

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 help 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. o 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 and 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 decision making 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 in-house training delivery capabilities rather than participate in joint training sessions with industry personnel at the local level. Given the logistics and time frames 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-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 food borne 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 of 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 handle 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.