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THE HACCP-BASED INSPECTION MODELS PROJECT

(A New Public Health Approach in the U.S. Slaughter Industry)

COUNTRY PAPER PROPOSED BY THE USA

SUMMARY

The U.S. Department of Agriculture's landmark 1996 rule, the "Pathogen Reduction; Hazard Analysis and Critical Control Point Systems (PR/HACCP)" final rule forms the cornerstone for the U.S. food safety strategy for meat and poultry products. However, the PR/HACCP rule did not extend HACCP concepts to slaughter. A new approach to food safety, the HACCP-Based Inspection Models Project (HIMP), was initiated. The new system enables establishments to fully integrate their production processes. Establishment employees conduct sorting activities based on initial anatomical and pathological examination of carcasses, followed by government inspection of each carcass and verification of the establishment HACCP and slaughter process controls.

The U.S. Department of Agriculture contracted with an independent private corporation to measure the organoleptic and microbiologic accomplishments of the traditional inspection system in young chickens, market hogs, and young turkeys. The Department developed new science based organoleptic performance standards from this data collection. Establishments in the HIMP initiative were provided flexibility in how best to meet those performance standards. Data collected in the project to date, by both the independent contractor and in-plant inspectors, show important improvements in both food safety and non-food safety conditions. The Department intends to propose the appropriate regulatory changes that adopt the new inspection system.

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INTRODUCTION

Since at least the 1980's, studies in the U.S., and internationally, described traditional slaughter inspection practices as inadequately protecting the public health from contemporary foodborne hazards associated with foods of animal origin. In the U.S., the National Academy of Sciences and the General Accounting Office recommended that the Department of Agriculture's Food Safety and Inspection Service (FSIS) reduce its reliance on organoleptic inspection, shift to prevention-oriented inspection systems based on risk assessment, and redeploy its resources in a manner that better protects the public from foodborne diseases.

The Agency's landmark 1996 rule, the "Pathogen Reduction; Hazard Analysis and Critical Control Point Systems (PR/HACCP)" final rule forms the cornerstone for the U.S. food safety strategy for meat and poultry products. However, the PR/HACCP rule did not extend HACCP concepts to slaughter. Beginning in 1997, the Agency initiated an open public process for the design and development of new slaughter inspection models in a HACCP environment. A new approach to food safety, the HACCP-Based Inspection Models Project (HIMP), was initiated.

When fully implemented, the HACCP-Based Inspection Models project will produce a flexible, efficient, and integrated system of process controls and regulatory actions. FSIS expects this system of establishment controls and Agency carcass and verification inspection to improve food-safety. The new system, by allowing official establishments to fully integrate their production processes, enables them to more effectively meet their responsibilities under the PR/HACCP regulations. Further, the new system facilitates risk based deployment of FSIS inspection resources.

DISCUSSION

In 1997, the FSIS initiated a public dialog on the concepts and protocols behind a new approach to food safety inspection at slaughter. In the HACCP-Based Inspection Models project, slaughter process control will be an industry responsibility subject to FSIS carcass and verification inspection. The plants are responsible for conducting the basic sorting and trimming work to produce safe and wholesome product.

The Agency described establishment process control responsibilities and FSIS inspection activities to be carried out during the pilot project. Project protocols were evaluated through a public process that included input from two technical advisory committees. The protocols described the microbial and organoleptic sampling and analysis procedures. Only plants that slaughter market hogs, young chickens and young turkeys are currently eligible to participate in the project. These classes comprise animals that are young, healthy, and uniform. FSIS is not planning to extend this project to other classes of animals that may have more complex pathology or other problems. The young chicken segment of the project is the most fully developed and is the focus of the balance of this paper.

The HACCP-Based Inspection Models Project has two phases – the baseline phase and the models or testing phase. Under the baseline phase the Agency collected organoleptic and microbial data that measured the accomplishments of the current, traditional, inspection system.

FSIS contracted with Research Triangle Institute (RTI), an independent consulting firm, to collect both microbiologic and organoleptic data. Between 1998 and 1999 RTI collected baseline data in 16 young chicken plants. Over a six-week period in each plant, 300 microbial samples were collected and analyzed for *Salmonella* and for generic *E. coli*. Over a five week period in each plant, 2000 carcasses were scored for a variety of organoleptic diseases and defects.

The baseline organoleptic data formed the basis for the new species-specific performance standards for food safety and other consumer protection. These performance standards, although derived from the accomplishments of the current system, established a more stringent set of standards. Consistent with the Agency's HACCP philosophy, the Agency role is to set objective, science based performance standards, and provide industry the flexibility in determining how best to meet the performance standards. This does not mean that defects unacceptable under the traditional inspection systems are now acceptable. Rather, under the models project, the Agency is demanding an

improvement over what the traditional system is currently achieving. When plants enter HIMP, they must improve their process to meet these new, tougher, standards.

For young chickens, performance standards were set for seven categories of diseases and conditions detected at slaughter. Two categories address food safety, and five address other consumer protection, or non-food safety, concerns. For the two food safety categories, the performance standards are set at zero - no food safety diseases or conditions are permitted to pass slaughter critical control points. The food safety categories are for birds with septicemia/toxemia or fecal contamination. For the five other consumer protection categories, FSIS set the performance standards below the accomplishments of the traditional system. Birds with localized airsacculitis and carcass trim defects are examples of the non-food safety related conditions. (See Attachment 1)

To enter the models phase, the project involves new roles and responsibilities for participating plants. Each plant must modify its HACCP plan to include critical control points that address food safety diseases and conditions. In addition, each plant must develop and implement a process control plan with control points to address other consumer protection concerns associated with the non-food safety related diseases.

Establishment employees conduct anatomical and pathological examinations of carcasses, and FSIS inspectors evaluate and verify the effectiveness and reliability of the establishment HACCP and slaughter process controls. With HACCP and other process control programs in place, plants identify and remove from the slaughter process carcasses, and parts of carcasses, that are adulterated because they are diseased or otherwise unfit for human food.

When volunteer plants assume these process control responsibilities, the FSIS inspection team will implement new slaughter inspection procedures that verify the effectiveness of the process controls. New roles for FSIS inspectors were developed. To meet these new roles, inspectors were given additional HACCP training and carcass inspection and verification training. Supervisors are trained in techniques for auditing industry statistical process control programs. The project moves away from an inspection system in which most initial decisions were made by government personnel toward a flexible system based on integrated processes and final government inspection and verification.

In pilot plants, government slaughter inspection consists of two types of procedures: carcass inspection and verification inspection. During carcass inspection of young chickens, an FSIS inspector inspects each carcass on the line at a fixed location after the final wash and before the continuous immersion chiller. This inspection occurs after plant sorting, trimming, and washing activities are completed. The carcass inspector focuses on food safety and generalized carcass defects. Because the carcass inspection is located later in the process, after initial carcass decisions have been made by industry sorters, the government inspection activity becomes less resource intensive compared to traditional systems.

Verification inspection consists of inspectors taking samples of products and plant records. Verification inspection procedures are carried out after the establishments HACCP and other process control systems have been completed. Most verification testing is conducted at scheduled random times throughout a shift. With the staffing flexibility, more sampling is routinely completed than was possible in traditional systems. The FSIS veterinary inspector determines how to efficiently allocate inspection resources in the plant to conduct verification procedures. A key project feature is the staffing provision for unscheduled, or biased, sampling of carcasses whenever veterinarians have reason to question process controls.

When the plant HACCP and process control systems, and FSIS inspection procedures, are working as intended, RTI conducts follow-up organoleptic and microbiologic sampling using the same sampling frames and protocols as conducted during the baseline data collection phase. The achievements of the new system should meet or exceed the achievements of the current system as reflected by the baseline data in order for FSIS to consider the system successful. Early results from seven plants show encouraging trends. To summarize, for the first food safety category, which includes septicemia and toxemia, a 100 percent reduction in defects was recorded when comparing results from FSIS' traditional slaughter inspection system with the data under the new system. For the second food

safety category, which includes fecal contamination, a 92 percent reduction in defects was identified--even though the verification sampling rate quadrupled under HIMP. There are five "other consumer protection" categories. For OCP-1, which includes animal diseases, a 45 percent improvement was found in HIMP plants when comparing the results from traditional slaughter inspection with the models phase data. For the OCP-2 category, a 43 percent improvement occurred. In other categories, such as the one containing feathers, the percentage of defects has increased. Although more stringent criteria are used in the project, the Agency is investigating the reason for this increase. More detailed data are available at www.fsis.usda.gov.

In addition to the RTI sampling, FSIS inspection personnel also collect data and document results to verify plant performance and ensure regulatory compliance. FSIS takes action if the plant exceeds the performance standards. The specific actions taken depend on whether the performance standard is related to a food safety or other consumer protection category, and the degree to which the performance standard is exceeded. Inspection personnel take regulatory action under the same circumstances as they did under traditional inspection systems. Inspectors continue to have the authority to stop the line as appropriate, retain product that they believe is adulterated or misbranded, to withhold the marks of inspection, and to reject facilities, equipment, or any parts of the plant they determine are not in compliance with the regulations.

CONCLUSION

The models project has been developed and tested using an open public process. The project raises the bar for food safety and other consumer protection. With this pilot project FSIS has measured, for the first time, how many defects pass its traditional inspection system, put them into categories, and set pilot performance standards that participating plants must achieve. Plants have the responsibility to meet the pilot performance standards, and inspectors have the responsibility and authority to ensure that they do so.

FSIS inspectors are continuously present and inspect each carcass at a fixed location on the slaughter line. The pilot project, however, includes more verification to ensure standards are met, including four times as many food safety checks compared to traditional systems. Under the models, FSIS is testing the feasibility of deploying inspection resources more effectively within plants, consistent with our farm-to-table food safety strategy.

Data collected in the project to date, by both an independent contractor and in-plant inspectors, show important improvements in food safety and other consumer protections. The Agency finds these results encouraging, but more work can be done. The new models capitalize on the food safety and other consumer protections gains garnered by the HIMP project thus far, while still meeting the demands of the inspection laws. The Agency intends to propose regulatory changes that adopt the HACCP-based inspection models program as the young chicken inspection system in the U.S. Pilot testing other species will follow.

MODEL PHASE PERFORMANCE STANDARDS FOR YOUNG CHICKEN PLANTS

<u>Performance Standard Categories</u>	<u>Performance Standards</u>
FS 1 -- Condition -- Infectious (For example: septicemia, toxemia)	Zero
FS 2 -- Contamination – Digestive Content (fecal material)	Zero
OCP-1 -- Condition - Animal Diseases* (For example: airsacculitis, arthritis, ascites, avian leukosis complex, avian tuberculosis, cadaver, enteritis, erysipelas, inflammatory process, nephritis, osteomyelitis, tumors (carcinoma, sarcoma, etc.) pericarditis, salpingitis, tenosynovitis)	1.7%
OCP-2- Condition – Miscellaneous (for example: breast blister, bruises, external mutilation, fractures, overscald, scabs, and localized inflammatory process)	52.5%
OCP-3 - Contamination - Digestive Content (for example: ingesta)	18.6%
OCP-4- Dressing Defects – Other (for example: extraneous material—other, feathers, lung, oil gland, and trachea, bile)	80.0%
OCP-5- Dressing Defects – Digestive Tract Tissue (for example: bursa of fabricius, cloaca, crop, esophagus, intestine)	20.8%

* Conditions exhibiting a septicemia or toxemia are considered food safety hazards.