reducing food-borne illnesses, and is therefore a "failure", those closed plants will not resume operations. They will have ceased to exist, and the communities around them will have been irreparably affected.

Implementing HACCP in an industry with such diversity as the meat and poultry industry will require a tremendous effort and commitment from both industry and the regulatory agency that inspects it. Training for every plant down to the smallest 4-person small town slaughter plant is a daunting task. The three year accommodation for small plants is sorely needed to adequately train and develop the required HACCP plans, and to develop a good working understanding of HACCP by all plant personnel. The same training and understanding by the inspection force must also be addressed, especially in today's climate of budgetary reductions and personnel constraints. The training of inspection personnel will also have to be accomplished without interrupting the normal operations of industry, and may prove to be a difficult task with limited inspection personnel resources.

It is recommended that the actual implementation of the mandated HACCP in the final rule be reviewed for effectiveness in providing a safer product to the consumer. At this point, there is less than a full consensus from food safety experts as to the benefits that a HACCP system at the slaughter and processing level will have on the incidence of food-borne illnesses at the food-service and consumer level. Concentrating on the mid-point of the chain between farm and

table, without considerable emphasis at points beyond the processing plant, seems to be lacking in sound logic.

According to experts in this field, a successful HACCP program demands a thorough understanding and appreciation of HACCP by the individuals who will be implementing the program. This requires a strong educational effort down to the very small plant, and to each employee. A focus on education and phasing HACCP into the industry will produce better, sustained results in the area of food safety than an accelerated, mandated program. It is difficult to explain to a plant operator who has been in operation for thirty years without a single incident of a food-borne illness just how HACCP will result in clear, tangible benefits. There is no evidence that HACCP will increase profits for a plant. There should be some increased efficiency in a plant, and the increased documentation should provide a measure of protection to a plant involved in any liability lawsuits, but the industry-wide conviction of HACCP's practical usefulness has not been seen yet.

Instead, the widespread opinion among the very small plants and their faithful clientele is that this proposed rule represents an unwanted, unwarranted intrusion into their lives by the federal government. It is seen as an overreaction to sensational journalism by an agency that is trying to force a "one size fits all" solution on an industry that is fiercely independent and individualistic in its membership. When the Centers for Disease Control and Prevention (CDC) estimate that 97% of all food-borne illnesses occur as the result of the mishandling of food items at the food-service and consumer level, one must question the wisdom of emphasizing change at the processing level. If the stated goal is to reduce food-borne illnesses by 90%, then concentrating efforts on 3% of the problem seems misguided. Efforts should be directed at reforming those segments of the food chain that are responsible for the preponderance of the problems.

Due to the lack of consensus from all parties involved, it is recommended that the HACCP provision remains in this proposed rule, but phased in with careful consideration for the very small operations. Increased work with small-plant HACCP studies should be ongoing, and independent cost/benefit analyses for public health and environmental concerns should be conducted.

Throughout these comments, reference has been made to "small plants" and "very small plants" when discussing the impact of this proposed rule. The proposed rule defines a "small entity" as "an establishment with a sales volume of meat and/or poultry products of no more than $2.5 million per year.". This definition overlooks the size and scope of a tremendous number of meat and poultry plants that operate today. The average plant in Kansas, and many other states, has no more than ten employees and has a sales volume well under $1 million per year. Many plants in our program are family-owned and operated, with multiple responsibilities for each employee.

It is therefore recommended that accommodations be developed to address the unique characteristics of these plants. A "very small plant" would be defined based on the number of employees (no more than 20 full-time), slaughter volume

(no more than 2,500 animals per year), or processing volume (100,000 pounds of meat and/or poultry products per year). A plant in this category would be required to implement the provisions of the proposed rule pertaining to sanitation SOP's and time-temperature requirements. Antimicrobial treatment of carcasses would be voluntary, and such a plant would be exempted from microbial testing as proposed. Implementation of a HACCP program would be initially voluntary, and phased in with considerations in the areas of documentation and record-keeping for the limited work force.

On behalf of the Kansas Department of Agriculture, I submit these comments for full consideration. While the goal of increased food safety is one that should be paramount in any program involving meat and poultry inspection, saddling the industry with even more restrictive regulations is not the route to take. It is hoped that a meaningful balance can be achieved on this matter. The recent calls for negotiated rulemaking that would include all segments of the affected industry and regulatory agencies would permit a collaborative, cooperative effort to be undertaken in the achievement of the common goal. I urge that this option be taken, and would welcome the opportunity to participate in such an effort.

Sincerely,

Alice A. Devine
by GPE

Alice A. Devine
Secretary of Agriculture
Kansas Department of Agriculture
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KANSAS DEPARTMENT OF AGRICULTURE

September 28, 1995

Ms. Diane Moore, Docket Clerk
Rm. 3171, South Building
U.S. Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

Subject: Docket No. 93-016P: Proposed Rule: Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems

Dear Ms. Moore:

The following information has been developed to augment the official comments from this agency that were submitted during the comment period. It is intended that this supplemental information be utilized to expand on specific related topics generated by the proposed rule.

Sincerely,

Alice Devine

Alice A. Devine, Secretary
Kansas Department of Agriculture
(913) 296-3558

House Agriculture Committee
February 20, 1997
Attachment 5

PATHOGEN REDUCTION ACT/HACCP
SUPPLEMENTAL INFORMATION

1. LAYERING OF REGULATIONS

Currently, every aspect of an inspected meat or poultry establishment is affected by regulations from the FSIS or State program. From the actual design of a meat plant, to its operations, to the labels on its products, to the type of soap used to clean the plant, regulations exist that specify what is acceptable for the production of meat and poultry items.

Plant operators have been known to complain that the regulations even tell them when to cut their grass. In a sense, the section of the regulation concerning plant sanitation does specify that "...every practicable precaution shall be taken to exclude flies, rats, mice, and other vermin from official establishments". Overgrown weeds and grass can serve as a harborage for rodents, and therefore a plant operator could be required to keep the grassy areas around his plant cut at the discretion of an inspector.

Unfortunately, as the move to a more science-based inspection system is promulgated, the reduction of these regulations is not keeping pace. New regulations that cover the use of a HACCP system, or deal with the various aspects of the Pathogen Reduction Act, would augment the existing system. Plant operators would be faced with having to comply with the requirements that have been in effect for years, as well as a brand new set that could conceivably conflict with the established system. Such a layered system could severely hamper the operator of a small plant when making any science-based improvements in the operation.

The development of any such new regulations must be tempered with a review of existing applicable regulations. There should be a synchronous reduction in those regulations when a conflict develops with, or when the existing regulations prevent the advancement of, a science-based system.

2. HACCP vs. INTERSTATE SHIPMENT

As long as state inspection programs have been approved by FSIS, products from these programs have been subject to an unfair marketing practice; i.e., the restriction from interstate commerce. State meat and poultry inspection programs are required to be "at least equal to" federal standards, yet the products from their meat or poultry plants do not enjoy "at least equal to" benefits. Recent discussions on the removal of this restriction have revealed that food safety is not the issue in this debate. Instead, representatives of large industry have claimed that the small state-inspected plants would enjoy an unfair economic advantage in the production of specialty meat products that are not economically viable for a large operation.

Not all state-inspected plants have a desire to enter into interstate commerce with their products. Most of these plants serve a limited geographic area with a limited population. However, for those plants that are large enough

to reach across state lines, or those that produce a certain type of product that is readily marketable, or those that just happen to be located close to a state line, this restriction limits their ability to operate in a free-market society.

Developing and implementing a HACCP program would be much easier, in terms of management attitude and cooperation, for such a plant if there was the opportunity to engage in interstate commerce. With the restriction lifted, there is some tangible benefit that could offset the costs associated with the program. The plants are not in this business for the sheer enjoyment of it. Giving them an incentive, such as access to interstate commerce, would be very beneficial in developing the necessary attitude toward HACCP. With some accommodations for the extremely small plants in the area of documentation, many small plants would be interested in tying interstate shipment to implementation of a HACCP plan.

Using interstate shipment as an incentive to adopt HACCP, however, will not appeal to all small plants; for example, those that have their area of operation well within state borders. These plants have never needed nor desired interstate privileges, and it is unlikely that their motivation to adopt HACCP will increase. For these plants, the adoption of HACCP into their plants will require a great deal of education and enough time to develop their own plans for implementation.

When surveying the meat plants in the Kansas program, it is therefore imprudent to categorize them as all "for" or "against" interstate shipment. There are numerous plants that would take advantage of such an opportunity to increase their market. However, those small plants whose operations deal with a limited geographic area would not be directly affected by such.

3. ECONOMICS OF IMPLEMENTING HACCP

A typical Kansas meat plant consists of fewer than ten employees, including the owners/operators. A high school education is the norm, but is not required. Typical work days last ten to twelve hours, with some reduction on weekends. More often than not, the plant is truly family-owned and family-run, often spanning three generations of the family. Specialization is out, cross-training and cross-utilization is in. An efficient use of the minimum number of employees results in lower business overhead, and a net profit for the year.

Implementing HACCP in a small plant is a project with many steps. During the development of a HACCP system, personnel must be trained, HACCP plans must be developed for each product line, and equipment must be purchased or upgraded. Once the HACCP plan is in place, there will be continuing costs as a result of laboratory sampling, documentation of operations, and verification of HACCP effectiveness.

A. TRAINING

Personnel training, the first step, must be completed before any HACCP plans can be developed or implemented. Each plant will need at least one employee fully qualified in HACCP principles, and the remaining plant employees should

be fairly knowledgeable of HACCP to ensure its implementation. Having a second HACCP-trained employee on site would be prudent in order to avoid problems with illness, injuries, vacations, or employee turnover of the first HACCP trained employee.

Approved training programs in HACCP are currently offered through the national meat associations, and becoming more available with time. Unfortunately, training sites have not been locally situated and result in expensive travel costs to attend. Attending a recent three-day meeting in San Francisco, for example, would have resulted in an overall cost of nearly $2,000 when factoring in registration costs, airfare, lodging, and expenses. That represents the weekly payroll expense for a typical processing plant with eight employees, according to its owner/operator.

University extension services are attempting to develop more affordable training programs that would take advantage of various media formats to deliver the training to the plants. Videotapes, satellite hookups, and correspondence courses are being investigated by Kansas State University and Utah State University to provide the needed training in a manner that will ensure the greatest chance for success. These programs under development will help to reach the isolated plants, but it may take more time than the three years being considered by FSIS to adequately train for and implement HACCP.

B. PLAN DEVELOPMENT

The development of the HACCP plans for a meat plant must be carefully addressed to ensure effectiveness. A plant operator could develop his own plan, or may hire a private consultant to do this. Current estimated costs for the use of a consultant range from $90-$125 an hour, with the initial plan requiring 30 to 400 hours to develop, depending on the complexity of the operation. Other product lines will also need a separate HACCP plan, although the cost of doing these would not be so high. Still, a USDA contractor estimated that eight to twenty-two hours may be needed to develop each additional plan.

The number of HACCP plans needed by a meat plant will be determined by the number and type of products produced by a plant. Separate plans will be needed for the slaughter of different species, for example, and the production of different ground meats or sausages. Cured or smoked products will also need separate plans. Although similarities will exist between plans, there will be unique characteristics for each. The small plant that produces a wide variety of products in smaller volumes will be much more affected by this aspect of a HACCP system than the large plant that mass-produces only a couple of lines of products.

C. EQUIPMENT

When HACCP is implemented into a plant, certain food safety or regulatory requirements may necessitate equipment purchases or upgrades to achieve compliance. This may involve incubators for microbiological or residue testing, separate refrigerators for meat samples, thermometers for monitoring water, product, or refrigeration temperatures, refrigeration upgrades to accommodate increased cooling demands, or test equipment to confirm proper sanitation levels.

4. STATE INSPECTION PROGRAM & HACCP

A. TRAINING

State inspection personnel will also need to undergo training to understand the HACCP system as it applies to the meat industry. This initial training will be utilized to ensure that the basic principles of HACCP are properly interpreted by the in-plant inspectors. As such, utilization of the same training programs already mentioned would be beneficial.

In addition to the basic HACCP training, additional training by FSIS will need to be completed to properly explain the inspectors' responsibilities in a HACCP program. This training, in terms of format or schedule of delivery, is only in the developmental stage.

The accomplishment of this training of inspection personnel will be hampered by personnel and fiscal constraints. Only small numbers of inspectors can be made available at one time without restricting the operations of the state-inspected meat plants. The cost to bring field personnel to a centralized location for either basic HACCP training or the FSIS-sponsored training must include all travel and lodging, per diem cost, as well as the increased utilization of replacement inspectors to cover assignments.

B. INSPECTION RESPONSIBILITIES

At this preliminary stage, FSIS guidelines have not stated the specific role of the inspector in a meat plant that has adopted and implemented a HACCP program. It is generally believed that monitoring the implementation of a HACCP program, as well as verifying its validity and success, will be paramount. However, the historical carcass-by-carcass inspection in the slaughter plant remains under evaluation. Utilization of a performance-based inspection system, such as the PBIS system used by FSIS, will continue to be brought on-line within the state system.

C. TESTING

Pathogen testing will be a tool used by the plants and inspectors to confirm that the HACCP program is working, but certain aspects of pathogen testing, such as specific responsibilities, interpretation of test results, and disposition of product tested, have not been finalized.

Refrigeration upgrades may require the repair or replacement of compressor units, the replacement or addition of insulating material to improve cooling capacities, or even the addition of new coolers to replace existing facilities or expand capacities. Capital outlays for such projects can run into the thousands of dollars. A new compressor for a small plant costs over $5,000, with installation costs increasing that by an additional $1,000-$2,000. A complete renovation of the coolers and freezers in one small plant recently cost $60,000.

D. IMPLEMENTATION

In addition to the actual equipment costs, a HACCP system requires the monitoring of all critical control points. Records must be generated to permit clear documentation of this, and those forms must be kept on file for a mandated length of time. The cost of those forms, document storage, and the actual time needed for record-keeping must all be taken into account when considering HACCP's cost.

A plant may decide to hire a trained HACCP coordinator to run the plant's HACCP program. This would remove the responsibility of the required documentation from the regular employees, but at the cost of another $20,000-$25,000 in payroll expenses for the coordinator.

E. TESTING

One of the methods used to monitor and verify HACCP effectiveness is the use of microbiological sampling of products for pathogen levels. This is the most expensive aspect of the HACCP system, as most small plants must rely upon private labs for their testing. Proposed testing frequencies in the Pathogen Reduction Act call for daily sampling of product. At the rate of $30 per test, this would result in annual costs of $7,800 for each product tested, when figuring a five-day production schedule. Plants producing several different products for testing, as well as slaughtering multiple species each week, could expect annual testing costs to reach over $25,000.

Sampling under a HACCP system may be less frequent than that of the Pathogen Reduction Act, but would still be needed. Even weekly sampling would generate almost $8,000 in annual costs for plants with slaughter and processing operations. This estimate is based on the slaughter of two species and the production of only three product lines each week. Each additional product line would entail an additional $1,560 in testing costs each year.

F. VERIFICATION

After a HACCP system is implemented, an annual assessment, or audit, must be performed to verify that the plans are working as intended. This verification process would need to be performed by an independent agent to maintain objectivity and program integrity. Currently, the cost of the use of such a firm to conduct this audit is estimated to be about $1,000. It is conceivable that either inspection personnel or university extension personnel could perform this task, at considerable savings to the plant. This aspect of the HACCP program, however, has not been finalized.

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KANSAS DEPARTMENT OF AGRICULTURE

DIVISION OF INSPECTIONS
Meat & Poultry Inspection

Dr. Joseph E. Beuerlein
Program Manager

ADOPTION OF HACCP AND ASSOCIATED FEDERAL REGULATIONS IN KANSAS STATE-INSPECTED MEAT AND POULTRY PLANTS

Presented to the
House Committee on Agriculture

February 20, 1997

House Agriculture Committee
February 20, 1997
Attachment 6

House Agriculture Committee
House Bill 2425
Feb. 20, 1997

I am Dr. Joe Beuerlein, Program Manager for the State of Kansas' Meat and Poultry Inspection Program. This program was developed and formally recognized by the USDA's Food Safety and Inspection Service in 1969. The program currently has sixty-four employees, sixty-one of whom are field staff. We provide inspection services to approximately 160 inspected and custom-exempt meat and poultry establishments throughout the state. Our activities also verify that meat and poultry products in commerce conform to all applicable state and federal regulations.

The Significance of "Equal To"

As confirmed by regular federal reviews, the state program has always operated on an "equal to" basis with the federal program. The "equal to" status is a requirement under Federal law. The "equal to" requirement applies to all state cooperative programs, as well as to all international programs in nations that export meat or poultry products to this country.

Adoption in Other States

The Federal regulations now being proposed are already in effect in all establishments under Federal inspection, as well as in fifteen of the twenty-six state inspection programs. Kansas is one of eleven state programs now in the process of adopting them. According to federal law, these regulations will be put into effect. All inspected establishments will have to comply with these new food safety rules. If a state inspection program declines to implement and enforce the regulations, the federal inspection system will take over and do so in lieu of the state.

Increased Assurance of Food Safety

The purpose of the regulations is to increase the safety to the consumer of meat and poultry products produced in the inspected establishments. These regulations will allow the everyday consumer of meat or poultry products to have an assurance that active steps have been taken, at the point of production, to decrease the incidence and degree of bacterial contamination of the meat or poultry. Since the greatest source of illness-causing bacteria on meat or poultry is animal feces, the consumer will benefit by receiving products that have not been adulterated with animal feces. The proposed regulations will be the mechanism that moves the meat industry into a modern system in which microbial testing and documentation of operations will be the evidence that every precaution is being taken to provide safe products to the families in this country.

Introduction in 1995

These regulations were first introduced to the general public in the spring of 1995. Considerable time was devoted to public meetings throughout the country. Special technical meetings were held with representatives from industry, academia, regulatory, and consumer groups to debate the many aspects of the regulations. Comments from interested parties were accepted by USDA until late in 1995, an exceptionally long comment period for proposed regulations. A copy of comments sent by the Kansas Department of Agriculture to USDA is attached.

The implementation of these regulations has already begun in the federal inspection program. USDA has allowed some flexibility to the states in their implementation of the regulations only due to individual state legislative requirements. Failure to implement the regulations in a timely manner will be viewed as a failure to

maintain the "equal to" status of the state program.

According to the federal regulations, over the next three years, several changes must be incorporated into an inspected establishment's operations. The first two are to take effect as soon as the regulations can be adopted. These are the written sanitation standard operating procedures (SSOP's) and testing for E. coli contamination in the slaughter plants.

Sanitation Standard Operating Procedures

SSOP's have been encouraged in all plants for years, and have been actually used by some plants voluntarily. The new regulation will now make this mandatory for all establishments.

SSOP's are simply a written description by the establishment of its operations and the steps that are taken to maintain sanitation at an acceptable level. It may be as simple or as complex as the establishment wishes, as long as it explains how sanitation will be maintained and how contamination of product will be dealt with. Records are required to show that the SSOP's are being followed, and to record how an establishment deals with a food-safety hazard when it occurs. If prepared conscientiously, the SSOP's can serve the plants as a complete sanitation training guide for new employees.

Efforts have been underway since August 1996 to explain the SSOP requirement to all inspected establishments. With the continued expertise of Kansas State University, training has been offered to all interested establishments. Throughout the state, inspection personnel and inspected plants have been cooperating to develop effective SSOP's. Many inspected establishments have completed their SSOP's, or are

now actively working on them.

E. Coli Samples

Taking samples for E. coli in slaughter establishments will greatly advance awareness of the level of sanitation during the actual slaughter process. E. coli is a bacteria found in the intestines of livestock. Fecal contamination during slaughter or processing leaves E. coli present on meat.

The sampling requirement calls for a plant employee to do a simple swabbing of a randomly-selected carcass each week during June, July, and August (the most conducive months for E. coli contamination). This will be analyzed to see if the animal carcass was contaminated with fecal matter during the slaughter operation. Plants will utilize this information to improve their employees' work habits so as to reduce the amount of contamination on carcasses. Less contamination of the carcass with manure results in a safer product for the consumer. Records maintained on the sample results will be another bit of evidence that verifies the safety of the product coming from an establishment.

HACCP to be Adopted Last

The final requirement, the Hazard Analysis and Critical Control Point (HACCP) food safety system, must be developed and implemented over the next three years, depending on the size of the inspected establishment. This program will provide the greatest safety for the consumer by requiring that a meat or poultry establishment review every step of its operation, identify the risks that could result in a food safety danger, and take appropriate steps to control that risk. Once again, good record-keeping will be a major component of such a system. Training and understanding by

all employees will be vital to a HACCP program's success. Many plants may need to upgrade their establishments to ensure a safer work environment with respect to food safety. For some establishments, it may be the first upgrade since original construction.

If the state of Kansas were to decide not to adopt and implement the federal regulations, FSIS would view our inspection program as less than equal to. FSIS would immediately take steps to assume inspection in those establishments which were under state inspection. This would affect more than just meat inspection.

Consequences to Small Plants and the State

State meat or poultry establishments would incur several expenses in the shift from state to federal inspection. All product labels would have to be changed to bear federal inspection marks, architectural blueprints would need to be submitted for approval, some plant upgrades may be required before inspection begins, and changes to operation schedules may be implemented.

Under the Kansas Meat and Poultry Inspection Act, animals such as buffalo, domesticated deer, ostriches, emus, and rheas are all inspected without an additional user fee. Under the federal system, any slaughter of these animals would require the payment of an hourly user fee for a federal veterinarian to conduct inspection. Currently, that rate is nearly $35 per hour.

If operations in an inspected plant extend past eight hours, overtime is charged to the establishment. Overtime rates for federal inspectors is $30 per hour, compared with $18 per hour for the state inspector.

The state meat inspection program also provides important consumer protection

activities, including investigation of fraudulent operations such as illegal farm slaughtering, poaching incidents, and illegal door-to-door sales of meat by unscrupulous vendors. The federal program does not have the same duty, resolve, or obligation to assist in such local consumer protection matters.

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TOPEKA

HOUSE OF
REPRESENTATIVES

COMMITTEE ASSIGNMENTS
AGRICULTURE
EDUCATION
TRANSPORTATION

Thank you Committee Chairwoman Flower and Committee:

I introduced HB 2425 as a direct result of my frustration dealing with the issue of meat safety. The Federal government says we have to make efforts to strengthen food safety and consumer confidence. Our Secretary of Agriculture expresses this same message. We are "lining up" agencies to help accomplish this. My question is, have we ever had a serious problem with our little processing plants that would warrant the action we are taking? I understand that no one in Kansas has ever become sick or died because of something that was done wrong.

It has been estimated that at least one third of our plants will go out of business. Also it is estimated that the remaining plants will have to spend $25,000 to $200,000 to comply with these new regulations. I don't understand what changes have to be made, and I believe most little processing plants don't either.

Loosing over 50 plants across Kansas will have a devastating effect on the communities were they are located.

We seem to make every effort to encourage businesses to come to Kansas. Here we have an opportunity to save many businesses if we try a little harder.

I understand that HACCP has been criticized by some associations and corporations. For example:

The National Grain and Feed Association said the commercial animal feed industry should be excluded from HACCP.

The National Cottonseed Products Association told FDA that imposing mandatory HACCP requirements on the vegetable protein industry "will not address the real problem of food borne pathogens and it cannot be cost justified".

Purina Mills of St. Louis said if a safety issue cannot be clearly defined or scientifically supported"it is doubtful that HACCP would improve safety".

I believe that meat safety has not been defined as an issue in our little processing plants. Also we have not been told the impact and ramifications because of HACCP. I hope you will support HB2425 in its efforts to get some of these questions answered. Thank you.

House Agriculture Committee
February 20, 1997
Attachment 7

Thank you for letting me testify.

Have been under inspection for 27 years and never though I should rock the boat as I prefer having local rather than national in all aspects of governmental bureaucrats.

Meat inspection is purely socialistic and has to have mandates that carry punishments for disobedience. Operators come under the control of inspectors and there is no mechanism set up to hear complaints of operators.

Would like to see legislation set up a mediator on a fee basis to be a referee, listen to operator problems and try to mediate problems to satisfy inspection, take care of customers and make it easier to be under inspection. You might remember that we were in busiess and government actually came in to run our busiess. We do want to put out a ssafe and wholesome product that is good for customers.

Peace be with you

Gene Steffes

Gene Steffes
Food Bank
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House Agriculture Committee
February 20, 1997
Attachment 8