Proposed Rules

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

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 308, 310, 318, 320, 325, 326, 327, and 381

[Docket No. 95–046N]

Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems—Issue Papers

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed Rule; issue papers.

SUMMARY: On September 13–15, 1995 and September 27–29, 1995, the U.S. Department of Agriculture held issue-focused public meetings on the Food Safety and Inspection Service's (FSIS) proposed rule, ''Pathogen Reduction, Hazard Analysis and Critical Control Point (HACCP) Systems.'' At the meetings, FSIS made available issue papers on agenda topics. Those issue papers are published in this notice.

DATES: The comment period for the proposed rule, ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems'' (60 FR 6674, February 3, 1995), which reopened August 11, 1995 (60 FR 41029 August 11, 1995), will close, as announced in the Federal Register (60 FR 45380, August 31, 1995), on October 30, 1995.

ADDRESSES: Send an original and two copies of written comments to: FSIS Docket Clerk, DOCKET 93–016P, Docket Room 4352, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: Dr. Paula Cohen, Director, Regulations Development, Policy Evaluation and Planning Staff, FSIS, USDA, Room 3812, South Agriculture Building, Washington, DC 20250, (202) 720–7164.

SUPPLEMENTARY INFORMATION: The U.S. Department of Agriculture held issue-focused public meetings on September 13–15, and 27–29, 1995, on FSIS' proposed rule, ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems.'' The purpose of the meetings was to provide an opportunity for interested persons to directly discuss the key concerns that were raised during the comment period on the proposed rule, as well as the Agency's thinking about options under consideration in response to those concerns.

For the meetings, FSIS prepared brief issue papers on agenda items that were discussed. The issue papers are: Issue Paper 1. ''Regulatory Shift to Performance Standards—'Layering';'' Issue Paper 2. ''Overview of HACCP Proposal FSIS Oversight of HACCP Changing Role of Inspectors Under HACCP;'' Issue Paper 3. ''Pathogen Reduction Performance Standards;'' Issue Paper 4. ''Carcass Cooling Standards for Red Meat and Poultry;'' Issue Paper 5. ''Specific Economic Considerations and Issues;'' Issue Paper 6. ''Specific Product Considerations Involving Religious, Ethnic, and Cultural Food Handling Practices;'' Issue Paper 7. ''Antimicrobial Treatments in Slaughter Plants;'' and Issue Paper 8. ''Specific Product Considerations Involving International Trade.''

All information received at the issue-focused meetings and received during the reopened comment period will be considered in the development of the final rule for Pathogen Reduction/HACCP. FSIS is publishing the issue papers so they will be available to persons who were unable to attend the issue-focused public meetings and to enhance the opportunity for comments from all interested parties.

The issue papers are published below.

Issue Paper 1. ''Regulatory Shift to Performance Standards—'Layering' ''

I. Objective of Proposal

The goal of the Pathogen Reduction/HACCP Proposed rule is to adopt and implement an integrated, HACCP-based inspection system that clarifies and maintains a distinction between industry and FSIS responsibilities, targets the most significant hazards, and fosters flexibility, innovation and accountability for improving food safety. However, FSIS recognizes that to achieve this goal, it must also eliminate unnecessary and redundant regulations.

II. Description of Comments

Some commenters argued that the proposed pathogen reduction and HACCP requirements layer an additional set of regulations, and subsequently an additional program of inspection, on the current meat and poultry inspection regulations and inspection activity. Some commenters recommended that, prior to publishing the final rule, FSIS review and revise or eliminate current regulations, directives, and other FSIS guidances so that they are compatible with the proposed pathogen reduction/HACCP requirements.

Some commenters cautioned FSIS not to alter or eliminate current regulatory requirements and inspection procedures until more effective ones are operating in their place.

III. Issues Raised by Comments

FSIS recognizes the need to articulate how regulatory requirements and inspectors' roles would change under the regulatory system that would emerge from the proposed regulatory reforms. Key issues of concern raised by the comments include:

- HACCP clarifies the mutually exclusive roles of industry and Government and, along with responsibility, affords individual plants the flexibility to innovate and make site-specific decisions. The current inspection system makes the inspector responsible for ''approving'' production-associated decisions. How will inspection change under HACCP?
- Under what circumstances will FSIS continue to issue command-and-control-type requirements?
- How should the regulatory system be changed, and at what pace, to eliminate redundant and obsolete requirements, such as prior approval systems and command-and-control requirements?
- Has FSIS identified the regulations that need to be eliminated or changed to be compatible with HACCP? Given that the current inspection system is embedded in current regulations, the essential changes are likely to be extensive. Can all necessary changes be adopted prior to HACCP implementation?
- Will inspectors' roles change as a result of the shift from step-by-step, command-and-control requirements to performance standards? How? How will the transition to the new regulatory system—with plants accountable for meeting FSIS's requirements by methods not necessarily listed in the regulations or inspectional guidelines—be managed?
- What methods of dispute settlement should be available to handle the more

complex decisions that need to be made about compliance with regulations under HACCP?

IV. FSIS Current Thinking About Changes Needed to Address These Issues

Under the proposal in conjunction with the regulatory reforms now in progress, industry would assume full responsibility for production decisions and execution, and FSIS, having set food safety standards and public health objectives, would monitor and enforce plants' compliance with those standards and related requirements and, under HACCP, would verify process control. This would appear to imply the following:

- FSIS must review and revise or eliminate current regulations, directives, and other FSIS guidances to ensure their compatibility with HACCP requirements and the regulatory philosophy HACCP represents.
- Performance standards could be used to eliminate certain command-and-control requirements.
- With the distinct roles and responsibilities of FSIS and industry clearly defined, FSIS would be able to relieve inspectors of many tasks that should be performed by establishments, enabling inspectors to focus on, HACCP-related oversight tasks.
- In-plant inspection would have to be managed so that the skills necessary to evaluate the plant's performance under HACCP would be available in every plant.
- Lines of FSIS supervision and decision making would need to be shortened, clarified, and publicized, particularly with respect to fair, prompt, and effective dispute resolution.
- Unnecessary and redundant regulations would need to be eliminated.

Issue Paper 2. ''Overview of HACCP Proposal FSIS Oversight of HACCP Changing Role of Inspectors Under HACCP''

I. Objective of Proposal

The proposed rule embraced the recommendations of the National Advisory Committee on Microbiological Criteria for Food (NACMCF) concerning ''The Role of Regulatory Agencies and Industry in HACCP.'' Regarding food safety, the NACMCF advised that establishments operate effective HACCP systems, with the government focusing on verification that HACCP plans are working as intended. The Agency's stated intent was to review and revise existing inspection tasks to assure they are focused on the critical control points in HACCP plans. These revised tasks would be incorporated into the Performance Based Inspection System (PBIS) and become part of regular assignments.

FSIS inspectors would play a verification role to ensure that appropriate HACCP plans are in place, are being implemented properly, and are achieving the desired food safety results. This role would require increased activity by FSIS inspectors in the areas of record review, visual process verification, and product sampling. FSIS inspectors would have to develop new skills to carry out these activities within the HACCP framework.

II. Description of Comments

Commenters generally supported the need for government to maintain oversight of meat and poultry production to ensure that industry is using a system of process control that assures safe product. Some commenters stated government needs to relinquish at least some of the role it plays in making decisions about the production process itself; that is, industry should have the responsibility for deciding how meat and poultry products are produced, provided it can demonstrate that it is maintaining process control at the level necessary to produce a safe product, and meets other regulatory requirements. There was general support for HACCP as an acceptable industry process control mechanism, though commenters raised a number of issues concerning specific provisions of the proposed rule. Some commenters stated government requirements should be scientifically supportable and stated as non-prescriptively as possible (as performance standards).

Commenters also raised concerns about the amount of discretion inspectors would have to suspend plant operations due to alleged deficiencies in either the design or operations of a HACCP plan. They expressed concern about the limited amount of procedural due process afforded to establishments faced with suspended operations due to an inspector's judgment on the adequacy of their HACCP program. Some commenters objected to the proposed hearing process and requested a more expedient way to resolve disputes before requiring suspension of operations or withdrawal of inspection. Some urged the Agency to make clear to inspectors that such extreme actions are to be reserved for only those situations in which continued operation of the establishment presents an imminent public health risk. Finally, commenters raised questions concerning the uniformity and depth of HACCP training inspectors should receive.

Some commenters, while supporting the enhancement of industry's responsibility for food safety that is embodied in HACCP and performance standards, expressed concern about how plants would be held accountable for meeting their enhanced food safety responsibilities. These commenters called for vigorous inspectional oversight of HACCP including substantial microbial sampling and testing by FSIS to verify HACCP and enforce performance standards. Some commenters called for retaining current inspection procedures until HACCP is implemented and FSIS can have confidence that alternative procedures will be more effective than current ones. To increase industry accountability, some commenters called for clear delineation of the plant's legal obligations under HACCP, public access to HACCP records, and whistleblower protection for plant and FSIS employees.

III. FSIS Current Thinking on Selected Issues

FSIS recognizes the need to articulate in more detail how FSIS oversight of meat and poultry production operations under a HACCP process control system will change, how FSIS regulatory roles will be altered, and how these changes will affect inspectors' roles. The following issues must be addressed to develop and implement a final rule:

- How will FSIS oversee a plant's operation under HACCP, compared with the current system.
- How should inspector roles be changed to distinguish between industry and government responsibilities.
- How should the inspector's role and priorities be redefined to focus on the greatest public health risks.

A. Transition to a System Focusing on Industry Process Control and Other Systems and Safety Standards

The regulatory environment envisioned by the proposed rule, in which industry would operate under a process control system (HACCP) and inspection personnel would ensure that HACCP is working by overseeing the effectiveness of that process control system in producing safe product and by enforcing performance standards and other requirements, calls for a significant shift in FSIS oversight. This shift would focus regulatory activities on process control and other systems and the enforcement of government safety requirements (to the extent possible issued as performance standards) rather than on prescriptive measures for controlling industry production practices.

The implementation of the proposed requirements would significantly change the roles and responsibilities of Agency personnel performing in-plant

regulatory activities. Inspection roles and responsibilities would shift from DETECTING facility and production problems to VALIDATING and VERIFYING that plants are producing safe meat and poultry products that meet the newly established requirements.

Agency activities and individual inspectors' tasks would need to reflect these proposed new requirements, and would need to be timed to conform to the phase-in schedule for the new requirements. During the transition from the current inspection system to the system envisioned by the proposal, it would be critical to provide for an interface between what FSIS is presently doing and what the Agency would be doing when initial implementation of these requirements occurs. Therefore, FSIS' current thinking about how inspection will change entails determining how existing and familiar systems may be used to support the transition, while the Agency prepares inspectors and supervisors for their changed roles under the new program.

Inspection roles are envisioned to consist of three primary activities—validation, verification, and enforcement. Inspection validation activities would include assessments of whether plants comply with the specific elements of the regulation and that HACCP systems encompass all seven HACCP principles. Inspection verification activities would include an evaluation of records to verify that the establishment is complying with its written HACCP plan along with in-plant visual observations, microbial testing, and other inspectional tasks to ensure that HACCP is being properly implemented and performance standards are being met.

Formal enforcement actions, including retention of products or suspension of operations, would be instituted when inspection personnel identify and document occurrences of direct product contamination, insanitary conditions where the product may have become adulterated or contaminated or where it may have been rendered injurious to health, or failure of the HACCP plan. Lines of supervision and decisionmaking would be shortened and clarified with respect to dispute resolution. FSIS recognizes that the appeal process must be more expeditiously handled under the proposed program.

Inspection activities would be accomplished within the framework of existing support systems. For example, the Performance Based Inspection System (PBIS) would serve as the primary vehicle to schedule, record, and report all validation and verification tasks. The PBIS corrective action system, which consists of the deficiency classification guide and process deficiency record, would be used to identify, document, and act upon occurrences of direct product contamination and system failures. The system would be modified to incorporate all slaughter-related activities, except carcass-by-carcass inspection.

The movement to a HACCP work environment would represent the most significant change to the regulatory process in the history of the inspection program. This would require that the field work force be trained to understand and perform new work tasks and to adapt to the changing regulatory focus. The initial training would focus on three aspects—(1) to equip employees to handle the regulatory tasks associated with the near term initiatives such as verifying the SOP records; (2) to equip employees to understand and appreciate the cultural changes that will take place in a HACCP work environment its effects on their actions; and (3) to equip front line supervisors to lead the cultural change. Subsequent training would be provided on a sequential basis to correspond with the HACCP phase-in schedule. In this way, inspectors would be able to directly apply ''just learned'' knowledge and procedures within days of receiving training. Training would be delivered by Agency personnel at the local level, using standardized materials developed expressly for that purpose.

FSIS shares the objective of some commenters of ensuring that inspectors and plant employees are given a common understanding and approach to HACCP and its application to meat and poultry production. However, FSIS believes it must place full reliance on its inhouse training delivery capabilities rather than participate in joint training sessions with industry personnel at the local level. Given the logistics and timeframes involved in training Agency personnel, the Agency could not accommodate the additional burden of coordinating its training delivery activities with industry. FSIS is, however, committed to sharing its curricula with interested parties, in order to ensure that the scientific and technical principles which undergird HACCP are viewed consistently.

B. Other Changes Beyond the Transition to HACCP

Along the farm-to-table continuum there are several opportunities for Federal, State, and local government regulators to foster or establish standards so industry can reduce the possibilities for product adulteration and subsequent foodborne illness.

For animal production, producer associations could promote the development of quality assurance programs that focus on risk reduction strategies for pathogen control in live animals. Further research by government, industry, and the scientific community is also necessary to acquire the scientific information about pathogen colonization, its characterization, prevalence, and incidence in animal populations, which is necessary for designing effective intervention programs.

For transportation and storage, industry associations could promote, and individual transportation and storage firms could adopt, special systems for handling meat and poultry that ensure minimal growth of pathogenic organisms. Development of Good Manufacturing Practices (GMP's) for this sector to address problems such as sanitation and temperature control and periodic reviews to determine conformance with such GMP's are also envisioned. These reviews would provide the basis for determining rates of industry compliance.

In the retail and restaurant sector, FSIS would continue its ongoing, direct regulatory authority over adulterated and misbranded product. This would include product control actions, such as voluntary destruction, detention, and judicial seizure. It also would include the issuance of letters of warning and referrals to the Department of Justice for injunctions or criminal action.

FSIS would expand its support to State and local inspection and enforcement agencies by: (1) Supporting the development and adoption of model food codes; (2) facilitating the standardization of state and local enforcement protocols in concert with the Food Code; and 3) evaluating state and local food regulatory agency inspection and enforcement programs for meat and poultry processing and handling.

In the area of food handler and consumer education, FSIS would continue its current program and would seek ways to expand its collaboration with all interested parties in government, industry and other private organizations to foster the effective delivery of safe handling messages to consumers in a manner that would improve safe food handling practices.

Issue Paper 3. Pathogen Reduction Performance Standards Microbial Testing

I. Objective of Proposal

The objective of the proposed interim targets for pathogen reduction and daily microbial testing requirement is to establish a measure of accountability for adopting process controls in slaughter plants and plants producing raw ground product that effectively control and reduce harmful bacteria on raw products. *Salmonella* has been selected in the proposed rule to serve as both an indicator of process control and as the basis for a pathogen-reduction performance standard.

II. Description of Comments

The two issues most commonly addressed by the commenters concerning the proposed microbial testing requirements were the proposed selection of *Salmonella* as the indicator organism and the frequency of proposed testing. Commenters generally supported the concept of HACCP-based process control and the goal of reducing harmful bacteria on raw products.

Some commenters supported the proposed use of *Salmonella* as the indicator organism because it is a leading cause of foodborne illness, and, among common enteric pathogens, it is among the most prevalent and relatively simple tests are available to detect it.

Some commenters opposed the use of *Salmonella* as the indicator organism because its low incidence in beef makes it a poor indicator of pathogen reduction in that species; the yes/no test result is a weak measure of process control; and, compared to some non-pathogenic alternatives such as generic *E. coli*, *Salmonella* tests are more difficult, time-consuming and costly. Some commenters recommended FSIS consider an alternative indicator organism such as generic *E. coli* as a preferable process control indicator organism because it can serve effectively in all species as an indicator of fecal contamination.

Some commenters recommended retaining *Salmonella* as the target or performance standard for pathogen reduction but adding a requirement for *E. coli* testing because it is a preferable tool for verifying process control. Some commenters recommended requiring testing for additional pathogens in selected species or products based on the degree of public health risk posed by the pathogen. With regard to sampling frequency, some commenters supported the one sample per day testing requirement as an efficient means of verifying process control.

The comments received on the frequency of testing centered upon suggestions on the sampling frequency of one test per day for each species and for raw ground product. A sampling protocol based on production volume or product risk was suggested as an alternative. Some commenters opposed the proposed testing requirement stating that it was inadequate to verify process control reliably and recommended more frequent testing that would be more representative of a plant's production. Some commenters recommended basing the frequency of testing on a plant's volume of production and argued that the proposed sampling frequency and moving sum statistical procedure would allow a lack of process control to go undetected for excessive periods.

Some commenters criticized the proposed frequency, noting the cost burden of the testing and its financial impact on businesses, especially for small volume plants and plants producing multiple species and multiple ground products that would require multiple tests. Some commenters recommended less than daily testing or other changes to minimize the financial impact on small business.

Some commenters objected to the proposed test sample collection methodology, including the sample size. Recommendations included adopting the same sample size for all species. Some commenters preferred swab samples to samples taken by knife cuts.

Some commenters stated that proposed end product testing is inconsistent with HACCP principles and that establishments should decide for themselves through hazard analysis whether testing is needed and at what frequency.

III. FSIS Current Thinking on Selected Issues

The concepts of process control, microbiological testing to verify process control, and the establishment of practical measures of accountability for controlling and reducing harmful bacteria on raw products remain central to the FSIS food safety strategy. Based on the comments related to microbial testing, FSIS reviewed whether the pathogen reduction objectives of the rule can be accomplished without requiring near-term microbial testing. FSIS considers some appropriate approach to testing to be necessary as the means of ensuring that every establishment is working toward an acceptable level of pathogen control. The key issues raised by the comments involve how best to implement these concepts.

Relative to concerns about reducing the burden of testing, the Agency is reviewing: (1) The organism to be selected in testing; (2) the necessity for daily testing in every plant, including plants that grind raw meat and poultry obtained from other plants and (3) the necessity for testing each species slaughtered and each ground product produced.

The proposed rule relied on *Salmonella* as both a process control indicator and as the basis for a pathogen reduction performance standard applicable to all species. Based on the comments, FSIS is seriously considering generic *E. coli* as the process control indicator organism and the adoption of a quantitative *E. coli* standard as a measure of process control with respect to the prevention and reduction of fecal contamination in slaughter plants.

If FSIS moves to a quantitative *E. coli* standard as the means of verifying process control, the Agency will also need to resolve what the standard should be (i.e., the number of organisms).

FSIS continues to regard microbiological testing to verify process control to be an establishment's responsibility. FSIS is reconsidering the proposed one test sample per day requirement based on comments questioning both its adequacy and its cost impact on small plants. FSIS is considering alternatives that are based on the volume of production. FSIS is also considering alternatives that would reduce the cost impact of testing on very small-volume plants producing multiple species and multiple products.

FSIS is considering the adoption of pathogen-specific performance standards as a direct measure of accountability for controlling and reducing harmful bacteria on raw meat and poultry products. For example, the proposed interim targets for pathogen reduction based on *Salmonella* (or possibly other pathogens for specific species) could be adopted as performance standards and enforced by FSIS through its own compliance monitoring. Establishments not consistently achieving the targets would be required to take corrective action and could be subject to other regulatory action, as appropriate.

Issue Paper 4. Carcass Cooling Standards for Red Meat and Poultry

I. Objective of Proposal

The objective of the proposed carcass-cooling requirements as a near-term measure in the Pathogen Reduction/HACCP proposed rule is to ensure that establishments effectively control the

growth of pathogens on meat and poultry carcasses.

II. Description of Comments

Commenters generally supported the need for slaughter plants to chill carcasses as a means of minimizing the growth of harmful bacteria, but some commenters questioned the need for any new near-term regulatory requirements for carcass cooling. These commenters recommended instead that plants address carcass cooling as part of their HACCP plan at the time they implement HACCP. Some commenters opposed the ''command and control'' nature of the proposed requirements and said that relying instead on the incorporation of time and temperature controls in a plant's HACCP plan would provide maximum flexibility to adopt controls consonant with different products and environments.

Some commenters raised concerns about the specific time and temperature requirements in the proposed rule. Other comments included the pros and cons of surface versus internal temperatures as indicators of coldness. Some commenters supported the time and temperature requirements as proposed, noting that these controls are designed to minimize the potential multiplication of bacterial pathogens in carcasses and raw meat products and thus reduce consumer exposure to pathogenic bacteria. Some pointed out that the technology is available and generally being used in plants and that, furthermore, the proposed time and temperature controls are generally being adhered to by many establishments and therefore should not be an overwhelming burden. These commenters stated that the cooling rate proposed by FSIS is based on the best estimate of what is needed to minimize multiplication of pathogenic organisms and what is achievable in a well-controlled meat and poultry establishment.

Some commenters raised concerns about not having the cooling capacity to comply with the proposal and about the prohibitive cost of obtaining the necessary refrigeration equipment. Commenters advocated more realistic requirements that take into consideration plant/product variety, different processing operations, and diverse shipping and receiving norms. Commenters raised questions about disposition of product that did not meet temperature requirements.

Some commenters expressed concern about health problems that could result among their employees from working in a cold environment. Comments related to worker comfort and safety cited studies that concluded many human physical ailments are created or aggravated by cold temperatures. Worker safety was also cited as an issue on the ground that the difficulty of handling and cutting meat at such cold temperatures increases the potential for accidents.

III. FSIS' Current Thinking on Issues Raised by Comments

FSIS considers carcass cooling to control growth of pathogens to be a basic element of a safe food production process. Poultry slaughter plants are currently subject to an FSIS directive on carcass cooling, and many beef slaughter plants take appropriate measures to cool carcasses. FSIS continues to believe there is a need before and after implementation of HACCP for the establishment of some basic standards that can be used to ensure all plants meet carcass cooling standards.

FSIS recognizes the need to take a practical approach that acknowledges the diversity of production practices affected by carcass cooling requirements. FSIS is considering more flexible alternatives to the time and temperature requirements in the proposed rule, including adoption of pathogen growth performance standards (see options below).

FSIS acknowledges the need for a clarification of product disposition options for product that does not meet carcass cooling requirements. This remains under consideration.

IV. Options for Change

In addition to the currently proposed requirements, FSIS is considering the following options:

- Maintain the proposed requirements but raise the 40°F criterion to the highest level that would maintain the pathogen control objective and address at least some concerns about worker comfort and safety and equipment costs. The European Union, for example, uses a 44.6°F standard for red meat to control pathogens during slaughter operations.
- Establish a carcass cooling performance standard expressed as a maximum acceptable level of pathogen growth.
- Rely on microbiological targets, such as the proposed interim targets for pathogen reduction, as performance standards, monitored by periodic microbial testing, and have no specified cooling requirements. This option would provide establishments flexibility to use carcass cooling methods that meet their own needs as long as they meet the end product performance standard.

Issue Paper 5. Specific Economic Considerations and Issues

I. Objective of Proposal

The Pathogen Reduction/HACCP proposal acknowledged that the proposed requirements would have significant economic impact, particularly on small entities. Comments were requested on cost estimates for these impacts as well as on alternative regulatory approaches that could lessen this economic impact.

II. Description of Comments

Several themes emerged from the written comments received and oral statements made during public meetings on the Pathogen Reduction/HACCP proposed rule. A primary concern was that the proposal would have severe negative economic impacts on small businesses. Some commenters opposed mandatory HACCP, daily microbial testing, and stringent time and temperature requirements.

While most commenters supported HACCP in principle, small businesses expressed concern about hazard analysis and plan development costs, equipment purchases, plant personnel training, and records maintenance. Suggested alternatives included voluntary HACCP, a 5-year implementation period, increased financial and technical support, alternative training options, inplant demonstration projects and generic HACCP plans.

Daily microbial testing of carcasses from each species slaughtered and of each type of raw ground product was cited as an unfair burden on small plants that slaughter only a few animals, a variety of species, or produce several different raw ground products. Some commenters proposed a frequency of microbial testing based on production volume or simply once per week or month in small plants. It was also suggested that federally-subsidized laboratories conduct the testing, an indicator organism instead of *Salmonella* be selected, and that either FSIS inspectors or, in the case of State-inspected plants, State inspectors conduct the sampling.

In response to the proposed carcass cooling time and temperature mandates, small businesses voiced a need for more realistic standards that reflect small plant product variety, processing operations, and shipping norms. Some said they would need to purchase additional refrigeration equipment for compliance with the proposed requirements. Others cited the ''command and control'' nature of these proposed standards and argued that

they are impractical restrictions on a variety of their operations. A common theme was that these proposed controls should be restated as guidelines.

Commenters also voiced economic objections to the antimicrobial treatments and asked for greater scientific justification. Comments also included cautions about worker safety and environmental hazards, and requested a change from mandatory to voluntary implementation.

Some commenters asserted that within the small plant category is a subgroup of State-inspected plants with the same concerns as those stated above and additional ones due to their very small size and diverse operations. These commenters requested identification of a ''very small'' sub-category of plants defined as those with annual sales less than $1 million, fewer than 20 employees and limited production volume. Exemptions and implementation delays were requested for plants in the proposed ''very small'' category.

Another issue raised was State-provided implementation assistance for State-inspected plants and whether matching Federal funds would cover State programs that provided more help than USDA regulations required.

III. Issues Raised by Comments

After reviewing the small business concerns expressed in the comments, FSIS is considering whether the food safety and public health objectives of this proposal can be accomplished by means that would reduce the regulatory burden and resulting costs of the proposed requirements on small businesses.

FSIS continues to believe that mandatory HACCP is central to the FSIS food safety strategy and reform of the meat and poultry inspection system. Given this, can FSIS significantly reduce the economic impacts on small business by any of the generally applicable modifications to the proposed rule or by using its available resources to provide implementation assistance?

For example, small business objections to the burden of daily microbial testing of each species and ground product for *Salmonella* require FSIS to determine whether another microorganism, reduced frequency of testing, and/or FSIS assumption of a greater testing role would be equally effective in verifying process control and attaining pathogen performance standards and, at the same time, reduce the economic burden.

Raw product time and temperature specifications and antimicrobial treatments for carcasses are techniques for pathogen reduction that have been criticized as command-and-control regulatory approaches. FSIS is considering whether these proposed requirements can be replaced by a performance standard or otherwise modified to achieve the food safety objectives while mitigating the economic burden on industry, including small plants.

After publication of final Federal meat and poultry Pathogen Reduction/HACCP regulations, all State inspection programs must establish requirements at least equal to the Federal requirements. Due to variations in State regulatory processes, some intrastate inspection programs may match the Federal regulations within a year while others may take two years in cases where inspection program regulations must be approved by the State legislature. Once new regulations are in place, State plants would have to be given adequate time to meet the new requirements. In particular, State implementation of the near-term initiatives would likely occur on a longer time line than that proposed for Federal plants. FSIS is considering ways to minimize any inequity between Federal and State-regulated plants.

Another State-specific concern relates to Federal matching funds for up to 50 percent of State inspection program budgets. The HACCP proposal raises questions about what activities will be covered by matching funds. For example: If State inspection programs provide HACCP training for industry employees in State plants, assist State plant owners in HACCP plan development and implementation, or offer ongoing technical assistance to State plant operators, can/shall Federal matching funds be provided?

A further question is whether certain small businesses should be separately identified from others by defining a new ''very small'' business category. Available data indicate, for example, that among all state-inspected plants, approximately 75 percent employ fewer than 8 employees. Given the likelihood of longer implementation times for most intrastate plants due to the normal process of State compliance with Federal inspection program changes, is there a reasonable justification for longer times for all such ''very small'' plants in terms of attainment of national pathogen reduction and process improvement requirements?

IV. FSIS' Current Thinking on Issues Raised by Comments

To address small business concerns, FSIS proposes to use a three-part regulatory policy that would apply to every Federal and State-inspected plant: (1) Fundamental public health and food safety principles must not be compromised, (2) Regulatory flexibility will be provided to plants by establishing performance standards, and (3) Direct and indirect assistance will be provided by FSIS to small plants that need help in reaching those goals.

FSIS is considering appropriate regulatory flexibility options that would minimize small business impacts as they attain performance goals. In the other issue papers on carcass cooling requirements, antimicrobial treatments, and microbial and testing standards, FSIS has outlined alternatives that could mitigate both the technical and economic considerations raised by small businesses about these proposed requirements. Remaining concerns to be addressed are focused on the HACCP implementation schedule and technical assistance.

HACCP Implementation Schedule

As noted above, FSIS is considering ways to adjust the implementation schedule to ensure that small businesses under Federal regulation and those under State regulation are treated equitably with respect to the time period allowed for compliance with the provisions of the final rule.

HACCP Implementation Assistance

Federal Assistance to Industry: FSIS is considering a program to develop implementation aids that should greatly reduce the uncertainty small plants have expressed about a mandatory HACCP program. These aids would include: (1) Information publications, such as a HACCP Handbook that explains how a plant can effectively and economically incorporate the seven HACCP 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 plant 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. These materials would provide the means for all plants to meet HACCP regulatory requirements. FSIS is also planning to sponsor inplant demonstration projects to generate real-world information and guidance about near-term and HACCP implementation issues in small businesses.

Federal Assistance to States: FSIS would continue its technical assistance to State programs by including State training officials in 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 inplant demonstration projects referenced above would focus on small plants under State regulation as well as those under Federal regulation.

Issue Paper 6. Specific Product Considerations Involving Religious, Ethnic, and Cultural Food Handling Practices

I. Objective of Proposal

The objective of the Pathogen Reduction/HACCP proposed rule is to take a comprehensive approach to improving the safety of meat and poultry products.

II. Description of Comments

Many commenters identified unique product considerations that they felt were threatened or undermined by certain requirements in the proposed rule. These unique product considerations principally involved religious, ethnic, and cultural issues centered around three product types: kosher products, Chinese poultry, and ''hot'' specialty items usually for Moslem, Chinese, Hispanic, and Hawaiian markets.

Comments related to kosher products identified two specific areas of concern. First, antimicrobial treatments would cause a serious problem under kosher dietary laws if applied before the salting process and would cause practical problems if applied after the salting process. Second, the time and temperature requirements for carcass cooling might significantly shorten the available time for ritual salting, particularly for religious holidays, which might limit the availability of kosher meat. For these reasons, commenters requested exemptions from using antimicrobial treatments and from following proposed time and temperature requirements for meat and poultry products that are certified and sold as kosher.

The Chinese-American community expressed concern about the added cost of whole birds prepared for religious purposes. Commenters requested an exemption for such products.

Other commenters noted that proposed time and temperature requirements for carcass cooling conflict with ''hot pork,'' a process during which hogs are slaughtered and delivered to customers in some ethnic markets with little or no chilling. A similar process is used with lamb, goat, and beef for Moslem customers. An exemption was also requested for these products.

III. FSIS' Current Thinking on Issues Raised by Comments

FSIS is examining how it can provide the regulatory flexibility needed to adequately address the concerns noted above and still achieve its food safety and public health objectives.

FSIS expects the final rule to contain changes that will as a general matter increase industry's flexibility to use alternative technologies and procedures which reduce and control pathogens to meet the microbial performance standards. This approach may help address some of the concerns expressed by religious and cultural groups. If any individual group's unique problems are not adequately addressed by this approach, the agency would consider other alternatives that respect well established religious, ethnic, and cultural practices as much as possible while assuring fundamental public health and food safety objectives are achieved.

Issue Paper 7. Antimicrobial Treatments in Slaughter Plants

I. Objective of Proposal

The objective of the proposal in the Pathogen Reduction/HACCP proposed rule, to require the application of at least one effective antimicrobial treatment in slaughter plants, is to establish a minimum standard of care regarding the use of available technology to reduce pathogens on carcasses leaving slaughter plants and to gain a net reduction in the occurrence of pathogens on carcasses in the near term, while HACCP is being implemented.

II. Description of Comments

Some commenters supported the proposal to mandate the use of at least one antimicrobial treatment, subject to reservations concerning the effectiveness of the available treatments for specific pathogens, the possibility of cross-contamination, and the need to maintain careful, hygienic slaughter practices.

Some commenters opposed the proposed antimicrobial treatments, raising concerns about the ''command and control'' nature of the proposal and the lack of sufficient empirical data to justify mandatory antimicrobial treatments.

To alter the ''command and control'' nature of the proposal, some commenters recommended eliminating the formal approval process for antimicrobial treatments and allowing any treatment that meets stated conditions (such as, ''meets a pathogen reduction standard,'' ''does not adulterate product, create insanitary conditions, or result in misbranded product.'') Other suggestions included accepting irradiation and salt as antimicrobial alternatives. Some commenters stated that use of antimicrobial treatments should be a control measure plants consider during HACCP plan development, not before.

Some commenters noted that certain foreign countries do not permit antimicrobial treatment of meat and poultry products. Acknowledging the proposed exemption for exported product included in the proposed rule, commenters still expressed concern that it was impractical for a slaughter operation to separate domestic and export product.

III. FSIS' Current Thinking on Issues Raised by Comments

FSIS continues to believe antimicrobial treatments in many slaughter plants play an important role in a pathogen reduction strategy. FSIS is reconsidering whether the proposed across-the-board mandate is the optimal approach to fostering adoption of appropriate antimicrobial technologies or whether more flexible alternatives, including reliance on end-product performance standards, would be equally or more effective.

IV. Options for Change

FSIS is considering the following possible alternatives to the proposed antimicrobial treatment requirements:

- Adopt the near-term requirement for slaughter establishments to apply an antimicrobial treatment to meat and poultry carcasses, with modification of some technical details (such as timing application, and proposed requirements for ensuring the efficacy of specific treatments).
- Adopt the near-term requirement for slaughter establishments to apply an antimicrobial treatment to meat and poultry carcasses, with modification of some technical details (such as timing application, and proposed requirements for ensuring the efficacy of specific treatments), but add an exemption option for plants that can demonstrate near-term compliance with process control and/or pathogen reduction performance standards.
- Do not require establishments to apply an antimicrobial treatment to meat and poultry carcasses, but rely instead on appropriate identified performance standards and microbial testing for generic *E. coli, Salmonella* or other pathogens as an incentive to maintain good sanitation and hygienic slaughter practices and to adopt

technologies appropriate for achieving standards in particular plants.

Issue Paper 8: Specific Product Considerations Involving International Trade

I. Objective of Proposal

The objective of the Pathogen Reduction/HACCP proposed rule is to take a comprehensive approach to improving the safety of meat and poultry products while recognizing international agreements.

II. Description of Comments

Many commenters identified individual situations involving imported and exported products that they believe were potentially threatened or undermined by certain requirements in the proposed rule.

Commenters involved in the export of meat and poultry products raised objections to the proposed antimicrobial treatment requirements. They stated that European Union (EU) countries would not accept product treated with antimicrobial agents and that Canada would not accept product treated with chlorine at the levels required in the proposal. They recommended that FSIS accept Codex Alimentarius standards in lieu of those in the proposed rule. Commenters also explained that the proposed exemption for exported product was insufficient to address the realities of slaughter operations which make separation of domestic and export product impractical.

Questions were also raised about the requirements for foreign plants exporting meat and poultry product to the U.S. Commenters inquired if all foreign plants exporting products to the U.S. would be required to have HACCP systems, and if so, how would FSIS ensure compliance. Some commenters asked for clarification of ''equivalent standards'' language. They were concerned that domestic producers would be at an economic disadvantage if foreign competitors did not have to implement HACCP to sell product in the U.S.

III. FSIS' Current Thinking on Issues Raised by Comments

After reviewing the comments relating to specific product considerations, FSIS is examining how it can provide the regulatory flexibility needed to adequately address the concerns noted above, meet the requirements of international agreements and still achieve its food safety and public health objectives.

Export Issues

The EU member states and Canada are the only countries, to our knowledge, which restrict the use of antimicrobials on meat and poultry carcasses

Plants producing meat and poultry for export to the EU or Canada can choose to treat carcasses with hot water, which is currently recognized by FSIS, the EU and Canada as an acceptable antimicrobial treatment when applied at 165°F for at least 10 seconds. Use of this particular treatment would also preclude the need to segregate product.

FSIS is also considering alternative approaches for achieving the same objective sought from antimicrobial treatments. Please refer to the previously distributed paper entitled ''Antimicrobial Treatments in Slaughter Plants.'' These alternatives, such as microbial performance standards, were discussed during earlier sessions of the public meetings. However, FSIS recognizes that during consideration of these approaches, the issues related to trade must be addressed.

Import Issues

As a signatory to the NAFTA and GATT agreements, the United States has agreed to permit the importation of meat and poultry products from countries which operate inspection systems judged to be equivalent to that of the United States.

The FSIS current thinking is that countries importing meat and poultry product to the United States would need to: 1) adopt performance standards which achieve levels equivalent to those of the United States, (e.g., microbial targets, chemical tolerances, economic adulterant limits (e.g., excess moisture), aesthetic defect limits (e.g., organ remnants), and 2) insure that process control systems equivalent to HACCP are utilized in the plants in order to meet U.S. performance standards and other regulatory requirements.

FSIS is currently engaged in the process of developing criteria which it will use to determine if foreign plants engaged in export to the United States are utilizing process control systems equivalent to HACCP. FSIS recognizes that societal, cultural, economic and other conditions are not exactly the same in foreign countries as those in the United States and that effective process control systems may vary from country to country.

Officials from some countries have proposed that their plant's current systems of process control which rely heavily on government intervention, control, and oversight are the most cost-effective way for their society and will result in product in full compliance with U.S. standards. Officials from other countries indicate they plan to require plants to use process control systems virtually identical to those being proposed by FSIS. As FSIS moves to establish appropriate criteria for judging equivalency, it will consider the various aspects of these alternative methods of assuring process control as compared to HACCP.

In summary, the current FSIS thinking revolves around (1) establishment of objective, science-based performance standards and (2) evidence that systems of control equivalent to those used in the United States are in place to insure compliance with the standards. Again, FSIS recognizes that during the consideration of these approaches, the issues related to trade must be addressed.

Done at Washington, DC, on October 18, 1995.

Michael R. Taylor,

Acting Under Secretary for Food Safety.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 95–ANM–21]

Proposed Amendments to Class E Airspace, St. George, UT

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would amend to St. George, Utah, Class E airspace to accommodate a new Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway 34 at St. George Municipal Airport, St. George, Utah. The area would be depicted on aeronautical charts for pilot reference.

DATES: Comments must be received on or before December 1, 1995.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, System Management Branch, ANM–530, Federal Aviation Administration, Docket No. 95–ANM–21, 1601 Lind Avenue S.W., Renton, Washington, 98055–4056.

The official docket may be examined at the same address.

An informal docket may also be examined during normal business hours at the address listed above.